Sunshine Act Meetings

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

DEPARTMENT OF DEFENSE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

Meeting Notice

TIME AND DATE: Full Board 2:00 p.m., May 15, 1992.

PLACE: Uniformed Services University of the Health Sciences, room D3-001, 4301 Jones Bridge Road, Bethesda, Maryland 20814-4799.

STATUS: Open—under "Government in the Sunshine Act" (5 U.S.C. 552b(e)(3)).

MATTERS TO BE CONSIDERED: 2:00 p.m. Meeting—Board of Regents.

(1) Approval of Minutes—February 3, 1992; (2) Faculty Matters;

(3) Report—Admissions; (4) Financial Report; (5) Associate Dean for Graduate Medical Education; (6) Report—President, USUHS; (7) Comments—Members, Board of Regents; (8) Comments—Chairman, Board of Regents; (9) Reports of Subcommittees on Planning and Oversight; (10) Report of Dean's Search Committee;

New Business.

CONTACT PERSON FOR MORE INFORMATION: David S. Trump, M.D., Executive Secretary of the Board of Regents, 301/295-3886.

Dated: April 24, 1992.

Linda Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 92-10030 Filed 4-24-92; 3:21 pm]

BILLING CODE 3810-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 1:04 p.m. on Thursday, April 23, 1992, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to certain financial institutions.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director T. Timothy Ryan, Jr. (Office of Thrift Supervision), and concurred in by Vice Chairman Andrew C. Hove, Jr., Chairman William Taylor, and Director Stephen R. Steinbrink (Acting Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(8), (c)(9)(A)(ii), and 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550-17th Street, N.W., Washington, DC.

Dated: April 23, 1992.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 92-9973 Filed 4-24-92; 11:19 am]

BILLING CODE 6714-0-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM: .

TIME AND DATE: 11:00 A.M., Monday, May 4, 1992.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED: .

1. Proposed Federal Reserve Service Automation Services compensation program.

2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 24, 1992.

Jennifer J. Johnson

Associate Secretary of the Board.

[FR Doc. 92-10019 Filed 4-24-92; 2:42 pm]

BILLING CODE 6210-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of April 27, May 4, 11, and 18, 1992.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of April 27

Wednesday, April 29

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting)

a. Revisions to Procedures to Issue Orders: Challenges to Orders that are Made Immediately Effective—10 CFR Part 2 (Tentative) (Postponed from April 24)

Week of May 4—Tentative

Friday, May 8

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of May 11—Tentative

Monday, May 11

8:30 a.m.

Discussion of Internal Management Issues (Closed—Ex. 2)

10:00 a.m.

Briefing on Status of Licensed Operator Requalification Program (Public Meeting)

Wednesday, May 13

12:00 noon

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of May 18—Tentative

Wednesday, May 20

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the Status of Meeting Call (Recording)—(301) 504-1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504-1661.

Dated: April 24, 1992.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 92-10013 Filed 4-24-92; 2:09 pm]

BILLING CODE 7590-01-M

Corrections

Federal Register
Vol. 57, No. 82
Tuesday, April 28, 1992

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-935-DR]

California; Amendment to Major Disaster Declaration

Correction

In notice document 92-6306 appearing on page 9552 in the issue of Thursday, March 19, 1992, make the following corrections:

1. In the third column, the docket number should read as set forth above.

2. In the same column, under **NOTICE**, after the second paragraph, the Catalog of Federal Domestic Assistance No. should read "83.516 SIC, Disaster Assistance".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-010-02-4333-02-241A]

Firearms Use Restriction and Closure Order Established; Squaw Leap Management Area, Hollister Resource Area, Bakersfield District, CA

Correction

In notice document 92-6368 appearing on page 9562 in the issue of Thursday, March 19, 1992, in the third column, the signature at the end of the document should read "Robert Beehler".

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Securities and Exchange Act of 1934 Release No. 30537; File No. 600-25]

The Registration as a Clearing Agency of the Participants Trust Co.; Order Granting Approval of Registration Until March 31, 1993

Correction

In notice document 92-8134 beginning on page 12351 in the issue of Thursday, April 9, 1992, in the second column, the release number and subject heading should read as set forth above.

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-30536; File No. SR-NYSE-91-42]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Amending NYSE Rule 758(b)(ii)(A) to Broaden the Limitations on Principal/Agency Trading by Competitive Options Traders and to Amend the NYSE's Minor Rule Violation Plan

Correction

In notice document 92-8136 beginning on page 12357 in the issue of Thursday, April 9, 1992, in the first column, the subject heading should read as set forth above.

BILLING CODE 1505-01-D

Federal Register

Tuesday,
April 28, 1992

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 2, et al.

Abbreviated New Drug Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 2, 5, 10, 310, 314, 320, and 433

[Docket No. 85N-0214]

RIN 0905-AB63

Abbreviated New Drug Application Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations for most of its requirements for abbreviated new drug applications (ANDA's). FDA published a proposed rule for ANDA's in the **Federal Register** of July 10, 1989 (54 FR 28872). These regulations implement title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments). This final rule covers subjects such as ANDA content and format, approval and nonapproval of an application, and suitability petitions. This rule does not finalize the provisions of the proposed rule on patent certification and market exclusivity; FDA is still examining the issues pertaining to those provisions and will finalize them in a future edition of the **Federal Register**.

EFFECTIVE DATE: The regulations will become effective on June 29, 1992.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION:

I. Background

A. New Drug Approval: 1938 to 1962

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (the act). The act created a premarket approval system for drug products that required applicants seeking drug product approval to submit a new drug application (NDA) to FDA. The NDA would contain information demonstrating, among other things, that the drug product was safe. The act also provided that an NDA would automatically become effective (i.e., the product could be lawfully marketed) within a fixed period unless the agency affirmatively refused to approve the application.

In addition to drug products that had an effective NDA, many products were marketed without effective applications. These products were identical, similar, or related to products with effective NDA's. The manufacturers of these products had concluded that their drug products were generally recognized as safe, or had received advisory opinions from FDA that an NDA was not required because the products were generally recognized as safe.

In 1962, Congress amended the drug approval provisions of the act to require affirmative approval to NDA's before marketing. The amendments required applicants to show that their products were both safe and effective (Pub. L. 87-781 (October 10, 1962)). Thus, on or after October 10, 1962, a person could not market a new drug without an approved NDA that contained sufficient safety information as well as substantial evidence establishing the drug's effectiveness for its intended uses.

The 1962 amendments also deemed NDA's that had become effective before October 10, 1962, to be approved. As with postenactment drugs, the 1962 amendments required these "pre-1962" drugs to be shown to be effective for their intended uses. Consequently, FDA began a program to evaluate the drugs that had been deemed approved to determine whether there was substantial evidence of their effectiveness. This systematic evaluation and the implementation of FDA's findings became known as the Drug Efficacy Study Implementation (DESI). Under DESI, FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC), which established expert panels to review available evidence of effectiveness and to provide recommendations to FDA. FDA considered the NAS/NRC panels' recommendations about the effectiveness of these DESI drugs, and announced its conclusions through **Federal Register** notices. These notices, known as DESI notices, contain the acceptable marketing conditions for the class of drug products covered by the notice.

B. The ANDA Procedure for Pre-1962 Drugs

If a manufacturer had a pre-1962 NDA in effect for a drug product, FDA continued its approval if the manufacturer submitted a supplemental new drug application to conform the product's indications for use to those determined to be effective in the DESI review. Yet, as stated above, many drug products had active ingredients and indications that were identical or very similar to the drug products found to be effective in the DESI review but lacked NDA's themselves. In implementing the DESI program with respect to these duplicate products, FDA concluded that each such drug product was a "new drug" that required its own approved NDA before it could be legally marketed (*United States* v. *Generix Drug Corp.*, 460 U.S. 453 (1983)). Additionally, FDA issued a policy statement in the **Federal Register** of May 28, 1968 (33 FR 7758) that revoked the earlier advisory opinions that drugs could be marketed without prior FDA clearance. This rule was codified at 21 CFR 310.100.

Shortly thereafter, FDA created the ANDA procedure for the approval of duplicate products in reliance on the DESI evaluation. In brief, after the DESI program had found a particular drug product to be effective and suitable for ANDA's, FDA published a **Federal Register** notice announcing its conclusions. Any manufacturer of a duplicate drug product that did not have an approved NDA was then required to submit an ANDA to obtain approval to market the duplicate version of the approved drug. (See 34 FR 2673, February 27, 1969; 35 FR 6574, April 24, 1970; and 35 FR 11273, July 14, 1970.)

Before 1984, FDA based these ANDA approvals on the theory that the evidence of effectiveness necessary for approval of an NDA had been provided, reviewed, and accepted during the DESI process. Evidence of the drug's safety had been determined on the basis of information contained in the pioneer NDA and by the subsequent marketing experience with the drug. FDA required ANDA applicants to submit information that showed the applicant's ability to manufacture a product of acceptable quality whose safety and effectiveness were equivalent to the drug product whose safety and effectiveness had been established. Thus, ANDA applicants provided information on the drug product's formulation, manufacture, quality control procedures, and labeling. DESI notices specified additional information, such as bioavailability/bioequivalence data, for the ANDA.

C. Procedures for Duplicates of Post-1962 Drugs ("Paper NDA" Policy)

FDA never extended its ANDA policy for pre-1962 drugs to duplicates of drugs first approved for marketing on or after October 10, 1962, although it did consider the possibility of such an extension either by regulation or through legislation. (See 54 FR 28872 at 28873 and citations therein.) As patents began to expire for many post-1962 drugs, including some high volume, therapeutically important drug products,

many manufacturers became interested in changing the NDA system to permit ANDA's for post-1962 drug products.

FDA did allow some duplicate drug products of drugs first approved after 1962 to be marketed under its "paper NDA" policy. (See 46 FR 27396, May 19, 1981.) This policy permitted FDA to approve NDA's for post-1962 drug products on the basis of safety and effectiveness information derived primarily from published reports based on well-controlled studies. This meant that manufacturers did not have to conduct their own tests, but adequate literature, including detailed reports of adequate and well-controlled studies, was available for only a fraction of the post-1962 drugs. Moreover, the staff effort involved in reviewing paper NDA's ultimately proved to be a substantial and inefficient use of agency resources.

D. The Drug Price Competition and Patent Term Restoration Act of 1984

From 1978 to 1984, Congress considered various bills that would have authorized an ANDA procedure for duplicate versions of post-1962 drug products. Other bills under consideration during this period sought to restore patent life lost while awaiting Federal marketing approval. Congress combined the ANDA procedure for post-1962 drug products and patent term restoration in the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417).

The law consisted of two different titles. Title I authorized the approval of duplicate versions of drug products, approved under section 505 of the act, under an ANDA procedure. Title II authorized the extension of patent terms for approved new drug products (including antibiotics and biological drug products), some medical devices, food additives, and color additives. Congress intended the two titles to provide a careful balance between promoting competition among brand-name and duplicate or "generic" drugs and encouraging research and innovation.

Title I amended section 505 of the act by establishing a statutory ANDA procedure for duplicate and related versions of human drugs approved under section 505(b) of the act. These procedures are inapplicable to antibiotics (which are approved under section 507 of the act) and biological drug products licensed under 42 U.S.C. 262. The statute adopted, with few modifications, the agency's ANDA procedure for pre-1962 drugs. It required all applicants to provide certain patent information; provided for the submission and approval of applications for which the investigations relied on by the applicant to satisfy the "full reports" of safety and effectiveness requirement were not conducted by or for which the applicant had not obtained a right of reference or use from the person who conducted the investigations; established rules for disclosure of safety and effectiveness data submitted as part of an NDA; and provided specific time periods during which ANDA's and NDA's for certain drug products may not be submitted or approved. The act also required FDA to promulgate new regulations implementing the statute. In the **Federal Register** of July 10, 1989 (54 FR 28872), FDA published a proposed rule on ANDA's. This final rule contains must of the provisions contained in that proposal.

FDA published a final rule implementing Title II in the **Federal Register** of March 7, 1988 (53 FR 7298). This rule is codified at 21 CFR Part 60.

II. Highlights of this Final Rule

This final rule amends 21 CFR Part 314 to establish new requirements and procedures for NDA and ANDA applicants under the 1984 amendments. The rule also revises the bioavailability and bioequivalence requirements at 21 CFR part 320 to conform to the 1984 amendments and current agency policy. Minor conforming amendments are made to 21 CFR parts 2, 5, 10, 310, 314, and 433. Additionally, because the agency will issue final regulations governing patent certification and marketing exclusivity requirements at a future date, FDA has revised or deleted cross-references to those provisions and, where possible, replaced them with statutory citations.

The final rule's major provisions are as follows:

A. Abbreviated Applications

The statutory provisions governing ANDA requirements and procedures are at section 505(j) of the act (21 U.S.C. 355(j)).

The statute permits ANDA's for: (1) A drug product that is the "same" as a drug product listed in the approved drug product list published by FDA (the "listed drug") with respect to active ingredient(s), route of administration, dosage form, strength, and conditions of use recommended in the labeling; and (2) a drug product with certain changes from a listed drug if FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed drug product.

Subpart C of part 314 addresses an ANDA applicant's requirements and responsibilities. The final rule is substantially similar to the proposal, although FDA has made some minor changes, such as requiring applicants to include a table of contents in the review copies of an ANDA (21 CFR 314.94(a)(2)), and other minor changes regarding periodic reports from ANDA holders (21 CFR 314.98). One noteworthy change concerns the chemistry, manufacturing, and controls section of an ANDA. Under the proposed rule, applicants would have been required to identify and characterize inactive ingredient differences between their products and those in the reference listed drug. FDA received numerous comments stating that, for many drug products, applicants would be unable to discover which inactive ingredients were used in the reference listed drug. Consequently, the final rule requires applicants to identify and describe such differences regarding inactive ingredients only for topical drug products, drug products intended for parenteral use, and drug products intended for ophthalmic or otic use. The inactive ingredients for these products are listed on the products' labels. For other drug products, the final rule requires applicants to identify and characterize only the inactive ingredients in their own products.

FDA has also revised some policies that were announced in the preamble to the proposed rule. For example, the preamble to the proposed rule indicated that FDA would accept an ANDA submission that contained a bioequivalence protocol. This policy had the unintended effect of encouraging applicants to file incomplete ANDA's. Therefore, FDA is announcing that it will no longer accept an ANDA that does not contain the results of a complete bioequivalence study if such a study is required for approval. These and other changes are described in more detail in the responses to comments below.

B. ANDA Suitability Petitions

Under section 505(j)(2)(C) of the act, an ANDA applicant may petition FDA for permission to file an ANDA for a drug product that has one different active ingredient in a combination product, or whose route of administration, dosage form, or strength differs from that of the listed drug. These are the only types of changes permitted in an ANDA.

The final rule, at 21 CFR 314.93, describes the information that a petitioner must include in its petition. The information must demonstrate that the change from the listed drug requested for the proposed drug product

may be adequately evaluated for approval without data from investigations to show the proposed drug product's safety or effectiveness and that a drug product with a different active ingredient may be adequately evaluated for approval as safe and effective on the basis of information required to be submitted in an ANDA.

In the preamble to the 1989 proposed rule, FDA invited comments on a policy that would provide for the confidentiality of any petition submitted under section 505(j)(2)(C) of the act until FDA either approved or disapproved the petition. At the time of the proposed rule, FDA's policy was to make these petitions available to the public. The agency received an equal number of comments in favor of and opposed to such a policy. The comments favoring confidentiality argued that the public availability of suitability petitions would adversely affect the petitioner's commercial interests. The comments opposing confidentiality said that the public availability of these petitions would enhance the decisionmaking process. FDA agrees with the latter view. By making suitability petitions publicly available, FDA has received valuable comments and information from third parties. These comments and information have contributed to the agency's evaluation of some suitability petitions. Consequently, FDA will continue its policy of making such petitions available to the public.

An ANDA submitted under an approved petition would generally be required to contain the same information as an ANDA for a drug product that is the same as a listed drug except that FDA may require additional information regarding the difference between the proposed drug product and the listed drug. Additionally, FDA requires that the listed drug referred to in the ANDA be the one upon which the petition was based and that the applicant refer to the petition in its ANDA and include a copy of FDA's response approving submission of an ANDA.

C. 505(b)(2) Applications

The 1984 amendments also amended section 505(b) of the act (21 U.S.C. 355(b)) to create another type of application. These applications, known as 505(b)(2) applications, are similar to applications under the agency's "paper NDA" policy. Unlike the paper NDA policy, however, section 505(b)(2) of the act applies to applications that contain investigations relied upon by the applicant to provide full reports of safety and effectiveness where the investigations were not conducted by or for the applicant and the applicant has not obtained a right of reference or use from the person who conducted the investigations. (See 21 U.S.C. 355(j)(2).) Thus, section 505(b)(2) of the act is not restricted to literature-supported NDA's for duplicates of approved drugs; it covers all NDA's for drug products that rely on studies not conducted by or for the applicant or for which the applicant does not have a right of reference.

A 505(b)(2) application is submitted under section 505(b)(1) of the act. Consequently, these applications are subject to the same statutory provisions as full NDA's. The statute, however, gives 505(b)(2) applicants additional obligations, such as patent certification, that are similar to those of ANDA applicants. The final rule addresses 505(b)(2) application procedures at 21 CFR 314.50.

The preamble to the proposed rule (54 FR 28872 at 28891) asked whether FDA should adopt a policy whereby a 505(b)(2) application for a drug product with a change in dosage form, strength, route of administration, or active ingredient would be treated as a petition under section 505(j)(2)(C) of the act. Most comments opposed such a policy, asserting that the policies and procedures for 505(b)(2) applications are or should be distinct from those for suitability petitions. After careful consideration, the agency believes that the policy would prolong review of 505(b)(2) applications and suitability petitions. Consequently, FDA will not adopt the proposed policy.

D. Withdrawal or Suspension of Approval of an ANDA

The statute authorizes the Secretary of Health and Human Services (the Secretary) to withdraw or suspend the approval of any ANDA for a generic drug if: (1) Grounds exist for withdrawal under section 505(e) of the act; (2) the approval of the listed drug referred to by the generic applicant is withdrawn or suspended; or (3) the manufacturer voluntarily withdraws the listed drug from sale for what the agency determines are safety or effectiveness reasons. The final rule contains provisions on withdrawal and suspension at 21 CFR 314.150 to 314.153.

III. Comments on the Proposed Rule

Section 10.30—Citizen Petition

Proposed § 10.30 (e)(2) and (e)(4) would have amended FDA's citizen petition regulations to provide for responses to petitions filed in accordance with section 505(j)(2)(C) of the act.

1. FDA received one comment on proposed § 10.30(e)(2). The comment agreed with the provision, and FDA has finalized it without change.

Section 10.45—Court Review of Final Administrative Action; Exhaustion of Administrative Remedies

2. Two comments objected to proposed § 10.45(d), which would make FDA's response to a petition for reconsideration, rather than a response to a petition under section 505(j)(2)(C) of the act, final agency action. Both comments said that FDA had no authority to require a petition for reconsideration and would give petitioners the right to request a hearing or declare FDA's response to the suitability petition to be final agency action.

FDA disagrees with the comments. FDA has the authority to require adherence to a petition for reconsideration procedure, and such a requirement is practical in this case. From a practical standpoint, the agency receives a large number of suitability petitions each year. If every response to a suitability petition were to be considered as final agency action, the agency would be obliged to devote more resources to each petition to create a comprehensive administrative record. This approach would prolong the review of all suitability petitions without any appreciable benefit to petitioners or the agency. In fact, requiring a petition for reconsideration is to the petitioner's benefit because it ensures that senior FDA officials review the decision on the suitability petition. As for the authority to require a petition for reconsideration, the agency does not agree that it lacks authority to establish by regulation what constitutes final agency action on a petition.

Section 310.305—Records and Reports Concerning Adverse Drug Experiences on Marketed Prescription Drugs for Human Use Without Approved New Drug Applications

3. FDA received one comment on proposed § 310.305 (a)(3) and (c)(4), which, in part, would require persons to report or review reports of therapeutic failure. The proposed rule would amend the existing regulation, which required manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA to maintain records and report to FDA "(1) all serious, unexpected adverse drug experiences associated with the use of their drug products and (2) any significant increase in the frequency of a serious, expected

adverse drug experience." The comment suggested that FDA delete "therapeutic failure" and replace it with "significant failure of expected pharmacological action."

The agency declines to adopt the comment's suggestion. Section 310.305 uses the term "therapeutic failure" to correspond to similar language for adverse drug experience reporting for drugs subject to premarket approval. (See § 314.80; 54 FR 28872 at 28911.) In the preamble to the proposed rule, FDA explained that it was deleting the word "significant" from the phrase "any significant failure of expected pharmacological action" because the word "significant" had been a source of confusion and ambiguity. (See 54 FR 28872 at 28889.) Thus, FDA proposed to amend §§ 314.80 and 310.305 to require reports of "therapeutic failure" to eliminate this confusion and require all reports of therapeutic failure (54 FR 28872 at 28889).

Section 314.1—Scope

4. FDA received no comments on the proposed changes to 21 CFR 314.1, but did receive two general comments regarding the proposed rule's scope. One comment asked FDA to permit ANDA's for duplicates of "drug substances for which the specifications are very tightly drawn for both potency and purity," such as insulin preparations, and for copies of biotechnology-derived drug products. The second comment recommended that FDA accept ANDA's with warnings or precautions in addition to those on the reference listed drug's label, provided that such information was not indicative of diminished safety or effectiveness of the generic drug product.

Section 505(j) of the act permits ANDA's only for duplicate and related versions of previously approved drug products. The ANDA applicant relies on a prior agency finding of safety and effectiveness based on the evidence presented in a previously approved new drug application. If investigations on a drug's safety or effectiveness are necessary for approval, an ANDA is not permitted. Thus, under the statute, an ANDA would only be permitted for a drug product with "tight specifications" or a biotechnology-derived drug product only if such a product is the same as a product previously approved under section 505 of the act or if FDA has approved submission of an ANDA under a petition filed under section 505(j)(2)(C) of the act.

As for accepting ANDA's with additional warnings or precautions, section 505 (j)(2)(A)(v) and (j)(3)(G) of the act requires that the applicant's proposed labeling be the same as that of the reference listed drug unless: (1) The labeling differences are due to an approved petition under section 505(j)(2)(C) of the act (otherwise referred to as a "suitability petition"); or (2) the drug product and the reference listed drug are produced or distributed by different manufacturers. (See 21 U.S.C. 355 (j)(2)(A)(v) and (j)(3)(G).) Thus, the exceptions in section 505 (j)(2)(A)(v) and (j)(3)(G) of the act are limited. In addition, under the patent and exclusivity provisions of the act, the ANDA labeling may be required to carry fewer indications than the reference listed product's labeling or to have other labeling differences. In the preamble to the proposed rule, the agency described various types of labeling differences that might fall within the permitted exceptions. An ANDA applicant is required to include in its ANDA a side-by-side comparison of the applicant's proposed labeling with the currently approved labeling for the reference listed drug. The agency will carefully review all differences annotated by the applicant in determining if such differences fall within the limited exceptions permitted by the act.

Section 314.3—Definitions

FDA received 14 comments concerning the definitions of "listed drug" and "reference listed drug" under proposed § 314.3. The proposed rule had defined a "listed drug," in part, as:

> * * * a new drug product that has been approved for safety and effectiveness under section 505(c) or approved under section 505(j) of the act, the approval of which has been withdrawn or suspended under section 505(e) (1) through (5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's inclusion in the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) or any current supplement to the list.

The proposed rule defined a "reference listed drug" as "the listed drug identified in an abbreviated new drug application or identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application."

5. With respect to the "listed drug" definition, one comment objected to the exclusion of drugs marketed in compliance with an over-the-counter (OTC) monograph and products with OTC and prescription indications. A second comment said that FDA must list DESI products and post-1962 approved drug products even if the drug products were no longer marketed by September 24, 1984, because section 505(j)(6)(A)(i) of the act requires those products be listed. Four comments objected to listing drugs that have delayed effective dates of approval, while one comment favored listing such drugs.

FDA agrees in part and disagrees in part with the comments. As defined in section 505(j)(6) of the act, a listed drug is one that was approved for safety and effectiveness under section 505(c) of the act or approved under section 505(j) of the act. Drug products marketed in compliance with an OTC monograph rather than pursuant to an approval under section 505(c) or (j) of the act are not listed drugs under the statute.

With respect to DESI products and post-1962 approved drug products that are no longer marketed, FDA stated its position in the preamble to the proposed rule. In brief, FDA declines to allocate its scarce resources to publish and maintain lists of drug products that no longer generate interest with respect to marketing (54 FR 28877 through 28878). FDA does, however, maintain a list of discontinued products as an appendix to the list, and has created a procedure to return these products and other discontinued products to the list where appropriate. If a drug firm wishes to submit an ANDA for a generic version of one of these drug products, it may petition FDA to relist the drug product and provide information to show that the drug product was not withdrawn from sale due to safety or effectiveness reasons.

With respect to drug products with delayed effective dates of approval, FDA has determined that such products should not be listed. An approval with a delayed effective date is tentative and does not become final until the effective date. FDA has concluded that only drug products with final, effective approvals are to be listed under section 505(j)(6) of the act. FDA has amended the definitions of "listed drug" and "the list" to clarify that only drugs with an effective approval are listed drugs.

Similarly, with respect to drug products that are subject to the DESI program and do not meet the conditions for approval of effectiveness as set forth in a DESI notice, FDA has reexamined its policy and no longer regards the DESI notice published in the **Federal Register** as a "listed drug." Section 505(j)(6) of the act describes a "listed drug" as a drug that has been approved for safety and effectiveness. A drug product that must satisfy the conditions for approval of effectiveness as set forth in a DESI notice, therefore, does not fall within section 505(j)(6) of the act and cannot be a listed drug. Therefore, the

agency has revised the definition of listed drug so that a DESI notice will not suffice as a "listed drug."

6. Five comments addressed the definition of "reference listed drug." Three comments suggested that the oldest or first NDA product be the reference listed drug while one comment suggested that any FDA-approved drug be a "referenced listed drug." Another comment recommended designating "reference listed drugs" in the publication titled, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

As noted in the preamble to the proposed rule, FDA intends the reference listed drug to be the same drug product selected by the agency as the reference standard for bioequivalence determinations. Therefore, FDA has revised the definition of "reference listed drug" to make clear that a "reference listed drug" is a listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application. In some instances, such as the submission of an ANDA for a product with multiple strengths, there may be more than one reference listed drug. In these instances, FDA considers each strength to represent a different drug product and will require an ANDA applicant to demonstrate that each proposed drug product is bioequivalent to its corresponding reference listed drug. FDA will identify in future editions of the Orange Book those approved drugs that FDA regards as reference listed drugs. In the interim, FDA will maintain a list of reference listed drugs at the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857, until the Orange Book can be revised. FDA hopes that designating a single reference listed drug against which all generic versions must be shown to be bioequivalent will avoid possible significant variations among generic drugs and their brand name counterparts. Such variation could result if generic drugs established bioequivalence to different reference listed drugs.

7. One comment recommended defining "appropriate reliance" for purposes of section 505(b)(2) applications. The comment noted that the preamble to the proposed rule had stated "Appropriate reliance on an analysis of (spontaneous) adverse reaction reports will not cause application to be one described by section 505(b)(2) or 505(c)(3)(D)(of the act." (54 FR 28872 at 28891). The comment said it did not believe that an application containing an analysis of adverse reaction reports in place of safety studies "should be considered a full application for the purpose of 'breaking exclusivity' granted to another sponsor's drug."

FDA believes that the comment has misinterpreted the agency's position. The preamble to the proposed rule stated that, for drug products with a U.S. marketing history, an analysis of the spontaneous adverse reaction reports "may, in some cases, be substituted for some of the safety data" in a full NDA (54 FR 28872 at 28891). The agency believes that an analysis of spontaneous adverse reaction can provide some safety information when: (1) The drug product has a U.S. marketing history; and (2) there is a substantial amount of adverse drug reaction experience for that drug product. For example, an applicant could submit such an analysis to substitute for certain animal studies that would otherwise be required to show the kinds of risks that might be expected when the drug is tested in humans, or to show which certain, infrequent side effects occur rather than conduct large, Phase 3 clinical studies to prove the same result. Thus, FDA does not contemplate that an applicant under section 505(b)(1) of the act will substitute an analysis of adverse reaction reports for all safety information.

Section 314.50—Content and Format of an Application

The proposed rule contained several revisions and additions to the existing requirements at 21 CFR 314.50. The proposed revisions were minor. For example, under proposed § 314.50(a)(2), an applicant would be required to provide a statement whether the submission is an original application, a 505(b)(2) application, a resubmission, or a supplement to an application. The proposed additions focused on patent information and certifications and claimed exclusivity, and are not included in this final rule.

8. Proposed § 314.50(g)(3) would require an applicant who is submitting an application under section 505(b) of the act and who has a "right of reference or use" as defined in § 314.4(b) to include a "written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application." One comment would provide FDA access to the underlying raw data "only if FDA would not otherwise have access to the information that is needed for an adequate review of the application."

Section 314.50(g)(3) simplifies the process in which FDA can have access to raw data if such data are needed to review an application. Without this provision, if FDA determined that it needed to examine the raw data, it would be obligated to suspend the review process, request that the applicant obtain a written statement from the owner of the data to give FDA access to the data, and wait for the written statement to arrive before continuing its review. The provision, therefore, streamlines the review process by eliminating the need for requests and correspondence between FDA, applicants, and owners of data referenced by applicants after FDA had begun its review. The agency will utilize this authority when it believes that access to the raw data is necessary for reviewing the application.

Section 314.54—Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change from, a Listed Drug

FDA received two comments on proposed § 314.54. This provision would permit any person seeking approval of a drug product that represents a modification of a listed drug and for which investigations other than bioequivalence or bioavailability studies are essential to the approval of the change to submit a 505(b)(2) application.

9. One comment said FDA should revise proposed § 314.54(a) to state that a 505(b)(2) application is appropriate for changing a drug from prescription to OTC status.

FDA declines to adopt the comment. The regulation, as written, does not preclude submission of a 505(b)(2) application to change a drug from prescription to OTC status, so the suggested revision is unnecessary.

10. A second comment objected to proposed § 314.54(b) because it would prevent applicants from submitting applications requiring investigations for approval of a change from a listed drug for drugs whose only difference from the reference listed drug is that the extent to which the listed ingredients are absorbed or otherwise made available to the site of action to a lesser degree compared to the reference listed drug. The comment said FDA should judge drug products individually.

FDA declines to accept the comment. Differences in the extent to which a drug is absorbed will affect the drug's

therapeutic effectiveness. For example, a drug whose extent of absorption is less than that of the reference listed drug may be less effective or even ineffective. Consequently, FDA will not accept applications for products under § 314.54(b) whose extent of absorption is less than that for the reference listed drug.

FDA has, however, amended § 314.54(b) to state that it also will not accept an application under § 314.54 for a product whose only difference from the reference listed drug is an unintentional, lesser rate of absorption. FDA is making this change because a drug whose rate of absorption is unintentionally less than that of the reference listed drug may be less effective.

Section 314.55—Abbreviated Application; Section 314.56—Drug Products for Which Abbreviated Applications are Suitable

FDA received no comments on its proposal to remove these provisions, and, therefore, has removed them from 21 CFR part 314.

Section 314.60—Amendments to an Unapproved Application

11. FDA received two comments on proposed § 314.60. In general, proposed § 314.60 stated when an applicant could submit an amendment to an application filed under § 314.100 but not yet approved, and also stated when an unapproved application could not be amended. One comment asked FDA to explain how exclusivity would be affected if a section 505(b)(2) application is amended before another section 505(b)(2) application, which had been filed earlier, is approved. The second comment claimed that § 314.60(d) would permit section 505(b)(2) applications to become effective regardless of new drug exclusivity. This comment said FDA should revise the rule to declare that a section 505(b)(2) application "that would not be approvable but for a previously approved application * * * be made subject to the exclusivity of that previously approved application."

The preamble to the proposed rule explained that, for concurrently pending 505(b)(2) applications, any 505(b)(2) application submitted to FDA before the approval of another NDA that qualifies for exclusivity under section 505(c)(3)(D)(ii) of the act (granting 5 years of exclusivity) is "not affected by this exclusivity provision." (54 FR 28872 at 28901.) This is because section 505(c)(3)(D)(ii) of the act prohibits only the "submission," and not the approval, of a 505(b)(2) application that refers to a previously approved application. The only exception to the policy on concurrently pending 505(b)(2) applications is where "the first applicant to obtain approval and to qualify for exclusivity publishes its data and the competing applicant amends its application to include the first applicant's published data * * *. Where that data would be essential to the approval of the competing application, the second application will be deemed to refer to the first application" and not permitted to avoid exclusivity. Id. This policy is covered under § 314.60(b)(1)(ii), so the comment's suggestion is unnecessary.

FDA disagrees with the second comment's assertion that the rule permits section 505(b)(2) applications to become effective regardless of exclusivity. The statute clearly states that the Secretary may not approve, or, in one case, that applicants cannot submit, an application before an exclusivity period expires. (See 21 U.S.C. 355(c)(3)(D)(i) through (c)(3)(D)(v).) The rule observes these restrictions and pertains only to amendments to unapproved applications; it does not address approvals. Section 314.60(b) is, in fact, designed to protect an applicant's exclusivity under section 505(c)(3)(D)(ii) of the act while simultaneously preserving an applicant's incentive to publish the studies on which approval was based. Thus, FDA does not adopt the comment's suggested language.

Section 314.70—Supplements and Other Changes to an Approved Application

FDA received no comments on this provision, but has amended the provision to adopt references to statutory, rather than regulatory, provisions or to explain what information should be provided. However, the agency wishes to remind ANDA applicants that, as noted in paragraph 4 above, the labeling for an ANDA product must, with few exceptions, correspond to that for the reference listed drug.

Section 314.71—Procedures for Submission of a Supplement to an Approved Application

FDA received no comments on this provision and has finalized it without change.

Section 314.80—Postmarketing Reporting of Adverse Drug Experiences

FDA proposed several changes to 21 CFR 314.80 under the proposed rule. Section 314.80(a) under the existing regulation defined an "adverse drug experience," in part, as "any significant failure of expected pharmacological action." The proposed rule would delete the adjective "significant" from this definition and, as a result, require reporting of "any failure of expected pharmacological action." The proposed rule also would require applicants to review all adverse drug experience information "obtained or otherwise received by the application from any source, foreign or domestic," and to review periodically the frequency of reports of adverse drug experiences "that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible * * *."

12. FDA received several comments on adverse drug experience reporting under proposed § 314.80. Four comments supported the rule. Five objected to deleting the adjective "significant" from the phrase "any significant failure of expected pharmacological action" in the existing definition of "adverse drug experience," or asked FDA to limit the rule. The comments said the rule would require additional reports and generate reports with little value.

As stated in the preamble to the proposed rule, FDA deleted the word "significant" from § 314.80 because the word has been a source of confusion and ambiguity (54 FR 28872 at 28889). By amending the rule, FDA intended to require reports of any drug failure, as the agency considers all such failures to be significant. Id. This modification will provide a complete picture of adverse drug experiences, rather than selected reports, and will improve the agency's ability to determine whether it should take regulatory action.

13. One comment said a "therapeutic failure" should include excessive or exaggerated responses to a drug.

FDA declines to amend the rule as suggested. FDA does not consider such responses to be "therapeutic failures" under § 314.80. They are, however, covered under § 314.80 because they usually manifest themselves as adverse drug experiences. Consequently, applicants are obligated to report them as adverse drug experiences.

Section 314.81—Other Postmarketing Reports

The proposed rule would amend 21 CFR 314.81 to require applicants to submit a Form FDA 2657 (Drug Product Listing) within 15 working days of the withdrawal from sale of a drug product. The proposed rule also contained details regarding the information to be submitted, such as the National Drug Code number, the drug product's

established name and proprietary name, and the date of withdrawal from sale.

14. One comment asked FDA to clarify whether an applicant's obligation to submit postmarketing reports begins when FDA approves its ANDA or when the ANDA approval becomes effective.

Although the preamble to the proposed rule said proposed § 314.81 would apply upon ANDA approval regardless of the ANDA's effective date (54 FR 28872 at 28889), FDA has reconsidered this position in light of its policy on delayed effective dates and approvals. FDA does not consider a drug to be approved until the effective date of approval and regards those drug products with delayed effective dates as having tentative approvals. This policy affects § 314.81 because section 505(k) of the act authorizes reporting requirements for drug products that have an approval "in effect." Thus, an applicant's obligation to submit postmarketing reports will begin when the ANDA approval becomes effective.

15. Two comments addressed the 15-day reporting deadline in proposed § 314.81(b)(3)(iii)(*a*). One comment said a company "does not always know within 15 days of its last shipment that it intends to discontinue marketing a product" and "it is not always clear to a company whether a product is going to be withdrawn from marketing or just temporarily suspended." The comment would have applicants notify FDA that they will withdraw a product when they decide to permanently withdraw the product from sale. The second comment added that the existing rule's annual reporting requirement was satisfactory.

FDA believes the first comment misinterprets the provision. FDA does not expect parties to submit reports within 15 days from the date of their last shipment. The 15-day period begins from the time the firm decides to withdraw the product from the market. Such withdrawals are not limited to permanent withdrawals; FDA is interested in any decision to discontinue marketing because of the possible implications for the product's safety and efficacy. The agency also declines to replace the 15-day reporting period with an annual reporting requirement as suggested by the second comment. The withdrawal of an approved NDA drug product may affect the marketing of duplicate ANDA drug products, so timely reports of drug product withdrawals may be very important.

Section 314.92—Drug Products for Which Abbreviated Applications May be Submitted

FDA received four comments on proposed § 314.92. The proposed rule stated that abbreviated applications are suitable for certain drug products, such as drug products that are the same as a listed drug, drug products that meet the monograph for an antibiotic drug for which FDA has approved an application, drug products for which FDA has found an ANDA to be suitable and has announced such a finding in the **Federal Register**, and drug products that FDA has declared to be suitable for an ANDA submission under the petition procedures.

16. One comment asked FDA to refuse ANDA's for DESI drugs on the grounds that the statute only applies to post-1984 ANDA's. The comment noted that DESI drugs are reviewed by category rather than active ingredient and said some DESI active ingredient categories lack a "readily identifiable pioneer NDA product." Another comment supported ANDA's for DESI drugs.

The ANDA provisions of the 1984 amendments are applicable to all generic drugs for which approval is sought after September 24, 1984, the date on which the statute was enacted. Perpetuating different ANDA systems for pre-1962 drugs and post-1962 drugs would be needlessly confusing, illogical, and inefficient to FDA, the public, and industry. Therefore, FDA has included DESI drugs in these regulations.

Upon further consideration, FDA agrees that ANDA's may be inappropriate for some DESI drug products. In the DESI process, a DESI-reviewed NDA or ANDA is usually considered approved for safety and effectiveness through the approval of a supplement that brings the NDA or ANDA drug product into compliance with a DESI-upgrade notice. The DESI-upgrade notice describes what information the NDA or ANDA holder must provide in order for its drug product to be considered effective. If the NDA or ANDA holder complies with the notice through an approved supplement, then the drug product is considered to be safe and effective and can be listed in the Orange Book. Once this occurs, a person may be able to submit an ANDA for the product. However, if the NDA or ANDA holder fails to comply with the notice, the NDA or ANDA drug product is not considered to be approved for effectiveness and cannot be a listed drug. Under these circumstances, an ANDA cannot be submitted because there is no "listed drug." Therefore, FDA has revised § 314.92 by removing paragraph (a)(3) and renumbering paragraph (a)(4) as (a)(3). An applicant seeking to rely on the findings reflected in a DESI-upgrade notice, in the absence of a listed drug, should submit its application under section 505(b)(2) of the act.

Once a drug subject to a DESI notice is approved for safety and effectiveness and can serve as a listed drug, the agency will require the submission of an ANDA under section 505(j) of the act for a generic version of the product. As a matter of policy, the agency does not accept applications under section 505(b)(2) of the act when there is a listed drug that would provide a basis for an application under section 505(j) of the act. For clarity, FDA has added a new paragraph (d)(9) in § 314.101. The issue had been discussed in the preamble to the proposed rule (54 FR 28890 through 28891). At that time, the agency proposed to treat a 505(b)(2) application as submitted under section 505(j) of the act if the application was for a duplicate of a listed drug eligible for approval under section 505(j) of the act. Id. FDA believes that the policy it is describing in new § 314.101(d)(9), that an application for a drug such as this needs to be submitted by the applicant as an ANDA under section 505(j) of the act, is the preferable approach.

17. Two comments concerned proposed § 314.92(a)(1), which said, in part, that an ANDA would be suitable for a drug product that is the same as a listed drug and that the term "same as" means "identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted." The proposed rule would also require potential applicants to comply with § 314.122, "Submitting an abbreviated application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed," if the listed drug had been voluntarily withdrawn or not offered for sale by its manufacturer. One comment asked FDA to define "strength." The second objected to the language on voluntary withdrawals. The comment said NDA holders should disclose the reasons for withdrawing a product, and FDA should determine whether those reasons raise safety or efficacy questions, and then give ANDA holders an opportunity to examine and respond to the information on the withdrawal.

"Strength" refers to the amount of the product's active ingredient and is usually expressed in terms of weight. For example, a drug that is available as a 50 milligram (mg) tablet and a 100 mg tablet has two "strengths."

As for voluntary withdrawals and the reasons for a withdrawal, FDA refers

the reader to its discussion of identical comments at § 314.161 below.

17a. Additionally, although the preamble to the proposed regulation stated: "Section 507(a) of the act permits the submission of abbreviated applications for *duplicates* of all antibiotics the agency has already approved for marketing" (emphasis added) (54 FR 28872 at 28878), the proposed regulation (§ 314.92(a)(2)) referred only to products that meet the monograph. Because, in some instances, a generic antibiotic may be a duplicate of an approved antibiotic but may not meet the monograph in every respect for that approved antibiotic, the agency has broadened the language of the proposed regulation to include generic antibiotics that either are duplicates of, or meet the monograph for, the approved antibiotic. This change is made at the agency's initiative to reflect the intent of the agency expressed in the preamble to the proposed regulation.

Section 314.93—Petition To Request a Change from a Listed Drug

Proposed § 314.93(b) stated that a person who wants to submit an ANDA for a drug product "which is not identical to a listed drug product in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application."

18. Most comments agreed with the proposal, but one comment suggested that the rule be revised to state that FDA will not accept a suitability petition if the proposed drug product has different inactive ingredients which "may have some effect on the safety or efficacy of the altered product." Another comment asserted that the safety and effectiveness of a proposed new combination drug cannot be determined without drug interaction data.

FDA declines to accept the comments. Under the statute, suitability petitions are for drugs that have a different active ingredient, route of administration, dosage form, or strength. (See 21 U.S.C. 355(j)(2)(C).) A person seeking marketing approval of a drug product that differs from the listed drug product only with respect to inactive ingredients is not required to submit a suitability petition. FDA also notes that § 314.94(a)(9)(ii) requires applicants to identify and characterize the inactive ingredients used in the proposed drug product, and this information should permit FDA to determine whether the different inactive ingredients affect the product's safety. If FDA determines that the inactive ingredients of the drug are unsafe, the agency will refuse to approve the ANDA. (See 21 U.S.C. 355(j)(3)(H); 21 CFR 314.127.)

As for proposed new combination drug products, the statute expressly authorizes petitions for drugs with one different active ingredient. The petitioner must provide information to show that the different active ingredient is "an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p)" (21 U.S.C. 355(j)(3)(C)(iii)(II)). Although the statute does not expressly require drug interaction data, it authorizes FDA to refuse to approve a petition if "investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients" or if a drug product containing a different active ingredient "may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application" (21 U.S.C. 355 (j)(2)(C)(i) and (j)(2)(C)(ii)). Thus, if the agency determines that the safety and effectiveness of a proposed combination drug product cannot be shown without drug interaction data, FDA will not approve the petition. FDA has, on its own initiative, revised the language in § 314.93(d) to clarify the circumstances under which a petitioner may identify more than one listed drug. The revised language corresponds more closely to the statutory language.

19. One comment suggested that the agency revise proposed § 314.93(d)(3) regarding proposed combination drug products with one different active ingredient. The proposed rule would require petitioners to provide information to show that:

> If the proposed drug product is a combination product with one different active ingredient, including a different ester or salt, from the reference listed drug, that the different active ingredient has previously been approved in a listed drug or is a drug that does not meet the definition of "new drug" in section 201(p) of the act.

The comment suggested that § 314.93(d)(3) be revised to state that ingredients listed as Category I (generally recognized as safe or generally recognized as effective) in a tentative final or final OTC monograph are "substitutable ingredients."

FDA declines to revise the rule as requested. The rule is consistent with section 505(j)(2)(A)(ii)(III) of the act, which states that the different active ingredient must be "an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p) * * *." Therefore, in order to be a "substitutable ingredient," a Category I ingredient must be either an active ingredient of a listed drug or an active ingredient that does not meet the definition of a "new drug." An ingredient included in a final OTC drug monograph would be a "substitutable ingredient" because it does not meet the definition of a "new drug."

20. One comment asked FDA to accept petitions to submit an ANDA for a product whose labeling differs from the reference listed drug by being "more clear or offer better directions regarding how the drug should be taken."

FDA declines to accept the comment. Suitability petitions are for drugs that have a different active ingredient, route of administration, dosage form, or strength. (See 21 U.S.C. 355(j)(2)(C).) Labeling differences, therefore, are not proper subjects for a suitability petition.

FDA reminds applicants that the labeling for an ANDA product must be the same as the labeling for the listed drug product except for differences due to different manufacturers, exclusivity, etc. (See 21 U.S.C. 355(j)(3)(G).) An ANDA applicant who believes that the labeling for a proposed drug product should differ from that approved for the reference listed drug should contact FDA to discuss whether labeling for both generic and listed drugs should be revised.

21. One comment objected to proposed § 314.93(e)(1)(v) because FDA would refuse to approve a petition if the reference listed drug had been voluntarily withdrawn from sale and FDA had not determined whether the withdrawal was for safety or effectiveness reasons. The comment would revise the rule to require manufacturers to provide detailed reasons for withdrawing a drug product and, if FDA concluded that those reasons involved safety or effectiveness issues, require FDA to provide this information to prospective ANDA applicants or petitioners.

FDA declines to amend the rule as requested. The statute does not require FDA to determine why a listed drug was withdrawn from sale in every case, and the agency believes it would be impractical to do so. The agency discusses this subject in greater detail in its discussion of the comments to 21 CFR 314.151 through 314.152.

22. Five comments focused on the term "limited confirmatory testing" mentioned in the preamble to proposed § 314.93(e)(2). Proposed § 314.93(e)(2) stated that the phrase, "investigations must be conducted," meant "information derived from animal or clinical studies is necessary to show that the drug product is safe or effective." The

preamble to the proposed rule explained that:

> If preclinical or clinical data are needed to support safety, or if clinical data are needed to support the effectiveness of the requested change, then an abbreviated new drug application is not appropriate for the proposed drug product, and FDA will not approve a petition. However, under certain circumstances, data from limited confirmatory testing to show that the characteristics that make the proposed drug product different from the listed drug do not alter its safety and effectiveness may be accepted in a petition or as additional data to be included in an ANDA resulting from an approved petition.

54 FR 28872 at 28880.

One comment asked FDA to define "limited confirmatory testing." Two comments noted that the preamble to the proposed rule would permit limited confirmatory testing but that the rule itself would not approve a petition if animal or clinical studies are needed. The comments suggested revising the rule so a drug product "for which any testing other than bioavailability testing is required is ineligible for ANDA treatment." Two other comments said limited confirmatory testing would create a new class of applications or permit firms to avoid full NDA requirements; these comments would eliminate such testing or limit their use to "very rare circumstances."

As stated in the preamble to the proposed rule, by "limited confirmatory testing," FDA means "simple studies intended to rule out unlikely problems." (See 54 FR 28872 at 28880.) Such tests do not include animal or clinical studies whose information is necessary to show that the drug is safe or effective. (See 21 CFR 314.93(e)(2).) Thus, FDA does not intend to permit petitioners to substitute limited confirmatory testing for clinical studies or otherwise circumvent NDA requirements.

23. One comment objected to the language in proposed § 314.93(e)(3), which said FDA may "at any time during the course of its review of an abbreviated new drug application, request additional information required to evaluate the change approved under the petition." The comment argued that this language would permit FDA to revoke its approval of a petition even after an ANDA is submitted.

When read in its entirety, § 314.93(e)(3) states that when FDA approves a petition, the agency may describe what additional information, if any, will be required to support an ANDA for the drug product, and that this approval should not be construed as preventing FDA from requesting additional information to evaluate the ANDA. Thus, the provision concerns information needed to support approval of the ANDA rather than the information needed to evaluate the petition.

As for "revoking" approval of a suitability petition, FDA is amending § 314.93 by adding a new paragraph (f) to give the agency express authority to withdraw approval of a suitability petition if new information indicates that approval should be withdrawn. Such information can come from any source, including ANDA's submitted under the petition. This amendment will ensure that suitability petition approvals continue to reflect valid, scientific judgment and reasoning and prevent would-be ANDA applicants from relying on suitability petitions that, in light of new information, would not have been granted had the new information been available when the petition was under consideration.

Section 314.94—Content and Format of an Abbreviated Application

FDA received over 100 comments pertaining to ANDA format and content. Most recommended revisions or clarification while several expressed general agreement with specific provisions.

Table of Contents

24. One comment suggested that proposed § 314.94(a)(2), which would require the archival copy of an ANDA to contain a table of contents, be revised to require that both archival and review copies of an ANDA contain a table of contents.

Although the provision in question only pertains to archival copies of an application, FDA agrees with the comment and has amended § 314.94(d)(2) accordingly.

Basis for an ANDA Submission

25. Two comments addressed reference listed drugs under proposed § 314.94(a)(3)(i). The proposed rule would require an ANDA to contain "the name of the reference listed drug, including its dosage form and strength." The comments noted that the preamble to the proposed rule stated that the pioneer drug would "usually" be the reference listed drug, but, if more than one listed drug existed for the same drug product, the preamble recommended that applicants contact the Director of the Division of Bioequivalence before selecting a reference listed drug (54 FR 28880–28881). The comments asked FDA to explain how FDA determines which drugs should be reference listed drugs, and one comment proposed that the pioneer drug serve as the reference listed drug "unless there are sound scientific reasons for which a substitute may be preferred."

As stated above, FDA has revised the rule so that FDA will designate all reference listed drugs. Generally, the reference listed drug will be the NDA drug product for a single source drug product. For multiple source NDA drug products or multiple source drug products without an NDA, the reference listed drug generally will be the market leader as determined by FDA on the basis of commercial data. FDA recognizes that, for multiple source products, a product not designated as the listed drug and not shown bioequivalent to the listed drug may be shielded from direct generic competition. If an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA. Once FDA designates that reference listed drug, that drug will continue to be the reference standard even if the drug is later replaced as the market leader. The Orange Book will identify all reference listed drugs, so applicants are no longer instructed to call the Director of the Division of Bioequivalence. FDA has, however, deleted the language regarding **Federal Register** notices from § 314.94(a)(3)(i). As discussed elsewhere in this rule, the agency no longer regards a DESI notice as a listed drug and will not accept an ANDA in the absence of a listed drug.

Active Ingredients

26. Two comments sought more exacting standards or requirements for establishing that a generic drug and a listed drug contain the "same" active ingredients. Proposed § 314.94(a)(5)(i) would require an ANDA to contain information to show that the active ingredient in a single-active-ingredient product to be "the same as that of the reference single-active-ingredient listed drug." One comment stated that the active ingredients in the proposed drug product must be identical to those in the reference listed drug and that blood level comparisons are inadequate to establish such identity. The comment added that the rule should provide technical or scientific criteria for determining whether two active ingredients are equivalent.

The second comment would require applicants to demonstrate that their active ingredients "exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process; and that the stereochemistry characteristics

and solid state forms of the drug have not been altered."

Under the statute, an ANDA applicant must show that its active ingredient is the same as that in the reference listed drug (21 U.S.C. 355(j)(2)(A)(ii)). FDA will consider an active ingredient to be the same as that of the reference listed drug if it meets the same standards for identity. In most cases, these standards are described in the U.S. Pharmacopeia (U.S.P.). However, in some cases, FDA may prescribe additional standards that are material to the ingredient's sameness. For example, for some drug products, standards for crystalline structure or stereoisomeric mixture may be required. Should questions arise, an applicant should contact the Office of Generic Drugs to determine what information would be necessary to demonstrate that its active ingredient is the same as that in the reference listed drug.

As for possible impurities or residues in the ANDA product, ANDA applicants would be required to provide information on the drug substance and the drug product as part of the chemistry, manufacturing, and controls section of the application. (See 21 CFR 314.94(a)(9); 314.50(d)(1).) This would include information on impurities and residues. The "Guideline for Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances" suggests that impurities "should not only be detected and quantitated, but should also be identified and characterized when this is possible with reasonable effort." This guideline adds that "All major impurities should be individually limited. The maximum amount per unit dose of every individual impurity should be provided. If there is information on toxicity or information on toxic limits that have been set of these impurities, this information should be provided." If the manufacturing, packing, or processing controls cannot ensure the product's identity, strength, quality, and purity, or if the drug's composition is unsafe, FDA will not approve the ANDA. (See 21 U.S.C. 355 (j)(3)(A) and (j)(3)(H).)

27. One comment sought clarification of proposed § 314.94(a)(5)(ii)(A). That provision would require an ANDA for a combination drug product to contain information to show that the active ingredients are the same as those for the reference listed drug, or,

> * * * if one of the active ingredients differs from one of the active ingredients of the reference listed drug and the abbreviated application is submitted pursuant to the approval of a petition under § 314.93 to vary such active ingredient, information to show that the other active ingredients of the drug product are the same as the other active ingredients of the reference listed drug, information to show that the different active ingredient of another listed drug or of a drug which does not meet the definition of a "new drug" in section 201(p) of the act, and such other information about the difference active ingredient that FDA may require.

The comment asked FDA to clarify the phrase "such other information about the different active ingredient that FDA may require."

The phrase quoted by the comment reflects the statutory language at section 505(j)(2)(A)(ii)(III) of the Act. FDA has not requested any additional information from applicants under this authority, and cannot predict what type of information it would require. Nevertheless, the final rule keeps this language and will not foreclose its use.

Bioequivalence

FDA received nine comments on proposed § 314.94(a)(7). That section describes the kinds of information required to demonstrate bioequivalence.

28. One comment suggested that applicants be given the option of submitting a proposed bioavailability or bioequivalence study protocol for review and comment either as part of an ANDA or before submitting an ANDA so that applicants do not conduct questionable or unnecessary studies.

Since publication of the proposed rule, FDA has changed its policies regarding the submission of incomplete ANDA's. Under earlier policy, FDA permitted ANDA applicants to submit ANDA's with bioequivalence study protocols and to provide bioequivalence study data at a later date. This policy has resulted in a significant and unwarranted expenditure of resources in reviewing applications that had little potential for approval. FDA will therefore no longer accept an ANDA that does not contain complete bioequivalence study data if such data are required for approval. However, with respect to pre-ANDA submissions of bioequivalence protocols, FDA will continue, to the extent that time constraints and resources permit, to provide guidance on such protocols before an ANDA is submitted. Applicants wishing such guidance may submit requests for review of proposed protocols to the Director, Division of Bioequivalence. The Division will attempt to provide informal comments on such submissions as time and resources permit. The agency has also revised § 314.94(a)(7)(i) to delete the language concerning **Federal Register** notices. As stated earlier, the agency no longer regards a DESI notice as a listed drug and will not accept an ANDA in the absence of a listed drug.

29. One comment recommended that FDA give each holder of an NDA for an innovator drug an opportunity to comment on any bioequivalence study protocol proposed by an ANDA applicant if "nonabsorbed drugs" are involved. The comment would also establish deadlines for the NDA holder to respond to the protocol and for FDA to issue a decision.

FDA has considerable scientific expertise in the critical review of bioequivalence protocols. If additional expertise is necessary, the agency will seek advice from sources such as the Generic Drug Advisory Committee on an "as needed" basis. The agency also notes that, as a basic matter, giving NDA holders a role in reviewing the applications of potential competitors could create a conflict of interest and compromise an applicant's confidential information. Therefore, FDA is not adopting the comment.

30. One comment stated that an FDA request for additional information under proposed § 314.94(a)(7)(ii) should be made within 30 days after the initial submission of the ANDA. As drafted, proposed § 314.94(a)(7)(ii) would require an ANDA submitted under a suitability petition to vary an active ingredient to contain "the results of any bioavailability or bioequivalence testing required by the agency, and any other information required by the agency to show that the different active ingredient is of the same pharmacological or therapeutic class as that of the changed ingredient in the reference listed drug, and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug."

FDA declines to accept the comment. If FDA determines, after receiving an ANDA that was submitted pursuant to an approved suitability petition, that the ANDA applicant must submit additional information, this determination represents a finding that the information is necessary to ensure that the proposed ANDA drug product has the same therapeutic effect as the reference listed drug. (See 21 U.S.C. 355(j)(2)(A)(iv).) The agency will not, therefore, forego requesting such information simply because a specific time period has expired. FDA will act on ANDA's as expeditiously as agency resources and priorities permit, but cannot guarantee that the agency will be able to identify, within 30 days, all instances where it needs to request information.

31. One comment interpreted proposed § 314.94(a)(7)(ii) to mean that

safety and efficacy studies could be required and asked FDA to state that a product requiring more than bioequivalence testing cannot be the subject of an ANDA.

FDA will not require safety and effectiveness investigations under § 314.94(a)(7)(ii). As stated in section 505(j)(2)(C) of the act and § 314.93(e)(1)(i), if clinical investigations are needed to establish a product's safety or effectiveness, that product is not suitable for approval under an ANDA. FDA does not, however, interpret this section to preclude the use of data to demonstrate whether a proposed drug product will have the same therapeutic effect as a reference listed drug.

FDA has, however, revised § 314.94(a)(7)(ii) to state that an ANDA submitted under an approved petition must contain the results of any bioavailability or bioequivalence testing or any other information required by FDA to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. This change encompasses ANDA's for single-ingredient drug products submitted pursuant to an approved suitability petition. The proposed rule inadvertently omitted a reference to such ANDA's and unintentionally created a potential problem for some ANDA applicants. For example, if the approved suitability petition permitted a change in dosage form, it might be difficult for some applicants to demonstrate bioequivalence between the new dosage form and the dosage form of the reference listed drug, e.g., between a cream and a tablet. The change corrects this problem and corresponds to the statutory language in section 505(j)(2)(A)(iv) of the act.

32. Proposed § 314.94(a)(7)(ii)(A) stated that FDA would consider a proposed drug product to have the same therapeutic effect as a reference listed drug if the applicant provided information demonstrating that:

> There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product of the same safety and effectiveness.

One comment would delete the adjective "same" from the phrase "of the same safety and effectiveness" because "[i]t may not be possible to have exactly the same safety and effectiveness, for example, if a different active ingredient is included in a combination product and safety or efficacy is enhanced." The comment recommended replacing the words "of the same safety and effectiveness" with "whose safety and effectiveness have not been adversely affected."

FDA agrees and has revised the rule accordingly.

33. One comment suggested amending proposed § 314.94(a)(7)(iii) to state that waivers from the in vivo bioavailability or bioequivalence requirement are possible under 21 CFR 320.22. As drafted, proposed § 314.94(a)(7)(iii) made no reference to waivers.

FDA declines to adopt the suggestion. Section 314.94(a)(7), generally, and § 314.94(a)(7)(iii), specifically, do not require in vivo bioequivalence. The provisions state the statutory requirement that an ANDA contain information to show bioequivalence and that, if that information is obtained from an in vivo study, the applicant include in its application information about the analytical and statistical methods used and information to show that the study was conducted in compliance with 21 CFR parts 50 and 56. Information to show bioequivalence may, depending on the drug product, come from an in vivo or an in vitro study.

34. Two comments focused on institutional review board (IRB) and informed consent requirements at proposed § 314.94(a)(7)(iii). The proposed rule would have required a statement regarding compliance with the IRB and informed consent requirements at 21 CFR parts 56 and 50, respectively, for each in vivo bioequivalence study in an ANDA. One comment asked FDA to identify the party responsible for providing a statement on IRB review and informed consent. The comment suggested that the "sponsor," which FDA presumes is the ANDA applicant, make such statements only after the sponsor had conducted an "appropriate on-site inspection of the records and the informed consent process as the study is performed." The second comment suggested revising the regulation to identify the party making the statement. The comment explained that sponsors who have transferred their obligations to contract research organizations should be able to provide the names and addresses of such organizations rather than make the statements on IRB review and informed consent themselves.

FDA declines to accept the comments. The ANDA applicant is ultimately responsible for ensuring that the ANDA satisfies all statutory and regulatory obligations, including IRB review under 21 CFR part 56 and informed consent under 21 CFR part 50. This is true even if the ANDA applicant has elected to use a contract research organization to conduct the study. If an ANDA does not contain such a statement, FDA may refuse to receive it. (See § 314.101(b)(3); see also § 314.101(d)(7).)

Labeling

Proposed § 314.94(a)(8) set forth labeling requirements for ANDA's. The proposal would require applicants to provide copies of the currently approved labeling for the reference listed drug, labels and labeling for the proposed drug product, and a statement that the applicant's proposed labeling is the same as that for the reference listed drug except for certain differences, including, but not limited to, differences due to exclusivity or patent protection. The proposal, at § 314.94(a)(8)(iv), would also require applicants to provide a side-by-side comparison of the applicant's proposed labeling with the approved labeling for the reference listed drug. The proposed rule did not state how applicants could acquire copies of the reference listed drug's labeling, but the preamble said current approved labeling could be obtained under the Freedom of Information Act (FOIA) (54 FR 28872 at 28884).

35. Several comments stated that obtaining copies of drug labeling under FOIA would be time-consuming, difficult, or impractical. The comments suggested that FDA develop procedures to display such labeling or to provide them to applicants upon written or oral request. One comment also said that FDA should routinely provide ANDA applicants with updated labeling.

FDA disagrees that its FOIA system is inadequate for ANDA labeling purposes. The agency's FOIA system handles information requests in an orderly and expeditious manner. The procedure for requesting information is both simple and straightforward. (See 21 CFR 20.40.) Additionally, FDA regulations, in most instances, require the Freedom of Information Staff to respond to a freedom of information request within 10 working days. (See 21 CFR 20.41(b).) For these reasons, FDA declines to create an alternate system for providing drug labeling.

As for providing updated labeling information, the agency does not believe it is currently feasible to routinely provide updated labeling on all products eligible for ANDA's. The Office of Generic Drugs (OGD) encourages applicants to contact OGD before submitting an ANDA for advice on what labeling would be the most appropriate to use for its proposed product. Such

labeling can ordinarily be obtained from one or more of the following sources, including (1) OGD labeling guidance documents, (2) the innovator or generic drug product labeling from the product itself, (3) Physician's Desk Reference, (4) FDA's Freedom of Information Office, or (5) calling the Drug Information Services Branch directly at 301–443–3910. FDA also provides further guidance to an ANDA applicant after the applicant submits proposed labeling. After ANDA approval, FDA tracks the labeling status of the pioneer drug product and, if necessary, notifies ANDA holders when and how they must revise their labeling.

36. One comment asked FDA to clarify its policy regarding the use of the ANDA holder's name on the label and package insert when the ANDA holder neither manufactures nor distributes the drug product.

FDA's policy regarding the names on drug product labeling is set forth at 21 CFR 201.1 as authorized by section 502 of the act (21 U.S.C. 352). In general, § 201.1 states that, with few exceptions, no person other than the manufacturer, packer, or distributor may be identified on the label of a drug or drug product. The Orange Book discusses this subject in greater detail and recognizes that, under certain circumstances, the ANDA holder's name might not appear on the product's labeling. (See "Approved Drug Products with Therapeutic Equivalence Evaluations," pp. 1–3 (1991).)

37. One comment asked how ANDA applicants should present proposed labeling. The comment said that FDA should specify its exact requirements or permit applicants to submit labeling in any format they choose.

FDA believes that detailed instructions on the size and format of proposed labeling are not appropriate for this regulation. Applicants who have questions about the presentation of labeling in ANDA's should contact the Program Support Staff, Office of Generic Drugs, for guidance.

38. Proposed § 314.94(a)(8)(ii) would require ANDA applicants to provide copies of the label and labeling for the proposed drug product. Two comments suggested that FDA amend the rule to permit applicants to provide photographs of labeling rather than actual copies of the labeling when the label is printed on a tube or shipping carton.

FDA declines to accept the comment. Actual copies of tube labeling and other labeling help FDA determine the prominence of the information presented and whether the information is legible. These determinations cannot be easily made by the review of photographs. Ordinarily, however, FDA does not require submission of copies of shipping carton labeling as part of an abbreviated application.

39. Two comments opposed the requirement for a side-by-side comparison between the proposed ANDA drug product's labeling and the reference listed drug product's labeling under proposed § 314.94(a)(8)(iv). The comments said the comparison would be cumbersome and impractical, and suggested annotated changes or highlighted changes instead of comparisons.

In contrast, three comments supported side-by-side labeling but asked that ANDA holders be required to complete labeling revisions within 30 days of any change in the listed drug's labeling or to provide labeling comparisons every 6 months to ensure that the ANDA drug's labeling matched that of the listed drug. One comment said FDA should create a mechanism to compel ANDA holders to revise their labeling to conform to the listed drug product once the ANDA is approved.

The final rule retains the requirement of side-by-side labeling comparisons. Side-by-side comparisons enable FDA reviewers to readily identify differences between the ANDA applicant's and the innovator's product labeling. FDA does not believe that this requirement will impose a significant burden on ANDA applicants.

As for creating a mechanism to compel labeling revisions, section 505(e)(2) of the act authorizes the withdrawal of approval of an application if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." This provision applies to both ANDA and NDA drug products. Because an ANDA must have labeling that is the same as the reference listed drug under section 505(j)(2)(A)(v) of the act, FDA believes that a generic drug product approved on the basis of studies conducted on the listed drug and whose labeling is inconsistent with the listed drug's labeling might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the listed drug's labeling. FDA, therefore, has revised § 314.150 to permit the agency to withdraw approval of an ANDA if the applicant fails to maintain labeling in compliance with the requirements of the act.

As for requiring ANDA holders to submit drug labeling at periodic intervals, FDA believes that the existing reporting requirements at 21 CFR 314.70 and 314.81 ensure that labeling changes are brought to FDA's attention in an appropriate and timely fashion. The agency will advise ANDA holders of changes to be made after approval, but postapproval changes resulting from the expiration of exclusivity or patent protection are the responsibility of the ANDA holder.

40. Two comments said the labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information. One comment added that ANDA applicants should be allowed to delete some of the indications contained in the labeling for the reference listed drug.

FDA disagrees with the comments. Except for labeling differences due to exclusivity or a patent and differences under section 505(j)(2)(v) of the act, the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval. Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. (See 54 FR 28872 at 28884.) If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

41. One comment suggested revising proposed § 314.94(a)(8)(iv) to exempt ANDA holders from being required to submit pharmocokinetic data to support new labeling unless the new labeling pertained to serious health or safety effects. The proposed provision stated that differences between an ANDA applicant's proposed labeling and the labeling approved for the reference listed drug may include, among other things, differences in pharmacokinetics. The comment explained that "insignificant labeling changes otherwise could become a tool to impede the ability of generics to compete, or force them to raise prices to the consumer in order to absorb the cost of additional, insignificant and, perhaps, unnecessary pharmacokinetic studies."

The comment misinterpreted the proposed requirement. The provision

does not impose a pharmacokinetic data requirement for all labeling changes. In fact, FDA believes that most labeling changes that do not involve serious health or safety effects will be acceptable without new pharmacokinetic data. However, FDA also believes that some labeling changes may be formulation-specific and that such changes may require additional pharmacokinetic data (e.g., addition of a food effect statement). FDA, therefore, reserves the right to examine such labeling changes on a case-by-case basis to determine whether additional pharmacokinetic data are necessary before the ANDA holder changes labeling.

42. One comment proposed revising the third sentence in proposed § 314.194(a)(8)(iv), which listed certain permissible labeling differences between the ANDA drug product and the reference listed drug, to read as follows:

> Such differences protected by patent or accorded exclusivity by 505(j)(4)(D) of the act between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

The comment explained that the revision would protect ANDA applicants from "a possible claim of inducement or infringement where a nonapproved, but patented, method of administration is discussed in the innovator's label" or the labeling refers to more than one method of use and "some but fewer than all of the methods of use are entitled to nonpatent exclusivity."

FDA agrees in part with the comment and has amended the provision to state that differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include omissions of an indication "or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act."

Chemistry, Manufacturing, and Controls

FDA received a number of comments on the chemistry, manufacturing, and controls section of an ANDA.

43. Many comments sought further definitions or explanations regarding ANDA chemistry, manufacturing, and controls documentation requirements, including information on technical details, such as determining the source of impurities, potential degradation, and test methodologies. Two comments asked FDA to develop guidelines on acceptable levels of preservatives and other inactive ingredients.

These comments raise technical questions that are beyond the scope of this rule. FDA has already issued a number of guidelines addressing many of the questions. These guidelines apply to both full and abbreviated applications, and a list of available guidelines may be obtained from CDER Executive Secretariat Staff, Center for Drug Evaluation and Research (HFD–8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. FDA will consider the comments in determining whether to revise existing guidelines or to develop new guidelines.

44. Several comments objected to the provisions in proposed § 314.94(a)(9) requiring ANDA applicants to use the same inactive ingredients as the reference listed drug or to identify and characterize the differences between inactive ingredients. The comments stated that ANDA applicants might not know or might be unable to discover all inactive ingredients used in the reference listed drug. The comments suggested that FDA either not require that the inactive ingredients be the same or require the disclosure of the inactive ingredients used in the reference listed drug.

Because the labeling regulations do not require listing of inactive ingredients for drug products in an oral dosage form (see 21 CFR 201.100(b)(5)), ANDA applicants may be unable to discover what inactive ingredients were used in such drug products. Consequently, FDA has revised § 314.94(a)(9) to require ANDA applicants to include such a comparison only for drug products intended for parenteral use, ophthalmic or otic use, or topical use. ANDA applicants will be able to determine the inactive ingredients in reference listed drugs for these dosage forms because such ingredients are disclosed on the labeling. (See 21 CFR 201.100(b)(5).) For other drug products, FDA has revised § 314.94(a)(9)(ii) to require applicants only to identify and characterize the inactive ingredients in the proposed drug product and to provide information demonstrating that the inactive ingredients do not affect product safety.

45. Proposed § 314.94(a)(9)(iv) stated, in part, that:

> * * * an applicant may seek approval of a drug product (intended for ophthalmic or otic use) that differs from the reference listed drug in preservative, buffer, substance to adjust tonicity, or thickening agent provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product, except that in a product intended for ophthalmic use, an applicant may not change a buffer or substance to adjust tonicity for the purpose of claiming a therapeutic advantage over or difference from the listed drug, e.g., by using a balanced salt solution as a diluent as opposed to an isotonic saline solution, or by making a significant change in the pH or other change that may raise questions of irritability.
>
> (54 FR 28872 at 28923).

One comment objected to the example involving balanced salt solutions and isotonic saline solutions in proposed § 314.94(a)(9)(iv). The comment explained that changes in an ophthalmic buffer or tonicity agent from isotonic saline to balanced salt solutions do not raise serious safety questions, and FDA cannot presume that such changes are to claim a therapeutic advantage.

When read in its entirety, the second sentence in § 314.94(a)(9)(iv) simply states that an applicant whose product is intended for ophthalmic use cannot change a buffer or substance to adjust tonicity "for the purpose of claiming a therapeutic advantage over or difference from the listed drug * * *." The rule does not state that use of a balanced salt solution as opposed to an isotonic saline solution would be impermissible in itself or that FDA would presume such changes to be for claiming a therapeutic advantage. Determining whether the applicant claims a therapeutic advantage over or difference from the listed drug depends on the circumstances surrounding each case.

Samples

46. FDA received one comment regarding generic drug product samples under proposed § 314.94(a)(10). The proposed rule would require ANDA applicants to comply with the sampling provisions at 21 CFR 314.50 (e)(1) and (e)(2) but would not require ANDA applicants to submit samples until FDA requested them. The comment suggested revising the rule to require ANDA applicants to obtain samples and to retain them in their stability containers for all lots of a finished product. The comment added that FDA should "make itself available as a witness if requested for the distribution of samples to laboratories for bioavailability studies."

Under existing current good manufacturing practice (CGMP) regulations, manufacturers are already required to retain samples. (See 21 CFR 211.84 and 211.170.) FDA has also issued an interim rule that requires applicants who conduct in-house bioavailability and bioequivalence testing and contract laboratories who conduct such testing to

retain reserve samples of the drug products used to conduct the studies. The interim rule, which appeared in the Federal Register of November 8, 1990 (55 FR 47034), and existing CGMP regulations will help FDA ensure that the samples sent to laboratories match the drug product to be produced. Therefore, the suggestion that FDA be available to witness distribution of samples to laboratories is unnecessary. FDA anticipates publication of a final rule shortly.

Patent Certification

FDA received a number of comments regarding patent certifications under proposed § 314.94(a)(12). The agency is still examining these comments and will finalize the provisions for patent certification at a later date.

DESI Drugs

47. Two comments objected to the inclusion in proposed § 314.94(b) of DESI drugs in the ANDA regulations. The proposed rule would permit persons to file ANDA's for a duplicate of a drug product that is subject to the DESI review or a DESI-like review and also a listed drug. If the ANDA is for a drug product that is a duplicate of a drug product that is subject to the DESI review or a DESI-like review and not listed, the proposed rule would require applicants to comply with the conditions set forth in the applicable DESI notice or other notice with respect to conditions of use and labeling and the ANDA content and format requirements. One comment argued that the statute applies only to post-1984 ANDA's so including DESI drugs was inappropriate. The comment suggested deleting this provision but noted that "additional special considerations need to be recognized" when finalizing the rule because, for some DESI active ingredient categories, there is no readily identifiable pioneer NDA product. A second comment stated that, under proposed § 314.94(b)(2), DESI drugs cannot be reference listed drugs unless they are listed or the applicant has filed an application under section 505(b)(1) or (b)(2) of the act.

The ANDA provisions of the 1984 amendments are applicable to all generic drugs for which approval is sought after September 24, 1984, the date on which the statute was enacted. However, after careful consideration, FDA agrees that ANDA's are inappropriate if the drug product that is the subject of a DESI review or DESI-like review has not complied with the conditions for effectiveness set forth in a DESI notice or other notice. In the absence of an approved product that satisfies the conditions set forth in the DESI notice or other notice, there is no "listed drug" within the provisions of section 505(j)(6) of the act, and an ANDA cannot be submitted for that drug.

Therefore, FDA will no longer accept an ANDA for a DESI drug product when there is no listed drug for that product, and has deleted § 314.94(b)(2) entirely. An applicant seeking approval of a drug product covered by a DESI upgrade notice before a product is approved for safety and effectiveness under that notice should submit a 505(b)(2) application to the Office of Generic Drugs. Generally the 505(b)(2) application must contain the information specified in section 505(b)(2) of the act, except that the labeling must meet the conditions of use announced as effective in the relevant DESI upgrade notice. In satisfying the full reports of investigations requirement under section 505(b)(1)(A) of the act, the applicant may refer to the agency's conclusions in the DESI upgrade notice about the product's safety and effectiveness and must demonstrate that the proposed drug product is bioequivalent to the drug product that is the subject of the relevant DESI upgrade notice. The agency will generally employ the same mechanisms and standards in approving a section 505(b)(2) application for a DESI drug product that it would for and ANDA under section 505(j).

Section 314.96—Amending an Unapproved ANDA

FDA received a small number of comments concerning proposed § 314.96. The proposed rule would permit applicants to amend an ANDA that had been submitted, but not yet approved, to revise existing information or to provide additional information. The proposed rule also explained when an amendment might extend the review period.

48. One comment objected to a preamble statement which said "data from a bioequivalence study where only a protocol was contained in the original submission" could be an example of a major ANDA amendment. (See 54 FR 28872 at 28888.) The comment said that an ANDA application should be complete when submitted and not completed through amendments.

FDA agrees with the comment. Under current policy, FDA does not accept an ANDA that contains only a bioequivalance study protocol. This policy is consistent with the statutory provision requiring an ANDA to contain information showing that the applicant's drug product is, rather than "will be shown to be," bioequivalent to the reference listed drug. (See 21 U.S.C. 355(j)(2)(A)(iv).)

49. One comment asked whether ANDA applicants could amend applications without informing FDA of their intent to amend them or withdraw applications after receiving an approvable or not approvable letter.

Under 21 CFR 314.110(b), an ANDA applicant who has received an approvable letter must correct the deficiencies described in the approvable letter "by amendment within the specified time period" or FDA will refuse to approve the abbreviated application. The ANDA applicant may also ask the agency to provide an opportunity for a hearing. Under 21 CFR 314.120(b), an ANDA applicant who has received a not approvable letter must amend or withdraw the ANDA or notify FDA of an intent to file an amendment within 180 days after the date of the not approvable letter. Under 21 CFR 314.120(a)(3), an ANDA applicant may also ask the agency to provide an opportunity for a hearing. If an ANDA applicant fails to respond within 180 days to the not approvable letter, FDA will consider the ANDA applicant's failure to respond to be a request to withdraw the ANDA. Thus, an ANDA applicant that receives an approvable or not approvable letter may amend its ANDA without informing FDA of its intent to amend the ANDA. The regulations also do not require ANDA applicants to provide notice of intent to withdraw an ANDA.

50. Several comments discussed "major" and "minor" amendments in relation to proposed § 314.96(a)(2) and (a)(3). Proposed § 314.96 (a)(2) would permit FDA to extend the review period if the amendment contained significant new data requiring additional time for agency review. Proposed § 314.96(a)(3) would treat the submission of an ANDA amendment to resolve substantial deficiencies as set forth in a not approvable letter as an agreement between FDA and the applicant to extend the review period 120 days. Neither provision referred to "major" or "minor" amendments, but the preamble to the proposed rule explained that a major amendment would be one which required substantial review time. The preamble provided several examples of such major amendments, including amendments containing data from a new bioequivalence study or stability or sterility study submitted in support of a drug product reformulation or changes in the manufacturing or controls procedures.

One comment stated that an amendment, regardless of whether it

was a "major" or "minor" amendment, should not result in any extension of the review period if FDA had not begun to review the application. This comment also suggested that "minor" amendments, which it defined as requiring less than 8 hours of review time, only result in a 14-day extension to the review period.

FDA disagrees with the comment. A policy that would permit applicants to submit amendments containing significant data or information without extending the review period would encourage the submission of incomplete ANDA's and create new administrative problems between applicants and the agency. For example, disputes would arise as to whether an amendment had been submitted before review had begun or whether a particular FDA action constituted "review."

As for extension periods, FDA has decided not to adopt proposed § 314.96(a)(2). The agency found the proposed provision to be unfeasible and has decided to retain the concepts at § 314.60. Consequently, FDA has revised § 314.96(a)(2) to state that an amendment containing significant data or information requiring additional time for agency review will constitute an agreement by the applicant to extend the date by which the agency is required to reach a decision on the application. The revised paragraph states that FDA will ordinarily extend the review period "only for the time necessary to review the significant data or information," and this period will not exceed 180 days. This paragraph, as revised, is similar to the preexisting requirements under § 314.60 and encourages ANDA applicants to submit complete applications.

Proposed § 314.96(a)(2) also stated that FDA would notify an applicant of the length of the extension. The agency has decided not to adopt the notification provision. FDA's experience suggests that it is difficult and impractical to predict the length of an extension for an ANDA given the unpredictable nature of its workload. At the same time, FDA emphasizes that extensions under this paragraph will be "only for the time necessary to review the new information." The agency hopes to be able to limit extensions under § 314.96(a)(2), which applies to amendments submitted other than in response to a not approvable letter, to generally not more than 120 days if resources permit.

With regard to the comment regarding "minor" amendments, under current Office of Generic Drugs policy, FDA distinguishes between major and minor amendments only with regard to amendments submitted in response to a not approvable letter. These are covered under § 314.96(a)(3).

51. Three comments concerned extending the review period for amendments under proposed § 314.96(a)(3). One comment suggested that the extension be "not more than 120 days." Another comment said major amendments responding to FDA reviewers should not constitute an agreement to extend the review period. This comment added that if an extension were necessary, "it should not affect the entire ANDA, but only the discipline in which it is generated." The third comment objected to § 314.96(a)(3) entirely and claimed, without explanation, that it was inconsistent with the statute.

As stated above with regard to § 314.96(a)(2), FDA has decided against the adoption of proposed § 314.96(a)(3) and, instead, has revised § 314.96(a)(3) to state that the submission of an amendment containing significant data or information to resolve deficiencies in the application as set forth in a not approvable letter constitutes an agreement between FDA and the applicant to extend the review period. This paragraph, as revised, corresponds to similar requirements under § 314.60. The extension will only be for the time necessary to review the significant data or information and would not exceed 180 days.

FDA notes that under current Office of Generic Drugs policy, FDA distinguishes between major and minor amendments submitted in response to not approvable letters. (See memorandum issued July 11, 1991, from the Director, Office of Generic Drugs, to Office Division Directors, Deputy Division Directors, Associate Office Directors, and Branch Chiefs). FDA currently considers a minor amendment to be one that an experienced chemist reasonably can be expected to take less than 1 hour to complete the review. Under current policy, FDA commits to make every attempt to take action on a minor amendment within 60 days of its receipt, subject to applicable agency clearances such as a field inspection or microbiology consult.

Although the agency would like to be able to review all major amendments and applications within the 180-day period provided by statute, and would like to establish goals for reviewing these submissions in even shorter time periods, current resources do not provide a basis for establishing such goals for the foreseeable future. The Agency's goal at this time is to meet its obligations under the statute and to review these submissions as efficiently and as expeditiously as possible without affecting the scientific integrity of the review.

The agency disagrees, however, with the comments that would prevent the agency from extending the review period. FDA's experience indicates that some amendments that are intended to respond to not approvable letters can be extremely complex and present new information. If the agency could not extend the review period after receiving such amendments, the only practical recourse would be not to approve the application and have the applicant submit a new ANDA. This would be inefficient and wasteful, so § 314.96(a)(3) treats an amendment under this paragraph as an agreement to extend the review period. This permits both FDA and the applicant to continue working on the ANDA.

FDA emphasizes, however, that an applicant who receives a not approvable letter and wishes to submit an amendment to resolve the deficiencies identified in the not approvable letter should confine its amendment to the subjects discussed in the letter. Completely new information on topics not raised in the not approvable letter only prolongs FDA review.

FDA disagrees with the comment claiming that the provision is inconsistent with the statute. Under section 505(j)(4)(A) of the act, FDA must approve or disapprove an application within 180 days after its initial receipt or "within such additional period as may be agreed upon * * *." The statute clearly recognizes that deciding whether to approve an application may require more than 180 days.

52. One comment said FDA should, upon submission of an ANDA, notify the applicant of the date on which the agency would approve or not approve the ANDA. Alternatively, the comment would require FDA to review an ANDA once it had been submitted to determine whether the application may be received.

FDA declines to adopt the comment. Under § 314.101(b)(2), FDA will notify applicants, in writing, whether the agency will receive an ANDA. (Such written notice, however, is not provided when FDA receives an ANDA supplement.) FDA will not, however, create a deadline for informing applicants whether an ANDA is received because such deadlines would be impractical. FDA cannot predict the number of applications it will receive in any given period and must remain flexible to assign its staff to respond to agency demands and priorities. As for notifying applicants of the latest date on

which FDA should approve or not approve an ANDA, § 314.100(a) states that FDA will send an ANDA applicant an approval letter, approvable letter, or not approvable letter within 180 days of receipt of an ANDA.

Section 314.97—Supplements and Other Changes to an Approved Abbreviated Application

FDA received no comments on this provision and has finalized it without change.

Section 314.98—Postmarketing Reports

Proposed § 314.98 would require an applicant that has an approved abbreviated antibiotic application or approved ANDA to comply with adverse drug experience reporting requirements. Proposed § 314.98(c), however, would not require holders of approved ANDA's or abbreviated antibiotic applications to submit periodic reporting of adverse drug experiences "if no adverse drug experience reports have been received and no labeling changes have been initiated by the applicant during the reporting interval."

53. Several comments, however, said postmarketing report requirements should be the same for NDA and ANDA holders. One comment said FDA should require ANDA holders to submit a periodic report that would indicate whether a company had received any adverse drug experience reports during the reporting period.

After careful consideration, FDA has revised § 314.98 to require ANDA applicants to submit a periodic report of adverse drug experiences even if the ANDA applicant has not received any adverse drug experience reports or initiated any labeling changes. As revised, the requirement is identical to that imposed on NDA holders. Periodic reports by ANDA holders will help FDA determine whether ANDA products have appropriate labeling and ensure that no adverse drug experiences go unreported.

54. FDA, on its own initiative, has amended § 314.98(a) to require abbreviated antibiotic application and ANDA applicants to comply with the recordkeeping requirements under § 314.80. This change corrects an inadvertent omission from the original proposal.

Section 314.99—Other Responsibilities of an Applicant of an Abbreviated Application

FDA received no comments on this provision and has finalized it without change.

Section 314.100—Timeframes for Reviewing Applications and Abbreviated Applications; Section 314.101—Filing an Application and an Abbreviated Antibiotic Application and Receiving an Abbreviated New Drug Application

Proposed § 314.100 discussed timeframes for reviewing applications and abbreviated applications. In general, the proposed rule would have FDA review an application or abbreviated application and send the applicant an approval letter, approvable letter, or not approvable letter within 180 days of receipt of an application under section 505(b) of the act, or an ANDA under section 505(j) of the act, or an abbreviated antibiotic application under section 507 of the act. Proposed § 314.101 concerned the circumstances under which FDA would file an application and an abbreviated antibiotic application and receive an ANDA. FDA received several comments suggesting additional agency obligations when an application or abbreviated antibiotic application is filed and when an ANDA is received.

55. One comment wanted the agency to amend proposed § 314.100 to require FDA to acknowledge receipt of an application and to issue an application number. The comment suggested that this occur within 14 days after the application is submitted.

Section 314.101 states that FDA will notify applicants, in writing, whether an application or abbreviated application is filed or received. (See 21 CFR 314.101(a)(2) and (b)(2).) These letters should contain an application number. As noted in paragraph 52 above, FDA believes that establishing a fixed time period for determining whether an application may be received would be impractical considering the number of applications and supplements FDA receives. As a result, FDA declines to amend the rule as requested.

56. Two comments suggested that either proposed § 314.100 or § 314.101 be amended to have FDA expressly determine whether an ANDA is "received" within 30 days of its submission.

FDA declines to accept the comments. As stated earlier, FDA cannot predict how many applications will be submitted in a given period, so it must retain flexibility to respond to any demands imposed on the agency. Creating an additional 30-day deadline in the ANDA review process would limit that flexibility without any significant benefit to FDA or to applicants.

57. Another comment said proposed § 314.101(b) should not authorize FDA to determine whether an abbreviated application may be received.

FDA rejects this comment. By determining whether an application is "received," FDA encourages applicants to submit ANDA's that comply with statutory and regulatory requirements and are sufficiently complete for substantive review to begin. This conserves FDA resources by permitting FDA reviewers to devote their time to examining reviewable applications.

58. Two comments stated that an ANDA lacking bioequivalence or bioavailability information, completed bioequivalence studies, or stability data to support at least a 24-month expiration date should not be received.

As stated earlier, FDA no longer accepts an ANDA that lacks complete bioequivalence or bioavailability information at the time of its initial submission. Consequently, the agency has deleted § 314.101(d)(8), which pertained to ANDA's that did not contain the results of any required or completed bioequivalence or bioavailability study.

As for the comment suggesting that an ANDA lacking stability data to support at least a 24-month expiration date not be received, FDA declines to adopt the comment. Although most ANDA's contain such stability data, applicants have submitted and FDA has approved ANDA's containing stability data that support a different expiration date.

59. FDA received two comments on proposed § 314.101(e)(1). The proposed provision stated that FDA will refuse to file an application or abbreviated antibiotic application or consider an ANDA not to have been received if the drug product that is the subject of the submission "is already covered by an approved application or abbreviated application and the applicant of the submission is merely a distributor and/or repackager of the already approved drug product." One comment suggested that the first sentence be revised to state that FDA "may refuse to file" an application or abbreviated application if any of the listed conditions apply. The comment explained that FDA should have discretion to file an application, notwithstanding the existence of an approved application, when the applicant could justify the need for the duplicate application or abbreviated application. The second comment asked FDA to file duplicate ANDA's if two or more companies jointly develop the product or if an exclusive licensee or distributor seeks to file an ANDA with the licensor's consent.

Section 314.101(e)(1) was intended to prevent distributors from forcing FDA to

review applications for drug products that are already covered by approved applications. Reviewing an application is extremely time-consuming, and FDA's resources are limited. To permit applicants to force review of an application for a product that is already covered by an approved application would result in a severe drain on FDA resources to review duplicate applications, create duplicate product and patent listings in the Orange Book, and contribute to the agency's accumulation of applications. FDA did not, however, intend to apply this provision against companies that jointly develop a product. The agency, therefore, is amending § 314.101 to change the refusal in proposed § 314.101(e)(1) to accept duplicate applications to a discretionary refusal to accept duplicate applications under a new § 314.101(d)(8). FDA has also revised § 314.101(d)(8) to clarify that the agency may refuse to file an application or refuse to consider an ANDA to be received for a drug product when the application already has an approved application or abbreviated application for the same drug product.

Additionally, the agency has created a new § 314.101(d)(9) to clarify that the agency may refuse to file a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the act.

60. One comment asked FDA to amend § 314.101(f)(2) to add time periods for setting a hearing date following ANDA disapproval and for issuing a decision on a hearing. The comment also requested procedures for appealing a disapproval that would give the applicant "immediate attention" and be considered to be "final agency action."

The regulation pertaining to not approvable letters to applicants, § 314.120, states that when the agency refuses to approve an application, abbreviated antibiotic application, or ANDA, it will give the applicant a written notice of an opportunity for a hearing under § 314.120(a)(3). Section 314.200 states that, if the Commissioner of Food and Drugs grants a hearing, the hearing will begin within 90 days after the expiration of the time for requesting the hearing unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval (§ 314.200(g)(5)). Thus, there is no need to amend § 314.101(f)(2) to set a hearing date.

FDA also declines to set a deadline for resolving hearings or appeals. The demands placed on the presiding officer and other FDA employees assigned to administrative hearings can be immense depending on, among other things, the number of documents submitted to the administrative record. A large administrative record, coupled with the other obligations placed on the agency's employees, makes a deadline for resolving these matters impractical.

Finally, the administrative hearing regulations contain procedures for appealing a disapproval (e.g., 21 CFR 10.33 and 10.35). Parties may also seek judicial review as provided in 21 CFR 314.235(b).

Section 314.102—Communications Between FDA and Applicants

FDA received four comments regarding communications between FDA and applicants under proposed § 314.102. The proposed rule was substantially similar to the existing provision at 21 CFR 314.102 with the exception of new language to account for abbreviated applications and the availability of conferences and meetings for abbreviated applications. Proposed § 314.102(b) said FDA reviewers would make every reasonable effort to inform applicants of easily correctable deficiencies found in an application or abbreviated application or whether the agency would need more data or information. Proposed § 314.102(c) provided for 90-day conferences "to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies which have been identified by that time and which have not already been communicated." These conferences would be available for applications for all new chemical entities and major new indications of marketed drugs. Proposed § 314.102(d) would provide end-of-review conferences "to discuss what further steps need to be taken by the applicant before the application or abbreviated application can be approved." Finally, proposed § 314.102(e) indicated that applicants could request other meetings to discuss scientific, medical, or other issues.

61. One comment would require FDA reviewers to call ANDA applicants before issuing deficiency letters. The comment claimed FDA reviewers misinterpret or misread applications and could resolve these misunderstandings without a deficiency letter if they called ANDA applicants.

FDA declines to adopt the comment. The agency fully intends to communicate with ANDA applicants to resolve issues that arise during the ANDA review process but believes that requiring FDA reviewers to call ANDA applicants would be impractical and an inefficient use of resources. Some issues cannot be resolved or adequately described in a telephone call.

62. One comment proposed amending § 314.102(d) to require FDA to hold an end-of-review conference within 30 days of the issuance of a not approvable letter. Two comments addressed meetings under proposed § 314.102(e). One comment would require FDA reviewers and chemists to meet with any applicant upon 30 days notice. Finally, another comment urged FDA to be "liberal and speedy in granting requests for meetings on issues that arise during the review process."

FDA declines to accept the comments. FDA will make every attempt to grant requests for meetings that involve important issues, but, due to limited resources and other demands on reviewers, will not conduct meetings on a regular basis. The agency reiterates that 90-day conferences are available "on applications for all new chemical entities and major new indications of marketed drugs" (21 CFR 314.102(c) (emphasis added)), and that end-of-review conferences are available on all applications and abbreviated applications "with priority given to applications for new chemical entities and major new indications for marketed drugs and for the first duplicates for such drugs" (21 CFR 314.102(d)). Thus, for ANDA's, 90-day conferences will generally be unavailable, and end-of-review conferences will be given low priority.

FDA adds that ANDA applicants who do request a meeting are encouraged to submit an agenda of important issues in advance for FDA's consideration. This will permit the agency to focus on specific issues and conserve resources.

Section 314.103—Dispute Resolution

FDA received no comments on this provision and has finalized it without change.

Section 314.104—Drugs with Potential for Abuse

63. Only one comment addressed proposed § 314.104, which states that FDA will inform the Drug Enforcement Administration (DEA) when an application or abbreviated application is submitted for a drug that appears to have an abuse potential. The comment supported the rule but asked FDA to "ensure the confidentiality of any information, including even the fact that an application has been submitted prior to providing that information to DEA."

Section 314.104 simply reflects FDA's obligation, under 21 U.S.C. 811(f), to forward to DEA information on any drug having a stimulant, depressant, or

hallucinogenic effect on the central nervous system if "it appears that such drug has abuse potential." (See 21 U.S.C. 811(f).) FDA's disclosure of information to another Federal agency does not necessarily result in the public disclosure of that information. (See 21 CFR 20.85.) Indeed, the regulation on public disclosure of information at § 314.430 states that FDA will not publicly disclose the existence of an application or an abbreviated application before sending the applicant an approval letter unless the application or abbreviated application's existence has been previously publicly disclosed or acknowledged (21 CFR 314.430(b)). This includes data in an application or abbreviated application (21 CFR 314.430(c)). Disclosure of any trade secret information obtained under section 505 of the act is also prohibited by section 301(j) of the act.

Section 314.105—Approval of an Application and an Abbreviated Application

64. FDA received two comments on proposed § 314.105(d). Under that provision, FDA will approve an ANDA and send the applicant an approval letter if the agency finds none of the grounds for refusing ANDA approval to apply. Both supported the rule, but one comment said an approval letter should not raise any new issues "except on the data submitted in response to an approvable letter."

With the exception of editorial matters or other minor deficiencies in an ANDA, approval letters should not raise new issues for applicants to resolve. Therefore, the comment's suggestion is unnecessary.

FDA has, on its own initiative, clarified that an approval with a delayed effective date is tentative and does not become final until the effective date. The agency has also amended § 314.105(c) to state that an abbreviated application must meet statutory standards for manufacturing and controls, labeling, and "where applicable, bioequivalence." This change reflects the statutory requirements for an ANDA.

Section 314.110—Approvable Letter to the Applicant

FDA received seven comments regarding approvable letters to applicants under proposed § 314.110. The proposed rule stated that FDA would send applicants an approvable letter "if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions * * * are agreed to by the applicant." Proposed § 314.110 (a)(1) through (a)(5) would give those submitting full or abbreviated antibiotic applications 10 days to respond to or act on an approvable letter, request a hearing, or agree to an extension of the review period. Under proposed § 314.110(b), FDA would send approvable letters to ANDA applicants only if the ANDA substantially meets FDA requirements and the agency believed that "it can approve the abbreviated application if minor deficiencies in the draft labeling are corrected and final printed labeling is submitted." The proposed rule did not give ANDA applicants a specific time period to respond to an approvable letter.

65. Two comments recommended revising proposed § 314.110(a)(3). That provision stated that an NDA applicant who receives an approvable letter may ask FDA to provide an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. One comment urged FDA to provide an opportunity for a hearing to ANDA applicants. The second comment suggested revising the rule to provide hearing dates.

With respect to ANDA applicants, FDA is amending § 314.110(b) to permit ANDA applicants to request, within 10 days after the date of an approvable letter, that FDA provide an opportunity for a hearing. This is consistent with the opportunity for a hearing provided to applicants who receive a not approvable letter under § 314.120, although the agency believes that most issues raised by approvable letters should be capable of being resolved without a hearing. The agency is also amending § 314.110(a)(3) to note that abbreviated antibiotic applications applicants will have an opportunity to request a hearing under § 314.125. The proposed rule inadvertently omitted such language even though §§ 314.101 and 314.125 suggested that these applicants had an opportunity for a hearing.

As for providing hearing dates, FDA believes that amending the rule to provide hearing dates would be impractical. FDA's experience with scheduling administrative hearings shows that finding mutually acceptable hearing dates can be difficult, and the parties often request postponements even after a hearing date has been set.

66. Two comments suggested that FDA prescribe time limits for its review of amendments submitted in response to an approvable letter. One comment would require FDA to review an ANDA applicant's response to an approvable letter within 45 days. A second comment would require FDA to review an ANDA applicant's response within 90 days.

FDA declines to amend the rule as suggested. Under § 314.110(b), FDA will send an approvable letter to an ANDA applicant only if the ANDA meets regulatory requirements under 21 CFR part 314 and FDA "believes that it can approve the abbreviated application if minor deficiencies are corrected * * *." However, FDA's ability to review an applicant's response to an approvable letter can vary due to a number of factors, such as the reviewer's skill, speed, and work load, the quality of the amendment or submission, and the complexity of the issues. Thus, the final rule does not require the agency to review an applicant's response within a single, predetermined time period. Unless the applicant's response to the approvable letter contains significant data or information requiring an extension of the review period, FDA should complete, and has the goal of completing, most of these reviews before 60 days have expired.

67. Two comments asked FDA to clarify when it would issue an approvable letter to an ANDA applicant. Under proposed § 314.110(b), FDA would send an ANDA applicant an approvable letter "only if the application substantially meets the requirements of this part and the agency believes that it can approve the abbreviated application if minor deficiencies in the draft labeling are corrected and final printed labeling is submitted." One comment said an approvable letter should be appropriate for more than minor labeling changes, and should also be used for changes such as a change in U.S.P. requirements, or the addition or deletion of an alternate analytical method. The second comment asked FDA to define the phrase, "substantially meets the requirements of this part."

FDA agrees that approvable letters may be appropriate for more than minor labeling deficiencies. Consequently, the agency has revised the rule to state that minor labeling deficiencies are simply an example of the type of deficiencies for which an approvable letter may be appropriate.

As for the phrase, "substantially meets the requirements of this part," FDA means that, with the exception of minor deficiencies, the ANDA complies with the requirements under 21 CFR part 314.

Section 314.120—Not Approvable Letter to the Applicant

Proposed § 314.120 described the circumstances under which FDA would send a not approvable letter. Proposed § 314.120(a)(1) and (a)(2) would require applicants to amend, withdraw, or notify FDA of an intent to amend an application or abbreviated application. Proposed § 314.120(a)(3) would permit applicants to ask FDA to provide a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act. Applicants would be required to respond to a not approvable letter within 10 days, except that ANDA applicants, under proposed § 314.120(b), would have 180 days to respond.

68. Most comments on proposed § 314.120 recommended changes to response times. One comment suggested amending § 314.120(a) to give applicants 30 days to respond to a not approvable letter. Two comments asked that the regulation require ANDA applicants to respond to a not approvable letter within 10 days rather than the 180 days given at § 314.120(b).

FDA declines to amend the rule as suggested by the comments. The comments did not contain any justification for revising the response times, and FDA sees no reason to do so.

69. One comment asked that proposed § 314.120(a)(3) be revised to make clear that ANDA and NDA applicants, upon receipt of a not approvable letter, have the right to request that the agency provide the applicant an opportunity for a hearing.

Section 314.120(a)(3) was intended to apply to both ANDA applicants and to NDA applicants. FDA, therefore, agrees with the comment and has revised the provision accordingly. FDA has also revised § 314.120(b) to clarify that an ANDA applicant must make its request for a hearing to FDA within 10 days after the date of the not approvable letter.

Section 314.122—Submitting an Abbreviated Application for, or a 505(j)(2)(C) Petition That Relies on, a Listed Drug That is no Longer Marketed

70. One comment suggested that the title be revised to read, "Submitting an Abbreviated Application for * * *." The comment said this change would be consistent with the definitions in § 314.3.

FDA agrees and has revised the title accordingly.

Section 314.125—Refusal to Approve an Application or an Abbreviated Antibiotic Application

FDA received no comments on this provision and has finalized it without substantive change.

Section 314.127—Refusal to Approve an Abbreviated New Drug Application

Proposed § 314.127 provided a list of reasons for refusing to approve an ANDA. In general, these reasons corresponded to those listed at section 505(j)(3) of the act.

71. One comment asked FDA to amend proposed § 314.127(c) to describe the type of information that it would require an ANDA applicant to submit to show that an active ingredient in an ANDA product is the same as the active ingredient in the reference listed drug. In brief, proposed § 314.127(c) would, in relevant part, have FDA refuse to approve an ANDA if there is insufficient information to show that the active ingredient(s) in the proposed drug product are the "same" as those in the reference listed drug.

Under 21 CFR 314.120, if FDA believes that an application is not approvable, it will notify the applicant in writing and describe the deficiencies in the application. Thus, in the situation described by the comment, the applicant could use the agency's written response to determine how it could demonstrate that its active ingredient is the same as that in the reference listed drug. Depending upon the circumstances, an applicant might find additional guidance in drug compendia or FDA guidelines. (See paragraph 26 above for a related comment.) The comment's suggestion, therefore, is unnecessary.

72. Proposed § 314.127(g) (now § 314.127(a)(7)) would permit FDA to refuse to approve an abbreviated application if information in the ANDA "is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug * * * except for changes required because of differences approved in a petition under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers." One comment said FDA should also require ANDA holders to obtain current labeling for the listed drug every 6 months and update their own labeling accordingly.

FDA has revised § 314.150 to require ANDA holders to maintain current labeling. Failure to do so may result in withdrawal of approval. FDA will not, however, require ANDA holders to obtain current labeling or to update their own labeling every 6 months because drug labeling does not change on a regularly scheduled basis.

73. A second comment recommended adding "or because of patent requirements" to the end of proposed § 314.127(g).

FDA agrees that a patent may be a valid reason for labeling differences between the reference listed drug and the ANDA drug product and that such differences should not be a basis for refusing to approve an ANDA. FDA has, therefore, revised the rule to indicate that labeling differences may also be due to patents or exclusivity. However, FDA cautions that it will not approve an ANDA with different labeling if the labeling differences affect product safety or efficacy. For example, if the patent protects information on a new dosing regimen and FDA concludes that the preexisting dosing regimen is unsafe, the different labeling for the proposed ANDA product would be grounds for refusing to approve the ANDA.

74. Proposed § 314.127(h)(1)(i) (now § 314.127(a)(8)(i)(A)) would permit FDA to refuse to approve an ANDA if FDA had any information that the proposed drug product's inactive ingredients are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed drug product's labeling. Proposed § 314.127(h)(1)(ii) (now § 314.127(a)(8)(i)(B) would permit FDA to refuse to approve an ANDA if the proposed drug product's composition was unsafe under the conditions prescribed, recommended, or suggested in the proposed labeling because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included. One comment asked FDA to merge proposed § 314.127(h)(1)(i) and (h)(1)(ii) or to explain their differences.

FDA declines to revise the rule as suggested. Section 314.127(a)(8)(i)(A) and (a)(8)(i)(B) (proposed § 314.127(h)(1)(i) and (h)(1)(ii)) reflects the statutory language at section 505(j)(3)(H)(i) and (j)(3)(H)(ii) of the act, respectively, and serves different purposes. To illustrate, if FDA concluded that an inactive ingredient in a proposed ANDA product was unsafe, it could refuse to approve the ANDA under § 314.127(a)(8)(i)(A). If the proposed ANDA product involved a combination of inactive ingredients and the combination (as opposed to each inactive ingredient), either by the type or quantity of an inactive ingredient or the manner of formulation of the inactive ingredients into the product, shows that the product was unsafe, the refusal to approve the ANDA would occur under § 314.127(a)(8)(i)(B).

FDA received four comments on proposed § 314.127(h)(2) (now § 314.127(a)(8)(ii)). Under the proposal, FDA would consider a drug product's inactive ingredients or composition to be unsafe and refuse to approve an ANDA if, on the basis of information available to FDA, "there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raise serious questions of safety."

75. One comment said FDA must have a valid scientific reason, rather than a "reasonable basis" under proposed § 314.127(h)(2)(i), to conclude that an inactive ingredient raises "serious questions of safety." A second comment would replace the list of examples with a shorter, generalized list of safety questions.

If the reference to "valid scientific reason" is meant to suggest that the agency must have proof that a drug is unsafe before taking action, FDA disagrees with the comment. The preamble to the proposed rule explained how FDA concluded that section 505(j)(3)(H) of the act asuthorizes the agency to refuse to approve an ANDA if there is a reasonable basis to conclude that a drug product's inactive ingredients or composition raises serious questions about drug safety. In brief, section 505(e) of the act permits FDA to withdraw ANDA approval if there is evidence that the drug "is not shown to be safe." FDA can invoke this provision whenever there is a reasonable basis to conclude that a drug is unsafe even if the agency lacks proof that the drug is unsafe (54 FR 28902). In comparison, section 505(j)(3)(H) of the act authorizes FDA to refuse to approve an ANDA if "information submitted in the application or any other information available to the Secretary" shows that the drug's inactive ingredients or composition is unsafe. If FDA construed section 505(j)(3)(H) of the act as requiring proof that a drug product is unsafe before it could act, the agency would be obliged to approve an ANDA and then immediately initiate a proceeding to withdraw approval.

The U.S. Supreme Court has held that, in interpreting the act, it must be given " 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose," and must not " ' impute to Congress a purpose to paralyze with one hand what it sought to promote with the other.' " *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 631–632 (1973) (quoting *Clark* v. *Uebersee Finanz-Korp.*, 332 U.S. 480, 488–489). It would be inconsistent with these principles to interpret section 505(j)(3)(H) of the act as imposing a burden of proof on the agency that would require aproval of potentially unsafe drugs, or require a greater showing that a drug is not safe to disapprove a product than is required to withdraw approval of it. Therefore, FDA is interpreting that section as authorizing disapproval of an ANDA on the same basis as withdrawal under section 505(e)(2) of the act. Thus, an ANDA may be disapproved if there is a reasonable basis to conclude that one of its inactive ingredients or its composition raises serious questions about the drug's safety.

As for deleting the list of examples of changes that raise serious questions of safety, FDA has elected to amend the last sentence in § 314.127(a)(8)(ii)(A) (proposed § 314.127(h)(2)(i)) to read, "Examples of the changes that may raise serious questions of safety include, but are not limited to, the following." This amendment shows that the list of examples is not exhaustive and that the described changes do not automatically raise serious safety concerns that preclude ANDA approval.

The proposed rule listed several examples of changes that raise serious questions of safety. These examples included the "use of a controlled release mechanism never before approved for the drug" (proposed § 314.127(h)(2)(i)(E)) and "a change in composition to include a significantly higher concentration of one or more inactive ingredients than previously used in the drug product" (proposed § 314.127(h)(2)(i)(F)).

76. The third comment asked FDA to delete § 314.127(h)(2)(i)(E) and (h)(2)(i)(F) (now § 314.127(a)(8)(ii)(A)(*5*) and (a)(8)(ii)(B)(*6*)). The comment claimed that the use of a different controlled release mechanism or a change in composition to include a significantly higher concentration of one or more inactive ingredients should not preclude ANDA approval. The comment also suggested revising § 314.127(h)(2)(i)(F) to read, "A change in composition to include levels of an inactive ingredient for which published data may exist showing such levels to be unsafe."

FDA declines to accept the comment. When read in its entirety, proposed § 314.127(h)(2) states that FDA will consider a drug's inactive ingredients or composition to be unsafe and refuse to approve an ANDA if "there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raise serious questions of safety." FDA believes that such a reasonable basis may exist in the absence of published data. As the rule and the preamble to the proposed rule note, the examples listed in proposed § 314.127(h)(2)(i)(E) and (h)(2)(i)(F) simply illustrate FDA's experience. (See 54 FR 28903.) Thus, if the proposed drug product uses a delivery or release mechanism that has never been approved for that drug or contains a higher concentration of one or more inactive ingredients, FDA will not automatically refuse to approve the ANDA. Instead, FDA will refuse to approve the ANDA only if there is a reasonable basis to conclude that the change raises serious safety questions.

FDA has, however, revised the wording in the final rule at § 314.127(a)(8)(ii)(A)(*5*) to replace "a controlled release mechanism" with "a delivery or a modified release mechanism." This change reflects the agency's experience with novel delivery or modified release mechanisms and places emphasis on the delivery mechanism or modified release mechanism itself whereas the proposed rule could have been interpreted as focusing concern solely on controlled release mechanisms.

FDA has also revised the final rule at § 314.127(a)(8)(ii)(A)(*6*) to replace "higher concentration" with "greater content." This change recognizes the fact that minutely higher concentrations of one or more inactive ingredients do not always present serious questions of safety. In contrast, a drug that has a greater content of one or more inactive ingredients often presents serious questions of safety.

77. Proposed § 314.127(h)(2)(ii) (now § 314.127(a)(8)(ii)(B)) said FDA would consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and refuse to approve the ANDA unless "it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product." A comment said that requiring information to show that changes in a preservative, buffer, or antioxidant do not affect safety was "unnecessarily excessive" because FDA knows commonly used preservatives, buffers, and antioxidants. The comment suggested revising the provision only to require submission of information on preservatives, buffers, and antioxidants that are not commonly used.

The statute authorizes the Secretary to withhold approval of an ANDA if

information submitted in the application or any other information available shows that "(i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included." (See 21 U.S.C. 355(j)(3)(H).) Thus, under the statute, the inquiry is not whether each preservative, buffer, and antioxidant is commonly used or known; instead, the inquiry is whether the preservatives, buffers, and antioxidants in the proposed drug product are safe under the conditions prescribed, recommended, or suggested in the labeling. Section 314.127(a)(8)(ii)(B) of this final rule reflects this concern, which is particularly acute for parenteral drug products. Therefore, FDA declines to revise the rule as suggested.

Section 314.150—Withdrawal of Approval of an Application or Abbreviated Application

Proposed § 314.150 concerned withdrawals of approvals of an application or abbreviated application under section 505(e) of the act. The proposed rule would permit FDA to withdraw approval of an application or abbreviated application under certain enumerated conditions, such as a finding that an imminent hazard to the public health exists (§ 314.150(a)(1)), or a finding that clinical data or other experience, tests, or scientific data show the drug is safe for use under the conditions of use approved in the application or abbreviated application (§ 314.150(a)(2)(i)).

78. Two comments said FDA should create a new provision authorizing the agency to withdraw an abbreviated application if the abbreviated application holder failed to modify its labeling to match labeling changes in the reference listed drug.

FDA agrees and has revised the rule accordingly. New § 314.150(b)(10) states that the ANDA applicant's failure to maintain drug labeling that is consistent with that of the listed drug may be grounds for withdrawing approval of the abbreviated application. The only exceptions to this withdrawal provision are labeling differences approved in the original ANDA or resulting from a patent issued on the listed drug after approval of the ANDA or from exclusivity accorded to the listed drug after approval. However, as noted in paragraph 39 above, if the agency concludes that a labeling difference resulting from patent protection or exclusivity compromises the safety or effectiveness of the generic drug product for any remaining conditions of use, FDA may withdraw approval of the ANDA under this provision.

Section 314.151—Withdrawal of Approval of an Abbreviated New Drug Application Under Section 505(j)(5) of the Act; Section 314.152—Notice of Withdrawal of Approval of an Application or Abbreviated Application for a New Drug

79. Proposed § 314.151 (concerning withdrawals of approval of ANDA's under 21 U.S.C. 355(j)(5)) did not provide ANDA applicants the opportunity for an oral hearing in the event of a withdrawal. FDA received seven comments claiming that ANDA applicants should have an opportunity for a hearing or an oral hearing when FDA proposes to withdraw approval of an application or abbreviated application. In general, the comments argued that ANDA applicants should have the opportunity for a hearing on due process grounds or to "assure fairness." One comment stated that section 505(e) of the act authorizes hearings whenever the agency proposes to withdraw approval of an application approved under section 505, and, therefore, ANDA holders were entitled to hearings because ANDA's are authorized by section 505(j) of the act. One comment, however, would deny ANDA applicants the opportunity for a hearing because an ANDA "is completely dependent on the continued approval of the reference listed drug" and the ANDA applicant "does not take the place of the listed drug applicant for purposes of exercising the right to protect that drug."

The statute and regulations contemplate withdrawing ANDA approval under two different circumstances. First, if FDA finds the ANDA product unsafe for use, lacks substantial evidence of effectiveness under the conditions of use prescribed, recommended, or suggested in its labeling, contains an untrue statement of material fact, or meets any of the other grounds for withdrawal under section 505(e) of the act, the agency may withdraw approval "after due notice and opportunity for hearing to the applicant" (21 U.S.C. 355(e)). For ANDA products, the regulations pertaining to a withdrawal of approval under section 505(e) of the act are at § 314.150. These regulations, contrary to some of the comments' assertions, do give ANDA holders an opportunity for a hearing on a proposal to withdraw approval of an ANDA to the extent that one or more of the grounds for withdrawal under section 505(e) of the act directly apply to the ANDA product. (See § 314.150 (a) and (b).)

The second situation in which ANDA approval may be withdrawn focuses on withdrawal of the listed drug rather than the ANDA product itself. Under section 505(j)(5) of the act, if the listed drug is withdrawn for safety or effectiveness reasons or any of the grounds listed in section 505(e) of the act, ANDA approval "shall be withdrawn or suspended * * *." The statute does not require FDA to give the ANDA holder an opportunity for a hearing before withdrawing or suspending ANDA approval.

The preamble to the proposed rule discusses this subject in greater detail. (See 54 FR 28904 through 28907.)

Notwithstanding the absence of a statutory requirement for a hearing, some comments claimed that due process requires FDA to give applicants an opportunity for an oral hearing for a proposal to withdraw ANDA approval under section 505(j)(5) of the act. FDA disagrees. As noted in the preamble to the proposed rule, courts have declared a "paper hearing" that provides adequate notice and a genuine opportunity to present one's case to be adequate. (See 54 FR 28904, July 10, 1989, and cases cited therein.) Section 314.151, therefore, gives ANDA holders a paper hearing and, if FDA cannot resolve the issues on the basis of the written submissions, permits FDA to hold a limited oral hearing. (See 21 CFR 314.151(b) and (c)(3).)

FDA believes these procedures are consistent with the statute and provide ANDA applicants adequate due process. Consequently, FDA declines to amend the rule as requested.

Section 314.153—Suspension of Approval of an Abbreviated New Drug Application; Section 314.161—Determination of Reasons for Voluntary Withdrawal of a Listed Drug

Proposed § 314.153(b) contained procedures for suspension of an ANDA when a listed drug is voluntarily withdrawn for safety or effectiveness reasons. The preamble to the proposed rule stated that "if a drug manufacturer withdraws a drug from the market which accounted for significant sales to that manufacturer, and there is no evidence to the contrary, it will be presumed that the withdrawal was for safety or effectiveness reasons" (54 FR 28907). The agency expressed its intent to employ the same presumption in applying proposed § 314.161.

80. FDA received eight comments on proposed §§ 314.153 and 314.161. All eight comments objected to the presumption stated in the preamble, but for different reasons. Many comments listed possible reasons why an NDA holder would voluntarily withdraw a drug for business or economic reasons alone. Some comments said ANDA holders should not have the burden of showing why the NDA holder voluntarily withdrew the reference listed drug. These comments would have FDA determine the reasons for a withdrawal or require the NDA holder to state its reasons for withdrawing the listed drug. Other comments said the presumption might adversely affect an NDA holder in product liability litigation. A minority of comments said the presumption's reference to "significant sales" was too vague and would produce different results between large and small firms; these comments argued that FDA, if it retained the presumption, should examine research and development expenses, percentage of a company's gross revenues, or the product's sales record for the previous year.

As stated in the preamble to the proposed rule, FDA is aware that companies may withdraw a drug from the market for reasons unrelated to the product's safety or effectiveness. (See 54 FR 28907.) The preamble also noted that FDA is not required to determine why a sponsor voluntarily withdrew a listed drug, and, considering the number of drugs withdrawn from the market every year, "it would be a needless expenditure of resources for the agency to determine the reason for each such withdrawal." Id. The comments have not raised any new issues or advanced any compelling justification for changing the presumption. The agency does note, however, that the presumption is a rebuttable one, and adds that the agency will, when the product is a top 200 drug (as reported in the April issue of Pharmacy Times which is based on data obtained from the National Prescription Audit conducted by IMS America, Ltd., Ambler, PA), and in other cases when it deems it to be necessary, contact the sponsor of the listed drug to inquire about the reasons for a voluntary withdrawal. In addition, the regulations do not prohibit NDA holders from disclosing their reasons for withdrawing a drug product from marketing, and FDA would consider that information in determining whether the withdrawal was for safety and effectiveness reasons. FDA would not consider the NDA holder's stated reasons for withdrawing a drug to be determinative because such remarks could be biased. Similarly, if an ANDA applicant can show that the reasons for withdrawal of the listed drug are not relevant to the safety or effectiveness of the ANDA drug product, the agency will not suspend ANDA approval. (See 21 CFR 314.153(b)(6).)

As for the comments suggesting alternatives to "significant sales," FDA agrees that the term may have different meanings to different companies, and will adopt a case-by-case approach when determining whether a product accounted for significant sales.

For these reasons, FDA has retained the presumption without change.

Section 314.160—Approval of an Application or Abbreviated Application for Which Approval Was Previously Refused, Suspended, or Withdrawn; Section 314.162—Removal of a Drug Product from the List; Section 314.200—Notice of Opportunity for Hearing; Notice of Participation and Request for Hearing; Grant or Denial of Hearing

FDA received no comments on these provisions and has finalized them without change.

Section 314.430—Availability for Public Disclosure of Data and Information in an Application or Abbreviated Application

81. FDA received four comments on proposed § 314.430. The proposal simply added the term "abbreviated application" to FDA's preexisting public disclosure policies and did not make any substantive changes to those policies. Two comments asked FDA to release a summary basis of approval (SBA) or permit ANDA sponsors to release their own SBA's when an ANDA is approved.

Section 314.430(e)(2)(ii) permits FDA to make an SBA available for public disclosure after FDA sends an approval letter. Hence, the comment's request to have FDA release an SBA is unnecessary. FDA also declines to amend the rule to permit sponsors to release their own SBA's. The rule pertains only to the release of information by FDA; sponsors are always free to disclose whatever truthful and nonmisleading information they wish about their own products.

82. One comment asked FDA to amend the rule to reveal the "presence" of a pending ANDA without any further identification so applicants could make "a more educated decision" about possible exclusivity.

While the comment has some merit, FDA declines to amend the rule at this time. The agency is reexamining certain aspects of its public disclosure policies, but notes that a suit to declare a patent to be invalid or not infringed by the manufacture, use, or sale of a drug product may suggest that an ANDA for that drug product has been submitted.

83. Another comment would give all NDA holders an opportunity to prevent disclosure of information for which they had previously requested confidentiality.

The act states that safety and effectiveness data submitted in an application under section 505(b) of the act and not previously disclosed to the public, "shall be made available to the public, upon request, unless extraordinary circumstances are shown." (See 21 U.S.C. 355(1).) Thus, the statute clearly favors disclosure of safety and effectiveness data except in limited situations. FDA is reexamining its policies with respect to section 505(1) of the act, and, until it completes its deliberations, declines to amend the rule as requested. FDA will continue its policy of consulting parties before disclosing information where the confidentiality of data and information is uncertain. (See, e.g., 21 CFR 20.45.)

Section 314.440—Addresses for Applications and Abbreviated Applications

FDA received no comments on this provision. However, due to reorganizations within FDA, the agency has revised the addresses to which abbreviated antibiotic application applicants and ANDA applicants are to send documents and correspondence.

Section 320.1—Definitions

Proposed § 320.1 defined "bioequivalence," in part, as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."

84. Six comments argued that § 320.1 should not include nonsystemically absorbed drug products and should not provide mechanisms other than blood level tests for bioequivalence. The comments noted that section 505(j)(7) of the act states that a drug shall be considered to be bioequivalent to a listed drug if, inter alia, "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental

conditions * * *." The comments claimed that this statutory provision precludes FDA from approving ANDA's for nonsystemically absorbed drug products because, the comments argued, the rate and extent of absorption of such products cannot be measured. One comment stated that in vivo bioavailability studies should be done to confirm that drugs not intended to be absorbed are not unintentionally absorbed.

The agency does not agree with the comments' interpretation of the statute. In 1977, FDA issued final regulations establishing the requirements for demonstrating the bioavailability and bioequivalence of drug products approved under both full new drug applications and ANDA's (21 CFR part 320). The definitions of "bioavailability" and "bioequivalence" adopted in those regulations were, in all pertinent respects, identical to the language used in section 505(j)(7) of the act. Although the 1977 regulations and the 1984 amendments to the act, which incorporate in the statutory provision on "bioequivalence" the language of those regulations, refer to "rate and extent of absorption," the 1977 regulations explicitly applies to drugs that are not intended for systemic absorption.

As originally proposed, the regulatory definition of "bioavailability" contained explicit reference to bioavailability studies other than systemic absorption studies. In the 1977 final rule, the Commissioner of Food and Drugs removed the references to the types of studies that can demonstrate bioavailability or bioequivalence as unnecessary and placed descriptions of appropriate studies in §§ 320.23, 320.24, 320.53, and 320.57. At the same time, the Commissioner of Food and Drugs specifically rejected a comment urging the definition of bioavailability to be restricted to products absorbed into the systemic circulation, stating that the concept of bioavailability applies to all drug products. (See 42 FR 1638 at 1639; January 7, 1977.)

All drug products must be absorbed through some physical barrier to reach the site of drug action, even if that absorption involves only dispersion into a body fluid pool or entry into surface cells. It is well established that drugs may be either locally or systemically absorbed, and nothing in the language of the statute requires that the absorption result in transit through cells or to the systemic circulation. Because Congress adopted the language of the 1977 regulations, and because the legislative history contains no evidence that Congress intended to exclude nonsystemically absorbed drugs from the coverage of the ANDA provisions of the 1984 amendments, FDA rejects the interpretation of section 505(j)(7)(B) of the act offered by these comments.

FDA also disagrees that blood levels are always appropriate or necessary measurements of bioequivalence. Bioequivalence can be established by pharmacodynamic measurement as well as by in vitro techniques and bioequivalence studies with clinical endpoints. The preferred method for establishment of bioequivalence, including the need to confirm that drugs not intended to be absorbed are not unintentionally absorbed, is determined on a case-by-case basis, depending on the drug under study.

Section 505(j)(6) of the act directs the Secretary to publish a list of all approved drugs for which ANDA's may be submitted and to state "whether in vitro or in vivo bioequivalence studies, or both such studies, are required * * *" (21 U.S.C. 355(j)(6)). In vitro studies are "test tube" studies intended to simulate drug effects in the human body, and are, by definition, indirect measurements of bioequivalence. Had Congress intended to require only direct measurements of the rate and extent of absorption in the human body, it would not have also permitted in vitro studies to satisfy the bioequivalence requirements. Thus, the statute permits and FDA's longstanding regulations provide for both indirect and direct measurements of bioequivalence applicable to nonsystemically absorbed drug products.

In summary, FDA's inclusion of nonsystemically absorbed drug products and inclusion of mechanisms other than blood level tests to establish the bioequivalence of drug products are consistent with the statute. The final rule therefore describes the types of studies that can be appropriately used to demonstrate bioavailability, and describes the bioavailability studies that are appropriate for nonsystemically absorbed durgs.

85. Proposed § 320.1 (a) and (e) defined "bioavailability" and "bioequivalence" using the phrase "active ingredient or active moiety." One comment proposed that the term "active moiety," which is used in proposed § 320.1 (a) and (e), does not find any statutory support and the regulations should instead use the statutory term "active ingredient." The comment's position was based on two court cases, *Abbott* v. *Young*, and *Glaxo* v. *Quigg*, which addressed the issue of using the term "active ingredient" as provided by statute instead of using the term "active moiety," with respect to the exclusivity provisions of title I and the patent term extension provisions of title II of the 1984 amendments, respectively. The comment stated that the courts concluded that there is a significant difference between the plain meaning of the statutory term "active ingredient" and the use of "active moiety." Equating the two is not permitted absent clear congressional intent. Thus, the comment argued that the term "active moiety" should not be used.

FDA disagrees with the comment. The court cases referred to by the comment are not relevant to FDA's use of the term "active moiety" in 21 CFR part 320. The statutory definition of "bioavailability" (section 505(j)(7)(A) of the act) uses the phrase "active ingredient or therapeutic ingredient," and the language on "bioequivalence" (section 505(j)(7)(B) of the act) uses the phrase "therapeutic ingredient." The agency is not substituting the phrase "active moiety' for the phrase "active ingredient." The phrase "active ingredient" remains in the definition of "bioavailability" in § 320.1(a) as in the statutory definition. The phrase "active ingredient" is not used in the statutory provision on "bioequivalence."

Congress clearly intended a meaning different from "active ingredient" by the term "therapeutic ingredient" or it would not have used both terms. The term "active moiety" refers to the molecule or ion in an active ingredient, excluding those appended portions of the molecule that cause the ingredient to be an ester, or a salt or other noncovalent derivative that is responsible for the physiological or pharmacological action of the ingredient. The agency believes that the term "active moiety" is more appropriate and has substituted this term for the term "therapeutic moiety" or "therapeutic ingredient" in defining the terms "bioavailability" and "bioequivalence."

86. One comment supported the proposed definition in § 320.1(e) of "bioequivalence" and opposed "across the board in vivo testing requirements." The comment asked FDA to "retain an open attitude toward the use of in vitro tests" and to have the regulations "reflect the fact that there are indeed other current and evolving methodologies, such as 'punch bioassays' and 'skin-blanching' tests, that will provide an equal measure of scientific comfort to demonstrate bioequivalence."

The final rule does not impose across-the-board in vivo testing requirements. With respect to drug products that are not included in the classes of drug

products described in § 320.22 for which the submission of evidence obtained in vivo is waived, FDA will consider requests for waiver of evidence obtained from in vivo testing on an individual basis. In addition, when other, more accurate, sensitive, and reproducible testing methods are not available, FDA will accept appropriately designed comparative clinical trials for purposes of demonstrating in vivo bioequivalence. Section 320.24 describes in vivo and in vitro testing approaches in descending order of accuracy, sensitivity, and reproducibility that are acceptable to FDA for determining the bioavailability or bioequivalence of a drug product.

87. The proposed definition of bioequivalence at § 320.1(e) provides that where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient of moiety becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations, and is considered medically insignificant for the drug.

One comment suggested that the last sentence in § 320.1(e) be amended by replacing the conjunction "and" with "or." The comment also suggested that FDA define an "intentional difference" as one that involves the improvement of patient compliance or the manufacture of a more pharmaceutically elegant dosage form.

FDA declines to revise the definition as suggested by the comment. The use of the conjunction "and" in the regulation is consistent with statutory language in section 505(j)(7)(B)(ii) of the act. FDA also declines to define "intentional difference" as one that involves the improvement of patient compliance or the manufacture of a more pharmaceutically elegant dosage form because there may exist other valid reasons for altering rate, for example, to reduce toxic effects produced by high concentrations of a drug in an immediate release formulation.

88. Proposed § 320.1(e) defines bioequivalence to mean the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives become available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Several comments asked FDA to clarify the meaning of the phrase "significant difference" in the definition. Two comments understood "significant difference" to mean a "medically significant" or "therapeutically significant" difference. Other comments interpreted the phrase as meaning a statistically significant difference.

The determination of a significant difference requires first a judgment as to what difference in a bioequivalence parameter of interest is medically important and, second, a statistical analysis of data for the parameter to ensure that the difference determined to be important is not likely to be exceeded. Thus, based on clinical experience, the agency has developed statistical criteria for determining the bioequivalence of drug products. For example, there is a presumption that most drug products show no significant difference from the rate and extent of absorption of the listed drug and that the differences are unlikely to be clinically significant in patients when their absorption (AUC and C_{max}) is within 20 percent of the listed drug in normal subjects, and the probability that the results occurred by chance is less than 5 percent ($p<.05$).[1] In other words, unless there is a justification for different limits, the extent of absorption of the generic product must be not less than 80 percent, and not more than 120 percent, of the extent of absorption from the listed or innovator product. However, FDA will reexamine approval criteria for products falling outside the established statistical boundaries when applicants submit to FDA convincing evidence to establish a greater window of bioavailability or bioequivalence.

89. One comment asked FDA to clarify the difference between bioequivalence and therapeutic equivalence for products with intentional rate differences. Another comment argued that to rate some controlled release dosage form drugs as bioequivalent to an immediate release listed drug, but not as therapeutically equivalent, would create two subsets of bioequivalent products—one where products are therapeutically equivalent, and another where products are not therapeutically equivalent, leading to confusion in interchangeability.

Therapeutic equivalence was defined in the Federal Register of January 12, 1979 (44 FR 2932 at 2937). To be rated as therapeutically equivalent, drug products must be pharmaceutical equivalents—i.e., contain identical amounts of the same active drug ingredient in the same dosage form—and meet identical compendia or other applicable standards of identity, strength, quality, and purity; must not present a known or potential bioinequivalence problem (or, if so, must meet an appropriate bioequivalence standard); must be adequately labeled; and must be manufactured in compliance with the regulations governing CGMP's. The agency will approve certain products with intentional rate differences as bioequivalent and rate them as therapeutically equivalent provided that they are pharmaceutical equivalents and the difference in rate at which the active ingredient or moiety becomes available at the site of drug action is intentional, reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug (21 CFR 320.1 (e)).

The agency believes that it is appropriate to approve certain controlled release dosage form drug products that are pharmaceutical alternatives, for which bioequivalence can be demonstrated, even though products that are not pharmaceutical equivalents cannot be rated as therapeutically equivalent. The agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) does not rate these products as therapeutically equivalent; thus, FDA does not consider them interchangeable. Because pharmaceutical alternatives are listed

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[1] See "Report by the Bioequivalence Task Force on Recommendations from the Bioequivalence Hearing Conducted by the Food and Drug Administration, September 29–October 1, 1986," report dated January 1988 (Ref. 1). "There was consensus at the Hearing that differences of less than 20% in AUC and Cmax between products in normal subjects are unlikely to be clinically significant in patients. * * * Under current review procedures, the 90% confidence interval for the ratio of the test product mean AUC to that of the innovator must lie entirely within the inverval (0.80, 1.20)." (Page 29.)

Attachment five to the Report by the Bioequivalence Task Force states "current practice is to carry out the two one-sided tests at the .05 level of significance."

Attachment ten to the Report by the Bioequivalence Task Force states "For approval in most cases, the generic manufacturer must show that a 90% confidence interval of the difference between the mean response of its product and that of the innovator is within the limits ± 20% of the innovator mean. * * * FDA should use the 90% confidence interval (i.e., two one-sided t-tests each at the .05 level of significance) to evaluate the difference between treatments."

See, also, Schuirmann (Ref. 2 at p. 676), "the common ± 20% criteria" and Nightingale and Morrison (Ref. 3 at p. 1200), "With very few exceptions, experts have concluded that differences of less than 20% in the mean AUC between brand name and generic copies are acceptable."

under separate headings, and because only products rated as equivalent under the same heading are interchangeable, there should be no confusion about their interchangeability.

90. One comment disagreed that a product whose absorption rate is intentionally different from the listed drug's absorption rate can nevertheless be bioequivalent. The comment cited nitroglycerine as a product whose absorption rate is critical to effectiveness. Another comment stated that the rate differences should not need to be intentional for these products to be bioequivalent.

Both the statute and the final rule consider a product with a different rate of absorption than the listed product to be bioequivalent to the listed product only if the difference in rate is (1) intentional, (2) reflected in the labeling, (3) not essential to the attainment of effective body concentrations on chronic use, and (4) considered to be medically insignificant. All four criteria must be met for a product with a different rate of absorption to be considered bioequivalent. Thus, a product cannot be rated as bioequivalent to a listed drug when there is a difference in rate of absorption that is not intended or when the difference in rate of absorption is medically significant.

91. One comment asked that FDA expand by example or therapeutic category the drugs that can differ in rate of absorption and still be bioequivalent.

The agency is unaware of any category of products that can differ in rate of absorption and still be considered bioequivalent. Because an intentional rate difference from the reference product would need to be shown to be medically insignificant, FDA believes that determinations of bioequivalence in such cases would need to be made on a case-by-case basis.

Section 320.21—Requirements for Submission of In Vivo Bioavailability and Bioequivalence Data

Proposed § 320.21 would revise FDA's existing requirements for submitting in vivo bioavailability data to include in vivo bioequivalence data.

92. One comment stated that § 320.21(b), which would require evidence of bioequivalence to be included in an ANDA, contradicts the agency practice of accepting applications containing only bioequivalence protocols.

As stated above at paragraph 28, FDA will only accept complete applications. Incomplete applications will not be accepted. Thus, § 320.21(b) of this rule is consistent with current agency practice.

93. Proposed § 320.21(c) would require any person submitting a supplemental application to include bioavailability or bioequivalence evidence if the supplemental application proposes: (1) A change in the manufacturing process; (2) a labeling change to provide for a new indication, if clinical studies are required to support the new indication, or (3) a labeling change to provide for a new dosage regimen or an additional dosage regimen for a special patient population, if clinical studies are required to support the new or additional dosage regimen. One comment suggested that § 320.21(c)(2) and (c)(3) apply only to supplements to applications submitted under section 505(b) of the act. A second comment recommended that § 320.21(c)(2) and (c)(3) be removed because, the comment declared, bioavailability or bioequivalence data should not be needed in addition to clinical studies.

FDA disagrees with the suggested changes. The regulation at § 320.21(c)(2) and (c)(3) applies to supplements to ANDA's approved under section 505(j) of the act as well as to supplements to NDA's approved under section 505(b). (Because such a supplement to an ANDA would require review of clinical data, FDA would treat it as a submission under section 505(b) of the act.) There are a number of reasons why the agency would want bioavailability or bioequivalence data to be included in a supplement for which clinical studies were being conducted. For example, when a supplement covers a new dosage regimen, the agency is concerned about the possibility of nonlinear kinetics. Likewise, for a new patient population, the agency is concerned about the way the drug is absorbed, distributed, and cleared by the body in the target population. Some supplements for a new labeling indication will be for drug products for which a bioavailability study was never performed. In addition, clinical studies are often not done using the final formulation, and the agency may need bioavailability or bioequivalence information on the final formulation. However, in vivo bioavailability or bioequivalence studies are not always needed, and paragrapohs (a)(2) and (b)(2) in § 320.21 provides for FDA to waive the requirement for in vivo studies based on the submission of adequate information.

94. Proposed § 320.21(g) would, under specific circumstances, require any person holding an approved full or abbreviated application to submit to FDA a supplemental application containing new evidence demonstrating in vivo bioavailability or bioequivalence. One comment asked that the information that would cause FDA to require new evidence demonstrating in vivo bioavailability or bioequivalence be made publicly available and that the source of such information be disclosed.

FDA's regulations governing public information are intended to "make the fullest possible disclosure of records to the public, consistent with the rights of persons in trade secrets and confidential commercial or financial information * * *" (21 CFR 20.20(a)). Publicly disclosable information includes information contained in citizen petitions as well as information submitted as part of an application under section 505(b) of the act. (See 21 CFR 10.20(j); 21 U.S.C. 355(l).) FDA will make every effort possible—consistent with its obligations to preserve certain trade secret and confidential commercial information—to make public any information it receives that would cause the agency to require new in vivo bioavailability or bioequivalence information.

95. One comment said that FDA should require retention of product samples tested for bioequivalence and that samples should be drawn from commercial-sized lots produced on the equipment that will be used to manufacture the marketed product.

FDA agrees in part with the comment. In the **Federal Register** of November 8, 1990 (55 FR 47034), FDA published an interim rule that requires retention of bioavailability and bioequivalence testing samples. The interim rule applies to manufacturers who conduct in-house bioavailability and bioequivalence tests and to facilities conducting such testing under contract for a drug manufacturer. FDA does not agree that bioequivalence studies need necessarily be conducted on commercial-sized lots if certain conditions are met. See Office of Generic Drugs Policy and Procedure Guide 22–90 (September 13, 1990).

Section 320.22—Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence

Proposed § 320.22 would, among other things, revise the existing criteria for waiving evidence of in vivo bioavailability to include waivers of in vivo bioequivalence, delete automatic waivers of in vivo bioavailability for certain drug products, and remove the list of "bioproblem" drugs.

96. One comment argued that the statute prohibits a waiver of in vivo bioequivalence data. Another comment urged that § 320.22 be revised to waive in vivo bioequivalence requirements for

topically applied preparations and drug products that are oral dosage forms not intended to be absorbed.

Although the statute requires ANDA applicants to provide bioequivalence information (except where the ANDA is being submitted for a change in a listed drug for which a suitability petition has been granted), it does not require that bioequivalence be shown through in vivo methods. For example, section 505(j)(6)(A)(i)(III) of the act requires the Secretary to publish and make available to the public "whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications * * *." If ANDA applicants were limited to in vivo bioequivalence methods, the statutory reference to in vitro methods would be superfluous. FDA, therefore, disagrees with the comment that the statute prohibits waivers of in vivo methods for demonstrating bioequivalence.

FDA has removed the automatic waiver of evidence of in vivo bioavailability for topically applied preparations and oral dosage forms not intended to be absorbed because the agency believes in vivo bioavailability may be required for certain products. Variations in the manufacturing process used by each individual manufacturer may result in differences in the bioavailability of these drug products. While neither topical drug products nor oral dosage forms not intended to be absorbed are listed in the class of products whose bioavailability may be considered self-evident based on other data in the application, applicants of such products may nevertheless request a waiver of the requirements for in vivo data under § 320.22(a). The agency will review each product on a case-by-case basis to determine if an in vivo study is necessary.

97. One comment said the proposed rule would increase duplicative safety and efficacy tests and increase the time and expense of obtaining ANDA's by reverting to "across-the-board" in vivo study requirements. It argued that removing automatic waivers for topical and nonsystemically absorbed drugs would make it nearly impossible for an ANDA applicant to obtain marketing approval and impose new bioavailability standards that exceed the pioneer's testing requirements.

Although § 320.22, as revised, removes the automatic waiver for topical and nonsystemically absorbed oral dosage products, this change does not require applicants to submit evidence of in vivo bioavailability or in vivo bioequivalence in every case. The elimination of the automatic waiver for nonsystemically absorbed oral dosage products simply reflects FDA's view that requests for waiver of in vivo bioavailability and bioequivalence for these products need to be reviewed on a case-by-case basis. While the amendments may well increase the number of in vivo studies required, the regulation does permit applicants to request a waiver of the requirement for the submission of evidence in the form of in vivo bioavailability or bioequivalence data provided the product meets the criteria in § 320.22.

FDA concedes that the burden of showing bioequivalence may sometimes be comparable to, or perhaps even greater than, the pioneer's burden of showing bioavailability. In such cases, FDA believes that the additional data are needed to meet current standards for bioequivalence. FDA also notes that the generic company's burden is not likely to be nearly as great as the pioneer's burden of showing that a drug product is safe and effective for its proposed uses.

98. Under proposed § 320.22(b)(1), FDA would waive the requirement for submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of drug products that are solutions for intravenous administration. The proposal stated that the in vivo bioavailability or bioequivalence of these drug products is "self-evident" provided that the drug products contain the same active and inactive ingredients in the same concentration as the listed drug product (21 CFR 320.22(b)(1)(ii)). Proposed § 320.22(c) would provide for a waiver of in vivo data requirement for those "parenteral drug products that are determined to be DESI-effective or that are shown to be identical in both active and inactive ingredient formulation" to a drug product that is currently approved in an NDA (provided that the drug is neither in suspension form, nor phenytoin sodium powder).

On its own initiative, FDA is revising § 320.22(b)(1)(i) to include solutions for all parenteral injections within its scope. As revised, the provision includes, among others, intraocular, intravenous, subcutaneous, intramuscular, intra-arterial, intrathecal, intrasternal, and intraperitoneal solutions intended for parenteral injection. The in vivo bioavailability or bioequivalence of any drug product in that class may be shown without in vivo data if the product contains the same active and inactive ingredients in the same concentration as a drug product that is a subject of an approved full new drug application. Because all parenteral solutions are now included at § 320.22(b)(1)(i), the agency has deleted § 320.22(c), which is no longer needed.

99. Proposed § 320.22(b)(3) would waive the requirement for submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of a product that is an oral solution, elixir, syrup, tincture, or similar other solubilized form provided that it contains: (1) An active ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application; and (2) no inactive ingredient that may significantly affect absorption of the active ingredient or active moiety. One comment asked that ophthalmic and otic solutions be added to the class of products described in § 320.22(b)(3) whose bioavailability or bioequivalence is deemed self-evident.

Although FDA does not believe that the in vivo bioavailability or bioequivalence of otic and ophthalmic solutions can be considered self-evident based on compliance with the criteria described in § 320.22(b)(3), FDA does believe that it can assume the bioavailability or bioequivalence of an ophthalmic or otic product, if the product meets the criteria described in § 320.22(b)(1)(ii), i.e., the product contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application. The regulation is revised accordingly.

100. Two comments objected to the requirement in § 320.22(b)(1)(ii) that inactive ingredients be the same as those in the listed drug, arguing that some differences should be allowed and that ANDA applicants do not know the inactive ingredients in the listed drug.

FDA declines to accept the comment. The final rule requires drug products intended for parenteral injection to contain the same inactive ingredients in the same concentrations to obtain a waiver from the in vivo bioavailability or bioequivalence requirement because FDA cannot always predict the consequences of minor changes (e.g., in salt concentration). FDA believes this criterion is important to retain even when the necessary information is not freely available to ANDA applicants. FDA notes that under 21 CFR 201.100(b)(5) drug products for other than oral use must usually list the names of all inactive ingredients except flavorings, perfumes, and color additives. In addition, under 21 CFR 201.100(b)(5)(iii), a drug product, "if it is intended for administration by parenteral injection, (must list) the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the PH or to make the drug isotonic may be declared by name

and a statement of their effect * * *." Thus, ANDA applicants should be able to determine the identity of inactive ingredients for all nonoral dosage forms and the quantity or proportion of inactive ingredients for many drug products, including all parenterals. In many other cases, the identity and quantity of inactive ingredients will be voluntarily disclosed on the listed drug's lable or otherwise ascertainable.

101. Proposed § 320.22(b)(3)(i) stated the conditions under which the bioavailability or bioequivalence of oral solutions, elixirs, syrups, tinctures, or similar products could be considered self-evident. One comment asked that § 320.22(b)(3)(i) be revised to include solutions for application to the skin.

The agency agrees that the in vivo bioavailability or bioequivalence of a solution for application to the skin may be considered self-evident, provided that it has the same active ingredients in the same concentration as the listed drug and no inactive ingredient or change in formulation that may significantly affect absorption of the active drug ingredient or active moiety. Therefore, the regulation at § 320.22(b)(3)(i) has been revised to include solutions for application to the skin. On its own initiative, FDA is revising § 320.22(b)(3)(iii) to make clear that the waiver in that section is conditioned on the applicant making no change in product formulation, including deletion of an inactive ingredient, that may significantly affect the absorption of the active drug ingredient or active moiety.

102. Existing § 320.22(d)(5) waives the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability of a drug product if the product contains the same active drug ingredient and is in the same strength and dosage form as a drug product that is the subject of an approved full or abbreviated new drug application, and both products meet an appropriate in vitro test. FDA proposed to remove this provision, stating that there was no evidence to show that in vitro data alone are regularly sufficient to assure bioequivalence. Three comments asked that existing § 320.22(d)(5) be retained. One comment contended that FDA had little evidence to show that in vitro data alone are not sufficient for the same product manufactured by the same sponsor.

FDA rejects these comments. The burden of showing that a new product is bioavailable or bioequivalent rests with the applicant. In general, the submission of in vivo data is required to support a new product unless there is a known in vivo/in vitro correlation, in which case in vitro data alone may be sufficient. Section 320.22(d) of this final rule lists certain classes of drug products whose bioavailability or bioequivalence may be demonstrated by evidence obtained in vitro in lieu of in vivo. (In addition, FDA continues to waive in vivo data for certain drugs determined to be effective for at least one indication under the DESI program.) As FDA has no evidence to show that in vitro data alone are regularly sufficient to support the bioequivalence of any other drug classes, the agency believes that it is inappropriate to retain existing § 320.22(d)(5). Section 320.22(d)(5) is, therefore, removed.

103. One comment urged that existing § 320.22(d)(5) be retained as a mechanism for waiving in vivo data requirements for minor formulation changes, i.e., changes in colors or flavor. The comment stated that some FDA review divisions require new applications for products that contain a new flavor or color, and concluded that these newly formulated products are not eligible for the waivers described in proposed § 320.22(e)(4).

The comment is incorrect in assuming that products that are reformulated to contain a new flavor, color, or preservative are ineligible for waiver under proposed § 320.20(e)(4) (§ 320.20(d)(4) in this final rule). Such new formulations are eligible for waiver whether they are covered by a new application or by a supplement to an approved application.

104. Proposed § 320.22(e)(2) (§ 320.22(d)(2) in this final rule) would waive the requirement for the submission of in vivo bioavailability evidence if the drug product "is in the same dosage form, but in a different strength, and is proportionally similar in its active and inactive ingredients to another drug product for which the same manufacturer has obtained approval" and the bioavailability of the other drug product has been demonstrated, both drug products meet an appropriate in vitro test approved by FDA, and the applicant submits evidence showing that both drug products are proportionally similar in their active and inactive ingredients. One comment suggested that the agency revise § 320.22(e)(2) to include all dosage forms, including extended release dosage forms. A second comment asked FDA to extend the waiver to extended release capsules whose active ingredients are beaded materials.

The agency never intended to include extended release dosage forms, and has modified § 320.22(d)(2) to so state. The agency disagrees that it would be appropriate to grant waivers to all extended release dosage forms or to all extended release capsules whose active ingredients are beaded materials because the current state of science and technology does not always permit meaningful correlations between in vitro dissolution rates and the rate and extent of in vivo bioavailability for these products. FDA believes that waivers may be appropriate under some circumstances for certain beaded extended release dosage forms. Waivers are ordinarily granted for certain beaded dosage forms, where bioavailability has already been established and the only difference between the reference product and the drug under study is not in the type of bead, but in the quantity of beads. However, waivers will not be granted for beaded dosage forms with nonlinear kinetics because differences of minor therapeutic consequence at lower dose could become greatly exaggerated at higher doses. FDA will consider waiver requests for such products on an individual basis.

105. Proposed § 320.22(g) would permit FDA to require in vivo bioavailability or bioequivalence data if it determines that any difference between the drug product and a listed drug may affect the bioavailability or bioequivalence of the drug product. One comment asked that § 320.22(g) not be used unfairly by pioneer companies to remove generic applicants from the market by bombarding the agency with small bioequivalence changes.

This provision, renumbered § 320.22(f), if not intended and would not be implemented to give unfair marketing advantage to any particular manufacturers. Rather, it permits FDA to impose additional requirements to ensure the continued bioavailability or bioequivalence of a drug product.

Section 320.23—Basis for Demonstrating in Vivo Bioavailability or Bioequivalence

The proposed amendments to § 320.23 would, among other things: (1) Permit applicants whose drug products are not intended to be absorbed into the bloodstream to demonstrate bioavailability by measuring the rate and extent to which the active ingredient or active moiety was absorbed and became available at the site of drug action (§ 320.23(a)(1)); (2) state that statistical techniques used shall be of sufficient sensitivity to detect differences in rate and extent of absorption that are not attributable to subject variability (§ 320.23(a)(2)); (3) rephrase the conditions under which a drug product whose rate of absorption

differs from the reference listed drug can be considered bioavailable (§ 320.23(a)(3)); and (4) declare two drug products to be bioequivalent if they are pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the active moiety under similar experimental conditions, either single dose or multiple dose (§ 320.23(b)).

106. One comment stated that proposed language in § 320.23(a)(2) on "differences in rate * * * of absorption" is ambiguous. The comment said the phrase could be interpreted to mean either differences in the "first-order micro-rate constant for absorption," or, alternatively, maximum concentration, C_{max}, and time to maximum concentration, T_{max}.

The comment correctly points out that the regulation does not specify how absorption rate should be measured. Because drug product parameters may vary, absorption parameters are determined based on the nature of the drug being evaluated.

Section 320.24—Types of Evidence to Establish Bioavailability or Bioequivalence

107. One comment asked that § 320.24 require that an applicant submitting an ANDA for a drug that has a significant difference in a pharmacodynamic parameter that is correlated with safety or therapeutic effect demonstrate that the difference is not clinically significant. The comment also asked that § 320.24 be revised to state FDA's willingness to accept in support of an ANDA pharmacodynamic evidence in lieu of pharmacokinetic profiles when one or more pharmacodynamic parameters correlate with a drug's therapeutic effect.

The ANDA process is intended to provide a rapid and efficient route for generic drug approval. Section 505(j)(7) of the act requires that FDA find a generic drug product to be bioequivalent to the reference listed drug if differences in their rates and extents of drug absorption fall within predetermined statistical limits.

Standards for determining bioequivalence for a product are intended to reflect the nature of the therapeutic response for that product. Once the therapeutic index has been determined, the equivalence of a product's therapeutic response can be measured via plasma drug concentrations, which are generally believed to provide a precise and accurate reflection of product performance. It is highly unlikely that a clinically significant difference in product safety and efficacy will exist for a product that meets an applicable bioequivalence standard. However, should postmarketing surveillance or other information suggest the possibility of therapeutic inequivalence, the approval criteria for that drug entity would be reevaluated.

In general, for systemically absorbed drugs, blood level profiles are a more sensitive index of rate and extent of drug delivery than pharmacodynamic measures. Therefore, except for cases where the agency has indicated otherwise, when blood levels of a drug are measurable, product bioavailability and bioequivalence will be based on pharmacokinetic rather than pharmacodynamic response.

108. Proposed § 320.24(a) stated that applicants should conduct bioavailability or bioequivalence studies "using the most accurate, sensitive, and reproducible approach * * *." One comment suggested that proposed § 320.24(a) be revised to state that applicants who have begun bioequivalence testing under an FDA guidance document would not have to recommence their studies if FDA's guidance changes in the interim.

FDA declines to adopt the comment. Generally, the agency will not ask an applicant to recommence a study that is conducted under an FDA guidance document. However, if new information suggests the need to reconsider agency guidance on study design, the agency will not be bound by that previous guidance. Therefore, under some important circumstances, it may be necessary for an applicant to recommence a study.

109. Proposed § 320.24(b) lists tests in descending order of accuracy, sensitivity, and reproducibility that are acceptable approaches for establishing the bioavailability and bioequivalence of a drug product. On its own initiative, the agency has added to the list of acceptable tests "currently available in vitro tests that ensure human in vivo bioavailability." The addition is intended for drug products determined to be effective under DESI for at least one indication that contain no active ingredients regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. These products are coded "AA" in the list of "Approved Drug Products with Therapeutic Equivalence Evaluations." The agency has created new § 320.24(b)(5) to list these in vitro tests, and has renumbered proposed § 320.24(b)(5) as § 320.24(b)(6).

110. One comment questioned whether the three tests listed in § 320.24(b)(1) are themselves listed in descending order of accuracy, sensitivity, and reproducibility. The comment suggested that FDA renumber the approaches to make clear its intent.

The approaches in § 320.24(b)(1) are listed in descending order of accuracy, sensitivity, and reproducibility. This means that the approach under § 320.24(b)(1), is preferable to §320.24(b)(1)(ii), as the comment suggested. The agency believes the regulatory language clearly captures the agency's intent, and does not believe that renumbering the approaches is needed. The comment is therefore rejected.

111. Under proposed § 320.24(b)(1), one approach for demonstrating bioavailability or bioequivalence would be through "an in vivo test in humans in which the concentration of the active ingredient or active moiety and its active metabolites, in whole blood, plasma, serum, or other appropriate biological fluid is measured as a function of time." One comment contended that measurement of active metabolites in an in vivo test should be the exception rather than the rule, and that measurement of metabolites should not be required where the activity of the metabolite is not well documented.

In general, the determination of whether a metabolite would be used in the assessment of a product's bioavailability or bioequivalence is dependent upon the pharmacokinetic characteristics of the drug (e.g., product input function, rate of metabolite formation, and half-lives of the various species). Section 320.24(b) has been revised to make clear that measurement of active metabolites will only be required when appropriate.

112. Two comments objected to the inclusion in the list of approaches to demonstrate the bioavailability or bioequivalence of a product of "well-controlled clinical trials that establish the safety and effectiveness of the product" (§ 320.24(b)(4)). The comments argued that clinical efficacy or safety trials to demonstrate bioequivalence are not bioequivalence determinations under the statute. The comments suggested that FDA should treat as a 505(b) application any ANDA application whose bioequivalency is based on clinical safety and effectiveness data.

As stated elsewhere in this document, the statute does not restrict applicants to a specific method for demonstrating bioequivalence. The preexisting regulations at 21 CFR 320.57 permitted applicants to demonstrate bioavailability and bioequivalence

through well-controlled clinical trials. The final rule retains this provision in § 320.24(b)(4). The measurement of clinical endpoints may thus be an acceptable approach for establishing bioequivalence for purposes of ANDA approval. The fact that clinical trial data are submitted to demonstrate bioequivalence does not therefore force FDA to convert an application to a section 505(b) application.

113. Proposed § 320.24(b)(4) would permit an applicant to determine a product's in vivo bioavailability or bioequivalence through well-controlled clinical trials or comparative clinical trials provided that analytical methods "cannot be developed" to determine that product's bioavailability or bioequivalence through the tests listed in proposed § 320.24(b)(1), (b)(2), or (b)(3). The comment urged that FDA replace the phrase "cannot be developed" with "have not been developed."

The agency declines to accept the comment because it believes that well-controlled clinical trials or comparative clinical trials should be used only when analytical methods cannot be developed using current technology. To allow clinical trials when such methods have not been developed would encourage their use in situations where technology exists, but an applicant prefers not to develop the analytical methods.

Section 320.30—Inquiries to FDA and FDA Review of Protocols

Proposed § 320.30 strongly recommends that persons planning to conduct a bioavailability or bioequivalence study submit proposed protocols to FDA for review before conducting the study. The proposed regulation also provided addresses for general inquiries on in vivo bioavailability and bioequivalence requirements.

114. Two comments suggest that the regulation be revised to require FDA to review proposed protocols. Two other comments asked that, to ensure timely review, the regulation specify a time period in which FDA must respond to requests for review of a protocol.

The agency will review proposed protocols as expeditiously as its resources and other agency demands permit. However, due to limited resources and an inability to predict the volume of submissions it will receive, the agency cannot commit itself to reviewing regularly all protocols nor will FDA specify a time limit for conducting reviews.

115. Proposed § 320.30(b)(2) would have FDA offer advice with respect to whether the reference material to be used in a proposed bioavailability or bioequivalence protocol is appropriate. One comment asked that, wher there are two approved innovator products that are not bioequivalent to each other, FDA allow either to be the reference standard.

As noted in the preamble to the proposed rule (54 FR 28872 at 28880), FDA intends to select reference listed drugs, which will be the reference standards for bioequivalence determinations. FDA will identify in future editions of the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" the reference listed drug. By designating a single reference listed drug against which all generic versions must be shown to be bioequivalent, FDA hopes to avoid significant variations among generically quivalent drug products. Also, as stated previously, if an applicant believes that there are sound reasons for designating another drug as a reference listed drug, it should consult FDA.

Section 320.31—Applicability of Requirements Regarding an "Investigational New Drug Application"

Proposed § 320.31 listed the types of bioavailability and bioequivalence studies for which an investigational new drug application (IND) would be required. Proposed § 320.31(a)(3) would require an IND if the in vivo bioavailability or bioequivalence study involved a cytotoxic drug product.

116. Two comments asked FDA to justify requiring IND's for cytotoxic products and for multiple-dose studies on controlled release products when no single-dose studies have been completed.

FDA believes that IND's are appropriate in these cases because of the potential risks to study participants through dose dumping or other toxic effects. FDA has 30 days to review and respond to an IND to determine potential safety problems and to assure effects that could threaten the safety of the subject participating in the study.

Section 320.51—Procedures for Establishing or Amending a Bioequivalence Requirement

117. The proposed rule proposed to remove 21 CFR 320.51, which sets forth procedurs for establishing or amending a bioequivalence requirement. One comment asked that § 320.51 not be removed because it requires FDA to use notice and comment rulemaking to develop or amend a bioequivalence requirement.

Because the 1984 amendments require that any new generic drug products be demonstrated to be bioequivalent to the reference listed drug (unless it is the subject of an approved ANDA suitaiblity petition), additional authority to impose bioequivalence requirements with respect to such products is not needed. However, on its own initiative, the agency has decided not to remove § 320.51 because it establishes a procedure to impose bioequivalence requirements on other classes of drug products not covered by the bioequivalence requirements in the 1984 amendments, including drug products not subject to premarket approval and drug products whose new drug status is not yet determined. In this final rule, § 320.51 has been redesignated and revised as § 320.32.

IV. Economic Assessment

FDA has considered the economic impact of this regulation which clarifies and facilitates the implementation of Public Law 98–417. Title I of Public Law 98–417 eliminated unnecessary regulatory barriers for generic drug products and has resulted in generic competition on many important post-1962 drugs. Generic drug sales account for a significant portion of total prescription drug sales, and many of these sales would not have occurred in the absence of Public Law 98–417.

Prior to the implementation of title I of Public Law 98–417, in order to market a generic post-1962 drug product, drug sponsors were required to duplicate the innovator's safety and efficacy testing and to submit a "duplicate" NDA. Under title I, sponsors no longer incur duplicate testing costs and are able to market generic products after submitting and gaining approval for an ANDA which does not include the duplicate testing requirement. The costs associated with preparing and submitting an ANDA are significantly lower than the costs for submitting duplicate NDA's for the same products.

The benefits of these implementing regulations for title I are twofold: (1) Savings to consumers who purchase generic post-1962 prescription drug products, and (2) savings to sponsors of generic drug products who submit ANDA's to the agency in order to gain approval to market their products. The consumer savings are the result of the increased availability of lower-priced generic drug products. As new generic products are made available annually (as their patents expire and generic drug products enter the marketplace) the savings to consumers should reach several billion dollars annually over the next 5 to 10 years. The savings to sponsors will vary depending on the

number of applications submitted annually. Small businesses will also be favorably affected because the barriers to market entry have been lowered thereby allowing these firms to enter the generic drug market without incurring duplicate safety and efficacy testing costs. Consequently, FDA concludes the benefits of these regulations implementing title I far exceed the costs. FDA also believes it has streamlined the ANDA process as much as possible thus minimizing the costs and maximizing the net benefits.

The regulatory framework for processing ANDA's under section 505(j) of the act has been in existence since the enactment of the Drug Price Competition and Patent Term Restoration Act in 1984. Thus, most required procedures and their associated economic consequences have been in effect since that time. This rule simply clarifies and facilitates the implementation of the act and will not affect the pace or magnitude of these impacts. Therefore, FDA concludes that this rule is not a "major rule" as defined by Executive Order 12291 and does not require a regulatory impact analysis. Similarly, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, and therefore does not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980 (Pub. L. 96–354).

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1980

This final rule contains information collections which have been submitted for approval to the Office of Management and Budget under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Abbreviated New Drug Application Regulations.

Description: The information requirements collect information from persons who must obtain FDA approval prior to marketing generic copies of previously approved drugs. These persons must submit information in the form of applications, notices, and certifications. FDA will use the information submitted to determine whether the proposed generic drug is eligible for consideration, under what provisions an application would be considered, and whether the proposed drug is identical to the pioneer drug it purports to copy.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
314.50(g)	1	1	1 hour	1
314.50(i)	8	1	2 hours	16
314.50(j)	50	1	2 hours	100
314.54	10	1	80 hours	800
314.80, 310.305	40	1	8 hours	320
314.81	700	1	10 min	119
314.93	82	1	10 hours	820
314.94	850	1	160 hours	136,000
314.110	10	1	40 hours	400
314.122, 314.161	1	1	10 hours	10
Total				138,586

There were no comments received on the Paperwork Reduction Act clearance submission or on the burden estimates. Therefore, no changes have been made to these burden estimates. However, the final rule does not finalize the provisions of the proposed rule on patent certification and market exclusivity. The agency has not included those estimates in the final rule.

VII. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Report by the Bioequivalence Task Force on Recommendations from the Bioequivalence Hearing Conducted by the Food and Drug Administration, September 29–October 1, 1986," January 1988.

2. Schuirmann, D. J., "A Comparison of the Two One-Sided Tests Procedure and the Power Approach for Assessing the Equivalence of Average Bioavailability," Journal of Pharmacokinetics and Biopharmaceutics, 15:6:657, 1987.

3. Nightingale, S., and J. Morrison, "Generic Drugs and the Prescribing Physician," Journal of the American Medical Association, 4:258:9:1200, 1987.

4. Skelly, J. P. et al., "Workshop Report: In Vitro and In Vivo Testing and Correlations for Oral Controlled/Modified-Release Dosage Forms," Pharmaceutical Research, 7:975–982, 1990.

List of Subjects

21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 433

Antibiotics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 2, 5, 10, 310, 314, 320, and 433 are amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: Secs. 201, 301, 305, 402, 408, 409, 501, 502, 505, 507, 512, 601, 701, 702, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374); 15 U.S.C. 402, 409.

2. Section 2.125 is amended by revising the introductory text of paragraph (h)(2) to read as follows:

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

* * * * *

(h) * * *

(2) An abbreviated new drug application conforming to § 314.94 of this chapter is acceptable in lieu of a full new drug application for any product included in the classes of products in paragraph (e) of this section if the product is one that is described under § 314.92 of this chapter. A finding has been made that an abbreviated new drug application may be submitted for the following products included in the classes of products listed in paragraph (e) of this section:

* * * * *

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

3. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

§ 5.80 [Amended]

4. Section 5.80 *Approval of new drug applications and their supplements* is amended in the introductory text of paragraph (c)(1) and paragraph (c)(2)(i) by removing "314.55, and 314.70" and replacing them with "314.70, and 314.94".

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

5. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034, secs. 2, 351, 354–360F, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b–263n, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. 551–558, 701–706; 28 U.S.C. 2112.

6. Section 10.30 is amended by revising the introductory text of paragraph (e)(2) and by adding a new paragraph (e)(4) to read as follows:

§ 10.30 Citizen petition.

* * * * *

(e) * * *

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

* * * * *

(4) The Commissioner shall furnish a response to each petitioner within 90 days of receipt of a petition filed under section 505(j)(2)(C) of the act. The response will either approve or disapprove the petition. Agency action on a petition shall be governed by § 314.93 of this chapter.

* * * * *

7. Section 10.45 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

* * * * *

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 *et seq.* and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

* * * * *

PART 310—NEW DRUGS

8. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 376); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

9. Section 310.305 is amended by revising paragraph (a), by removing the word "significant" in paragraph (b)(2), by revising the first sentence in paragraph (c)(4), and in paragraph (d)(1) by removing the words "(Drug Experience Report)" and replacing them with "(Adverse Reaction Report)" to read as follows:

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

(a) *Scope.* FDA is requiring manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application to establish and maintain records and make reports to FDA of:

(1) All serious, unexpected adverse drug experiences associated with the use of their drug products;

(2) Any significant increase in the frequency of a serious, expected adverse drug experience; and

(3) Any significant increase in the frequency of therapeutic failure (lack of effect).

These reports will enable FDA to protect the public health by helping to monitor the safety of marketed drug products and to ensure that these drug products are not adulterated or misbranded.

* * * * *

(c) * * *

(4) Each person identified in paragraph (c)(1) of this section shall review periodically (at least once each year) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), received or otherwise obtained, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a

significant increase in frequency exists.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

10. Part 314 is amended by redesignating existing Subparts C, D, E, and F as subparts D, E, F, and G, respectively, by adding new subpart C, consisting of §§ 314.92 through 314.99, by revising the table of contents with the authority citation continuing to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 376).

§ 314.1 [Amended]

11. Section 314.1 Scope of this part is amended in paragraphs (a)(1) and (a)(2) by adding the phrase "or abbreviated application" after the word "application".

12. Section 314.3 is amended by revising paragraph (b) to read as follows:

§ 314.3 Definitions.

* * * * *

(b) The following definitions of terms apply to this part:

Abbreviated application means the application described under § 314.94, including all amendments and supplements to the application. "Abbreviated application" applies to both an abbreviated new drug application and an abbreviated antibiotic application.

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–901 (21 U.S.C. 301–392)).

Applicant means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application.

Application means the application described under § 314.50, including all amendements and supplements to the application.

505(b)(2) Application means an application submitted under section 505(b)(1) of the act for a drug for which the investigations described in section 505(b)(1)(A) of the act and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

Approvable letter means a written communication to an applicant from FDA stating that the agency will approve the application or abbreviated application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application or abbreviated application and does not permit marketing of the drug that is the subject of the application or abbreviated application.

Approval letter means a written communication to an applicant from FDA approving an application or an abbreviated application.

Drug product means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Drug substance means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of

the human body, but does not include intermediates use in the synthesis of such ingredient.

FDA means the Food and Drug Administration.

Listed drug means a new drug product that has an effective approval under section 505(c) of the act for safety and effectiveness or under section 505(j) of the act, which has not been withdrawn or suspended under section 505(e)(1) through (e)(5) or (j)(5) of the act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification as a drug with an effective approval in the current edition of FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) or any current supplement thereto, as a drug with an effective approval. A drug product is deemed to be a listed drug on the date of effective approval of the application or abbreviated application for that drug product.

Not approvable letter means a written communication to an applicant from FDA stating that the agency does not consider the application or abbreviated application approvable because one or more deficiencies in the application or abbreviated application preclude the agency from approving it.

Reference listed drug means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

Right of reference or use means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

The list means the list of drug products with effective approvals published in the current edition of FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication.

13. Section 314.50 is amended by revising the first and fifth sentences in the introductory paragraph, paragraph (a)(2), and the second sentence in paragraph (c)(1), and by adding new paragraph (g)(3) to read as follows:

§ 314.50 Content and format of an application.

Applications and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. * * * These include an application of the type described in section 505(b)(2) of the act, an amendment, and a supplement. * * *

(a) * * *

(2) A statement whether the submission is an original submission, a 505(b)(2) application, a resubmission, or a supplement to an application under § 314.70.

* * * * *

(c) *Summary.* (1) * * * The summary is not required for supplements under § 314.70. * * *

* * * * *

(g) * * *

(3) If an applicant who submits a new drug application under section 505(b) of the act obtains a "right of reference or use," as defined under § 314.3(b), to an investigation described in clause (A) of section 505(b)(1) of the act, the applicant shall include in its application a written statement signed by the owner of the data from each such investigation that the applicant may rely on in support of the approval of its application, and provide FDA access to, the underlying raw data that provide the basis for the report of the investigation submitted in its application.

* * * * *

14. New § 314.54 is added to read as follows:

§ 314.54 Procedure for submission of an application requiring investigations for approval of a new indication for, or other change from, a listed drug.

(a) The act does not permit approval of an abbreviated new drug application for a new indication, nor does it permit approval of other changes in a listed drug if investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the change. Any person seeking approval of a drug product that represents a modification of a listed drug (e.g., a new indication or new dosage form) and for which investigations, other than bioavailability or bioequivalence studies, are essential to the approval of the changes may, except as provided in paragraph (b) of this section, submit a 505(b)(2) application. This application need contain only that information needed to support the modification(s) of the listed drug.

(1) The applicant shall submit a complete archival copy of the application that contains the following:

(i) The information required under § 314.50 (a), (b), (c), (d)(1) and (d)(3), (e), and (g).

(ii) The information required under § 314.50 (d)(2), (d)(4) (if an anti-infective drug), (d)(5), (d)(6), and (f) as needed to support the safety and effectiveness of the drug product.

(iii) Identification of the listed drug for which FDA has made a finding of safety and effectiveness and on which finding the applicant relies in seeking approval of its proposed drug product by established name, if any, proprietary name, dosage form, strength, route of administration, name of listed drug's application holder, and listed drug's approved application number.

(iv) If the applicant is seeking approval only for a new indication and not for the indications approved for the listed drug on which the applicant relies, a certification so stating.

(v) Any patent information required under section 505(b)(1) of the act with respect to any patent which claims the drug for which approval is sought or a method of using such drug and to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.

(vi) Any patent certification or statement required under section 505(b)(2) of the act with respect to any relevant patents that claim the listed drug or that claim any other drugs on which investigations relied on by the applicant for approval of the application were conducted, or that claim a use for the listed or other drug.

(2) The applicant shall submit a review copy that contains the technical sections described in § 314.50(d)(1) and (d)(3), and the technical sections described in § 314.50(d), (d)(4), (d)(5), (d)(6), and (f) when needed to support the modification. Each of the technical sections in the review copy is required to be separately bound with a copy of the information required under § 314.50 (a), (b), and (c) and a copy of the proposed labeling.

(3) The information required by § 314.50 (d)(2), (d)(4) (if an anti-infective drug), (d)(5), (d)(6), and (f) for the listed drug on which the applicant relies shall be satisfied by reference to the listed drug under paragraph (a)(1)(iii) of this section.

(b) An application may not be submitted under this section for a drug product whose only difference from the reference listed drug is that:

(1) The extent to which its active ingredient(s) is absorbed or otherwise made available to the site of action is less than that of the reference listed drug; or

(2) The rate at which its active ingredient(s) is absorbed or otherwise made available to the site of action is

unintentionally less than that of the reference listed drug.

§ 314.55 [Removed]

15. Section 314.55 *Abbreviated application* is removed.

§ 314.56 [Removed]

16. Section 314.56 *Drug products for which abbreviated applications are suitable* is removed.

17. Section 314.60 is amended by redesignating the existing paragraph as paragraph (a) and by revising the first sentence, and by adding a new paragraph (b) to read as follows:

§ 314.60 Amendments to an unapproved application.

(a) Except as provided in paragraph (b) of this section, the applicant may submit an amendment to an application that is filed under § 314.100, but not yet approved. * * *

(b)(1) An unapproved application may not be amended if all of the following conditions apply:

(i) The unapproved application is for a drug for which a previous application has been approved and granted a period of exclusivity in accordance with section 505(c)(3)(D)(ii) of the act that has not expired;

(ii) The applicant seeks to amend the unapproved application to include a published report of an investigation that was conducted or sponsored by the applicant entitled to exclusivity for the drug;

(iii) The applicant has not obtained a right of reference to the investigation described in paragraph (b)(1)(ii) of this section; and

(iv) The report of the investigation described in paragraph (b)(1)(ii) of this section would be essential to the approval of the unapproved application.

(2) The submission of an amendment described in paragraph (b)(1) of this section will cause the unapproved application to be deemed to be withdrawn by the applicant under § 314.65 on the date of receipt by FDA of the amendment. The amendment will be considered a resubmission of the application, which may not be accepted except as provided in accordance with section 505(c)(3)(D)(ii) of the act.

18. Section 314.70 is amended by adding new paragraph (e) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(e) *Patent information.* The applicant shall comply with the patent information requirements under section 505(c)(2) of the act.

19. Section 314.71 is amended in paragraph (b) by revising the first sentence to read as follows:

§ 314.71 Procedures for submission of a supplement to an approved application.

* * * * *

(b) All procedures and actions that apply to an application under § 314.50 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change. * * *

* * * * *

20. Section 314.80 is amended by removing the word "significant" in the definition of "Adverse drug experience" in paragraph (a), by revising paragraph (b), the first sentence in paragraph (c)(1)(ii), and the last sentence in paragraph (d)(1) to read as follows:

§ 314.80 Postmarketing reporting of adverse drug experiences.

* * * * *

(b) *Review of adverse drug experiences.* Each applicant having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

(c) * * *

(1) * * *

(ii) The applicant shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. * * *

* * * * *

(d) *Scientific literature.* (1) * * * The 15-day reporting requirements in paragraph (c)(1)(ii) of this section (i.e., a significant increase in frequency of a serious, expected adverse drug experience or of a therapeutic failure) apply only to reports found in scientific and medical journals either as the result of a formal clinical trial, or from epidemiological studies or analyses of experience in a monitored series of patients.

* * * * *

21. Section 314.81 is amended by adding new paragraph (b)(3)(iii) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(iii) *Withdrawal of approved drug product from sale.* (*a*) The applicant shall submit on Form FDA 2657 (Drug Product Listing), within 15 working days of the withdrawal from sale of a drug product, the following information:

(*1*) The National Drug Code (NDC) number.

(*2*) The identity of the drug product by established name and by proprietary name.

(*3*) The new drug application or abbreviated application number.

(*4*) The date of withdrawal from sale. It is requested but not required that the reason for withdrawal of the drug product from sale be included with the information.

(*b*) The applicant shall submit each Form FDA-2657 to the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(*c*) Reporting under paragraph (b)(3)(iii) of this section constitutes compliance with the requirements under § 207.30(a) of this chapter to report "at the discretion of the registrant when the change occurs."

* * * * *

22. Subparts C, D, E, and F are redesignated as Subparts D, E, F, and G, respectively, and new Subpart C, consisting of §§ 314.92 through 314.99, is added to read as follows:

Subpart C—Abbreviated Applications

§ 314.92 Drug products for which abbreviated applications may be submitted.

(a) Abbreviated applications are suitable for the following drug products within the limits set forth under § 314.93:

(1) Drug products that are the same as a listed drug. A "listed drug" is defined in § 314.3. For determining the suitability of an abbreviated new drug application, the term "same as" means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use, except that conditions of use for which approval cannot be granted because of exclusivity or an existing patent may be omitted. If a listed drug has been voluntarily withdrawn from or not offered for sale by its manufacturer, a person who wishes to submit an abbreviated new

drug application for the drug shall comply with § 314.122.

(2) Drug products that are duplicates of, or that meet the monograph for, an antibiotic drug for which FDA has approved an application.

(3) Drug products that have been declared suitable for an abbreviated new drug application submission by FDA through the petition procedures set forth under § 10.30 of this chapter and § 314.93.

(b) FDA will publish in the list listed drugs for which abbreviated applications may be submitted. The list is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202–783–3238.

§ 314.93 Petition to request a change from a listed drug.

(a) The only changes from a listed drug for which the agency will accept a petition under this section are those changes described in paragraph (b) of this section. Petitions to submit abbreviated new drug applications for other changes from a listed drug will not be approved.

(b) A person who wants to submit an abbreviated new drug application for a drug product which is not identical to a listed drug in route of administration, dosage form, and strength, or in which one active ingredient is substituted for one of the active ingredients in a listed combination drug, must first obtain permission from FDA to submit such an abbreviated application.

(c) To obtain permission to submit an abbreviated new drug application for a change described in paragraph (b) of this section, a person must submit and obtain approval of a petition requesting the change. A person seeking permission to request such a change from a reference listed drug shall submit a petition in accordance with §10.20 of this chapter and in the format specified in § 10.30 of this chapter. The petition shall contain the information specified in § 10.30 of this chapter and any additional information required by this section. If any provision of § 10.20 or § 10.30 of this chapter is inconsistent with any provision of this section, the provisions of this section apply.

(d) The petitioner shall identify a listed drug and include a copy of the proposed labeling for the drug product that is the subject of the petition and a copy of the approved labeling for the listed drug. The petitioner may, under limited circumstances, identify more than one listed drug, for example, when the proposed drug product is a combination product that differs from the combination reference listed drug with regard to an active ingredient, and the different active ingredient is an active ingredient of a listed drug. The petitioner shall also include information to show that:

(1) The active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those of the reference listed drug.

(2) The drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which the applicant seeks approval.

(3) If the proposed drug product is a combination product with one different active ingredient, including a different ester or salt, from the reference listed drug, that the different active ingredient has previously been approved in a listed drug or is a drug that does not meet the definition of "new drug" in section 201(b) of the act.

(e) No later than 90 days after the date a petition that is permitted under paragraph (a) of this section is submitted, FDA will approve or disapprove the petition.

(1) FDA will approve a petition properly submited under this section unless it finds that:

(i) Investigations must be conducted to show the safety and effectiveness of the drug product or of any of its active ingredients, its route of administration, dosage form, or strength which differs from the reference listed drug; or

(ii) For a petition that seeks to change an active ingredient, the drug product that is the subject of the petition is not a combination drug; or

(iii) For a combination drug product that is the subject of the petition and has an active ingredient different from the reference listed drug:

(A) The drug product may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted under § 314.94; or

(B) The petition does not contain information to show that the different active ingredient of the drug product is of the same pharmacological or therapeutic class as the ingredient of the reference listed drug that is to be changed and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the listed drug's labeling for which the applicant seeks approval; or

(C) The different active ingredient is not an active ingredient in a listed drug or a drug that meets the requirements of section 201(p) of the act; or

(D) The remaining active ingredients are not identical to those of the listed combination drug; or

(iv) Any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem; or

(v) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons.

(2) For purposes of this paragraph, "investigations must be conducted" means that information derived from animal or clinical studies is necessary to show that the drug product is safe or effective. Such information may be contained in published or unpublished reports.

(3) If FDA approves a petition submitted under this section, the agency's response may describe what additional information, if any, will be required to support an abbreviated new drug application for the drug product. FDA may, at any time during the course of its review of an abbreviated new drug application, request additional information required to evaluate the change approved under the petition.

(f) FDA may withdraw approval of a petition if the agency receives any information demonstrating that the petition no longer satisfies the conditions under paragraph (e) of this section.

§ 314.94 Content and format of an abbreviated application.

Abbreviated applications are required to be submitted in the form and contain the information required under this section. Two copies of the application are required, an archival copy and a review copy. FDA will maintain guidelines on the format and content of applications to assist applicants in their preparation.

(a) *Abbreviated new drug applications.* Except as provided in paragraph (b) of this section, the applicant shall submit a complete archival copy of the abbreviated new drug application that includes the following:

(1) *Application form.* The applicant shall submit a completed and signed application form that contains the information described under § 314.50(a)(1), (a)(3), (a)(4), and (a)(5). The applicant shall state whether the

submission is an abbreviated application under this section or a supplement to an abbreviated application under § 314.97.

(2) *Table of contents.* the archival copy of the abbreviated new drug application is required to contain a table of contents that shows the volume number and page number of the contents of the submission.

(3) *Basis for abbreviated new drug application submission.* An abbreviated new drug application must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the agency as the reference standard for conducting bioequivalence testing. The application shall contain:

(i) The name of the reference listed drug, including its dosage form and strength. For an abbreviated new drug application based on an approverd petition under §10.30 of this chapter or §314.93, the reference listed drug must be the same as the listed drug approved in the petition.

(ii) A statement as to whether, according to the information published in the list, the reference listed drug is entitled to a period of marketing exclusivity under section 505(j)(4)(D) of the act.

(iii) For an abbreviated new drug application based on an approved petition under § 10.30 of this chapter or § 314.93, a reference to FDA-assigned docket number for the petition and a copy of FDA's correspondence approving the petition.

(4) *Conditions of use.* (i) A statement that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the drug product have been previously approved for the reference listed drug.

(ii) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(5) *Active ingredients.* (i) For a single-active-ingredient drug product, information to show that the active ingredient is the same as that of the reference single-active-ingredient listed drug, as follows:

(A) A statement that the active ingredient of the proposed drug product is the same as that of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) For a combination drug product, information to show that the active ingredients are the same as those of the reference listed drug except for any different active ingredient that has been the subject of an approved petition, as follows:

(A) A statement that the active ingredients of the proposed drug product are the same as those of the reference listed drug, or if one of the active ingredients differs from one of the active ingredients of the reference listed drug and the abbreviated application is submitted under the approval of a petition under § 314.93 to vary such active ingredient, information to show that the other active ingredients of the drug product are the same as the other active ingredients of the reference listed drug, information to show that the different active ingredient is an active ingredient of another listed drug or of a drug that does not meet the definition of "new drug" in section 201(p) of the act, and such other information about the different active ingredient that FDA may require.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(6) *Route of administration, dosage form, and strength.* (i) Information to show that the route of administration, dosage form, and strength of the drug product are the same as those of the reference listed drug except for any differences that have been the subject of an approved petition, as follows:

(A) A statement that the route of administration, dosage form, and strength of the proposed drug product are the same as those of the reference listed drug.

(B) A reference to the applicant's annotated proposed labeling and to the currently approved labeling for the reference listed drug provided under paragraph (a)(8) of this section.

(ii) If the route of administration, dosage form, or strength of the drug product differs from the reference listed drug and the abbreviated application is submitted under an approved petition under § 314.93, such information about the different route of administration, dosage form, or strength that FDA may require.

(7) *Bioequivalence.* (i) Information that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies; or

(ii) If the abbreviated new drug application is submitted under a petition approved under § 314.93, the results of any bioavailability of bioequivalence testing required by the agency, or any other information required by the agency to show that the active ingredients of the proposed drug product are of the same pharmacological or therapeutic class as those in the reference listed drug and that the proposed drug product can be expected to have the same therapeutic effect as the reference listed drug. If the proposed drug product contains a different active ingredient than the reference listed drug, FDA will consider the proposed drug product to have the same therapeutic effect as the reference listed drug if the applicant provides information demonstrating that:

(A) There is an adequate scientific basis for determining that substitution of the specific proposed dose of the different active ingredient for the dose of the member of the same pharmacological or therapeutic class in the reference listed drug will yield a resulting drug product whose safety and effectiveness have not been adversely affected.

(B) The unchanged active ingredients in the proposed drug product are bioequivalent to those in the reference listed drug.

(C) The different active ingredient in the proposed drug product is bioequivalent to an approved dosage form containing that ingredient and approved for the same indication as the proposed drug product or is bioequivalent to a drug product offered for that indication which does not meet the definition of "new drug" under section 201(p) of the act.

(iii) For each in vivo bioequivalence study contained in the abbreviated new drug application, a description of the analytical and statistical methods used in each study and a statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105 of this chapter and that each study was conducted in compliance with the informed consent regulations in part 50 of this chapter.

(8) *Labeling*—(i) *Listed drug labeling.* A copy of the currently approved labeling for the listed drug referred to in the abbreviated new drug application, if the abbreviated new drug application relies on a reference listed drug.

(ii) *Proposed labeling.* Copies of the label and all labeling for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(iii) A statement that the applicant's proposed labeling is the same as the labeling of the reference listed drug except for differences annotated and explained under paragraph (a)(8)(iv) of this section.

(iv) A side-by-side comparison of the applicant's proposed labeling with the

approved labeling for the reference listed drug with all differences annotated and explained. Labeling (including the container label and package insert) proposed for the drug product must be the same as the labeling approved for the reference listed drug, except for changes required because of differences approved under a petition filed under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers. Such differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include differences in expiration date, formulation, bioavailability, or pharmacokinetics, labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(4)(D) of the act.

(9) *Chemistry, manufacturing, and controls.* (i) The information required under § 314.50(d)(1).

(ii) *Inactive ingredients.* Unless otherwise stated in paragraphs (a)(9)(iii) through (a)(9)(v) of this section, an applicant shall identify and characterize the inactive ingredients in the proposed drug product and provide information demonstrating that such inactive ingredients do not affect the safety of the proposed drug product.

(iii) *Inactive ingredient changes permitted in drug products intended for parenteral use.* Generally, a drug product intended for parenteral use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety for the proposed drug product.

(iv) *Inactive ingredient changes permitted in drug products intended for ophthalmic or otic use.* Generally, a drug product intended for ophthalmic or otic use shall contain the same inactive ingredients and in the same concentration as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug in preservative, buffer, substance to adjust tonicity, or thickening agent provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product, except that, in a product intended for ophthalmic use, an applicant may not change a buffer or substance to adjust tonicity for the purpose of claiming a therapeutic advantage over or difference from the listed drug, e.g., by using a balanced salt solution as a diluent as opposed to an isotonic saline solution, or by making a significant change in the pH or other change that may raise questions of irritability.

(v) *Inactive ingredient changes permitted in drug products intended for topical use.* Generally, a drug product intended for topical use shall contain the same inactive ingredients as the reference listed drug identified by the applicant under paragraph (a)(3) of this section. However, an applicant may seek approval of a drug product that differs from the reference listed drug provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety of the proposed drug product.

(10) *Samples.* The information required under § 314.50(e)(1) and (e)(2)(i). Samples need not be submitted until requested by FDA.

(11) *Other.* The information required under § 314.50(g).

(b) *Drug products subject to the Drug Efficacy Study Implementation (DESI) review.* If the abbreviated new drug application is for a duplicate of a drug product that is subject to FDA's DESI review (a review of drug products approved as safe between 1938 and 1962) or other DESI-like review and the drug product evaluated in the review is a listed drug, the applicant shall comply with the provisions of paragraph (a) of this section.

(c) *Abbreviated antibiotic application.* For applications submitted under section 507 of the act, the applicant shall submit a complete archival copy of the abbreviated application that contains the information described under § 314.50 (a)(1), (a)(3), (a)(4), and (a)(5), (b), (d)(1) and (d)(3), (e), and (g). The applicant shall state whether the submission is an abbreviated application under this section or a supplement to an abbreviated application under § 314.97.

(d) *Format of an abbreviated application.* (1) The applicant shall submit a complete archival copy of the abbreviated application as required under paragraphs (a) and (c) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. An applicant may submit all or portions of the archival copy of the abbreviated application in any form (e.g., microfiche, optical disc, and magnetic tape) that the applicant and FDA agree is acceptable.

(2) For abbreviated new drug applications, the applicant shall submit a review copy of the abbreviated application that contains two separate sections. One section shall contain the information described under paragraphs (a)(2) through (a)(6), (a)(8), and (a)(9) of this section 505(j)(2)(A)(vii) of the act and one copy of the analytical methods and descriptive information needed by FDA's laboratories to perform tests on samples of the proposed drug product and to validate the applicant's analytical methods. The other section shall contain the information described under paragraphs (a)(3), (a)(7), and (a)(8) of this section. Each of the sections in the review copy is required to contain a copy of the application form described under § 314.50(a).

(3) For abbreviated antibiotic applications, the applicant shall submit a review copy that contains the technical sections described in § 314.50 (d)(1) and (d)(3). Each of the technical sections in the review copy is required to be separate with a copy of the application form required under § 314.50(a).

(4) The applicant may obtain from FDA sufficient folders to bind the archival and the review copies of the abbreviated application.

§ 314.96 Amendments to an unapproved abbreviated application.

(a) *Abbreviated new drug application.* (1) An applicant may amend an abbreviated new drug application that is submitted under § 314.94, but not yet approved, to revise existing information or provide additional information.

(2) Submission of an amendment containing significant data or information constitutes an agreement between FDA and the applicant to extend the review period only for the time necessary to review the significant data or information and for no more than 180 days.

(3) Submission of an amendment containing significant data or information to resolve deficiencies in the application as set forth in a not approvable letter issued under § 314.120 constitutes an agreement between FDA and the applicant under section

505(j)(4)(A) of the act to extend the date by which the agency is required to reach a decision on the abbreviated new drug application only for the time necessary to review the significant data or information and for no more than 180 days.

(b) *Abbreviated antibiotic application.* The applicant shall comply with the provisions of § 314.60.

§ 314.97 Supplements and other changes to an approved abbreviated application.

The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

§ 314.98 Postmarketing reports.

(a) Except as provided in paragraph (b) of this section, each applicant having an approved abbreviated antibiotic application under § 314.94 or approved abbreviated new drug application under § 314.94 that is effective shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences.

(b) Each applicant shall submit one copy of each report required under § 314.80 to the Division of Epidemiology and Surveillance (HFD–730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Each applicant shall make the reports required under § 314.81 and sections 505(k) and 507(g) of the act for each of its approved abbreviated applications.

§ 314.99 Other responsibilities of an applicant of an abbreviated application.

(a) An applicant shall comply with the requirements of § 314.65 regarding withdrawal by the applicant of an unapproved abbreviated application and § 314.72 regarding a change in ownership of an abbreviated application.

(b) An applicant may ask FDA to waive under this section any requirement that applies to the applicant under §§ 314.92 through 314.99. The applicant shall comply with the requirements for a waiver under § 314.90.

23. The heading for subpart D is revised to read as follows:

Subpart D—FDA Action on Applications and Abbreviated Applications

24. Section 314.100 is revised to read as follows:

§ 314.100 Timeframes for reviewing applications and abbreviated applications.

(a) Within 180 days of receipt of an application for a new drug under section 505(b) of the act, or of an abbreviated application for a new drug under section 505(j) of the act, or of an application or abbreviated application for an antibiotic drug under section 507 of the act, FDA will review it and send the applicant either an approval letter under § 314.105, or an approvable letter under § 314.110, or a not approvable letter under § 314.120. This 180-day period is called the "review clock."

(b) During the review period, an applicant may withdraw an application under § 314.65 or an abbreviated application under § 314.99 and later resubmit it. FDA will treat the resubmission as a new application or abbreviated application.

(c) The review clock may be extended by mutual agreement between FDA and an applicant or as provided in §§ 314.60 and 314.96, as the result of a major amendment.

25. Section 314.101 is revised to read as follows:

§ 314.101 Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application.

(a)(1) Within 60 days after FDA receives an application or abbreviated antibiotic application, the agency will determine whether the application or abbreviated antibiotic application may be filed. The filing of an application or abbreviated antibiotic application means that FDA has made a threshold determination that the application or abbreviated antibiotic application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application or abbreviated antibiotic apply, the agency will file the application or abbreviated antibiotic application and notify the applicant in writing. The date of filing will be the date 60 days after the date FDA received the application or abbreviated antibiotic application. The date of filing begins the 180-day period described in section 505(c) of the act. This 180-day period is called the "filing clock."

(3) If FDA refuses to file the application or abbreviated antibiotic application, the agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the agency's notification an informal conference with the agency about whether the agency should file the application or abbreviated antibiotic application. If, following the informal conference, the applicant requests that FDA file the application or abbreviated antibiotic application (with or without amendments to correct the deficiencies), the agency will file the application or abbreviated antibiotic application over protest under paragraph (a)(2) of this section, notify the applicant in writing, and review it as filed. If the application or abbreviated antibiotic application is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an application or abbreviated antibiotic application that is filed over protest. If FDA refuses to file the application or abbreviated antibiotic application under paragraph (e) of this section, the applicant may amend the application or abbreviated antibiotic application and resubmit it, and the agency will make a determination under this section whether it may be filed.

(b)(1) An abbreviated new drug application will be reviewed after it is submitted to determine whether the abbreviated application may be received. Receipt of an abbreviated new drug application means that FDA has made a threshold determination that the abbreviated application is sufficiently complete to permit a substantive review.

(2) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for considering the abbreviated new drug application not to have been received applies, the agency will receive the abbreviated new drug application and notify the applicant in writing.

(3) If FDA considers the abbreviated new drug application not to have been received under paragraph (d) or (e) of this section, FDA will notify the applicant, ordinarily by telephone. The applicant may then:

(i) Withdraw the abbreviated new drug application under § 314.99; or

(ii) Amend the abbreviated new drug application to correct the deficiencies; or

(iii) Take no action, in which case FDA will refuse to receive the abbreviated new drug application.

(c) [Reserved]

(d) FDA may refuse to file an application or abbreviated antibiotic application or may not consider an abbreviated new drug application to be received if any of the following applies:

(1) The application or abbreviated application does not contain a completed application form.

(2) The application or abbreviated application is not submitted in the form required under § 314.50 or § 314.94.

(3) The application or abbreviated application is incomplete becasue it does not on its face contain information required under section 505(b), section 505(j), or section 507 of the act and § 314.50 or § 314.94.

(4) The applicant fails to submit a complete environmental assessment, which address each of the items specified in the applicable format under § 25.31 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.24 of this chapter.

(5) The application or abbreviated application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement for each nonclinical laboratory study that it was conducted in compliance with the requirements set forth in part 58 of this chapter, or, for each study not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(7) The application does not contain a statement for each clinical study that it was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter, or, if the study was subject to but was not conducted in compliance with those regulations, the application does not contain a brief statement of the reason for the noncompliance.

(8) The drug product that is the subject of the submission is already covered by an approved application or abbreviated application and the applicant of the submission:

(i) Has an approved application or abbreviated application for the same drug product; or

(ii) Is merely a distributor and/or repackager of the already approved drug product.

(9) The application is submitted as a 505(b)(2) application for a drug that is a duplicate of a listed drug and is eligible for approval under section 505(j) of the act.

(e) The agency will refuse to file an application or an abbreviated antibiotic application or will consider an abbreviated new drug application not to have been received if the drug product is subject to licensing by FDA under the Public Health Service Act (42 U.S.C. 201 *et seq.*) and subchapter F of this chapter.

(f)(1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either:

(i) Approve the application or abbreviated antibiotic application; or

(ii) Issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an application or abbreviated antibiotic application in response to an approvable letter or a not approvable letter.

(2) Within 180 days after the date of receipt, plus the period of time the review clock was extended (if any), FDA will either approve or disapprove the abbreviated new drug application. If FDA disapproves the abbreviated new drug application, FDA will issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an abbreviated new drug application in response to a not approvable letter.

(3) This paragraph does not apply to applications or abbreviated applications that have been withdrawn from FDA review by the applicant.

26. Section 314.102 is revised to read as follows:

§ 314.102 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an application or an abbreviated application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate to discuss the particular issue at hand. Communications shall be appropriately documented in the application in accordance with § 10.65 of this chapter. Further details on the procedures for communication between FDA and applicants are contained in a staff manual guide that is publicly available.

(b) *Notification of easily correctable deficiencies.* FDA reviewers shall make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application or an abbreviated application when those deficiencies are discovered, particularly deficiencies concerning chemistry, manufacturing, and controls issues. The agency will also inform applicants promptly of its need for more data or information or for technical changes in the application or the abbreviated application needed to facilitate the agency review. This early communication is intended to permit applicants to correct such readily identified deficiencies relatively early in the review process and to submit an amendment before the review period has elapsed. Such early communication would not ordinarily apply to major scientific issues, which require consideration of the entire pending application or abbreviated application by agency managers as well as reviewing staff. Instead, major scientific issues will ordinarily be addressed in an action letter.

(c) *Ninety-day conference.* Approximately 90 days after the agency receives the application, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies that have been identified by that time and that have not already been communicated. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon. Such meetings would not ordinarily be held on abbreviated applications because they are not submitted for new chemical entities or new indications.

(d) *End of review conference.* At the conclusion of FDA's review of an application or an abbreviated application as designated by the issuance of an approvable or not approvable letter, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to discuss what further steps need to be taken by the applicant before the application or abbreviated application can be approved. This meeting will be available on all applications or abbreviated applications, with priority given to applications for new chemical entities and major new indications for marketed drugs and for the first duplicates for such drugs. Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application.

(e) *Other meetings.* Other meetings between FDA and applicants may be held, with advance notice, to discuss scientific, medical, and other issues that arise during the review process. Requests for meetings shall be directed to the director of the division

responsible for reviewing the application or abbreviated application. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times. However, "drop-in" visits (i.e., an unannounced and unscheduled visit by a company representative) are discouraged except for urgent matters, such as to discuss an important new safety issue.

27. Section 314.103 is amended by revising paragraph (a), the first sentence in paragraph (b), and the fourth sentence in paragraph (c)(2) to read as follows:

§ 314.103 Dispute resolution.

(a) *General.* FDA is committed to resolving differences between applicants and FDA reviewing divisions with respect to technical requirements for applications or abbreviated applications as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative and procedural issues.* When administrative or procedural disputes arise, the applicant should first attempt to resolve the matter with the division responsible for reviewing the application or abbreviated application, beginning with the consumer safety officer assigned to the application or abbreviated application.

* * *

(c) * * *

(2) * * * Requests for such meetings shall be directed to the director of the division responsible for reviewing the application or abbreviated application.

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28. Section 314.104 is revised to read as follows:

§ 314.104 Drugs with potential for abuse.

The Food and Drug Administration will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 801) when an application or abbreviated application is submitted for a drug that appears to have an abuse potential.

29. Section 314.105 is revised to read as follows:

§ 314.105 Approval of an application and an abbreviated application.

(a) The Food and Drug Administration will approve an application or an abbreviated antibiotic application and sent the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the application or abbreviated antibiotic application applies. An approval becomes effective on the date of the issuance of the approval letter, except with regard to an approval under section 505(b)(2) of the act with a delayed effective date. An approval with a delayed effective date is tentative and does not become final until the effective date. When FDA sends an applicant an approval letter for an antibiotic, it will promulgate a regulation under § 314.300 providing for certification of the drug, if necessary. A new drug product or antibiotic approved under this paragraph may not be marketed until an approval is effective. Marketing of an antibiotic need not await the promulgation of a regulation under § 314.300.

(b) FDA will approve an application or abbreviated antibiotic application and issue the applicant an approval letter (rather than an approvable letter under § 314.110) on the basis of draft labeling if the only deficiencies in the application or abbreviated antibiotic application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling, and an abbreviated application after it determines that the drug meets the statutory standards for manufacturing and controls, labeling, and, where applicable, bioequivalence. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to the statutory standards and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards. FDA makes its views on drug products and classes of drugs available through guidelines, recommendations, and other statements of policy.

(d) FDA will approve an abbreviated new drug application and send the applicant an approval letter if none of the reasons in § 314.127 for refusing to approve the abbreviated new drug application applies. The approval becomes effective on the date of the issuance of the agency's approval letter unless the approval letter provides for a delayed effective date. An approval with a delayed effective date is tentative and does not become final until the effective date. A new drug product approved under this paragraph may not be introduced or delivered for introduction into interstate commerce until approval of the abbreviated new drug application is effective. Ordinarily, the effective date of approval will be stated in the approval letter.

30. Section 314.110 is revised to read as follows:

§ 314.110 Approvable letter to the applicant.

(a) In selected circumstances, it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application or abbreviated application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application or abbreviated application substantially meets the requirements of this part and the agency believes that it can approve the application or abbreviated application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed. For an application or an abbreviated antibiotic application, the applicant shall, within 10 days after the date of the approvable letter:

(1) Amend the application or abbreviated antibiotic application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to permit the agency to review the amendment;

(2) Withdraw the application or abbreviated antibiotic application. FDA will consider the applicant's failure to respond within 10 days to an approvable letter to be a request by the applicant to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling;

(3) For a new drug application or abbreviated antibiotic application, ask the agency to provide the applicant an opportunity for a hearing on the

question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD–360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application or abbreviated antibiotic application under § 314.105 or refuse to approve the application or abbreviated antibiotic application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act;

(4) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c) of the act, so that the applicant can determine whether to respond further under paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or the abbreviated antibiotic application under § 314.99. A decision to withdraw an application or abbreviated antibiotic application is without prejudice to a refiling.

(b) FDA will send the applicant of an abbreviated new drug application an approvable letter only if the application substantially meets the requirements of this part and the agency believes that it can approve the abbreviated application if minor deficiencies (e.g., labeling deficiencies) are corrected. The approvable letter will describe the deficiencies and state a time period within which the applicant must respond. Unless the applicant corrects the deficiencies by amendment within the specified time period, FDA will refuse to approve the abbreviated application under § 314.127. Within 10 days after the date of the approvable letter, the applicant may also ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the abbreviated new drug application. Applicants who request a hearing shall submit the request to the Division of Regulatory Affairs (HFD–360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

31. Section 314.120 is revised to read as follows:

§ 314.120 Not approvable letter to the applicant.

(a) The Food and Drug Administration will send the applicant a not approvable letter if the agency believes that the application or abbreviated antibiotic application may not be approved for one of the reasons given in § 314.125 or the abbreviated new drug application may not be approved for one of the reasons given in § 314.127. The not approvable letter will describe the deficiencies in the application or abbreviated application. Except as provided in paragraph (b) of this section, within 10 days after the date of the not approvable letter, the applicant shall:

(1) Amend the application or abbreviated application or notify FDA of an intent to file an amendment. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under § 314.60 or § 314.96;

(2) Withdraw the application or abbreviated application. Except as provided in paragraph (b) of this section, FDA will consider the applicant's failure to respond within 10 days to a not approvable letter to be a request by the applicant to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw the application or abbreviated application is without prejudice to refiling;

(3) For a new drug application or an abbreviated application, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFD–360), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the not approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application or abbreviated application under § 314.105 or refuse to approve the application or abbreviated antibiotic application under § 314.125 or abbreviated new drug application under § 314.127 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(1)(B) or (j)(4)(C) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) or (j)(3) of the act;

(4) For an antibiotic application, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act; or

(5) Notify FDA that the applicant agrees to an extension of the review period under section 505(c)(1) or (j)(4)(A) of the act, so that the applicant can determine whether to respond further under paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65 or abbreviated application under § 314.99. A decision to withdraw an application or abbreviated application is without prejudice to a refiling.

(b) With the exception of a request for an opportunity for a hearing under paragraph (a)(3) of this section, the 10-day time period in this section for responding to a not approvable letter does not apply to abbreviated new drug applications. FDA may consider the applicant's failure to respond within 180 days to a not approvable letter to be a request by the applicant to withdraw the abbreviated new drug application under § 314.99.

32. New § 314.122 is added to subpart D to read as follows:

§ 314.122 Submitting an abbreviated application for, or a 505(j)(2)(C) petition that relies on, a listed drug that is no longer marketed.

(a) An abbreviated new drug application that refers to, or a petition under section 505(j)(2)(C) of the act and § 314.93 that relies on, a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons. The petition must be submitted under §§ 10.25(a) and 10.30 of this chapter and must contain all evidence available to the petitioner concerning the reasons for the withdrawal from sale.

(b) When a petition described in paragraph (a) of this section is submitted, the agency will consider the evidence in the petition and any other evidence before the agency, and determine whether the listed drug is withdrawn from sale for safety or effectiveness reasons, in accordance with procedures in § 314.161.

(c) An abbreviated new drug application described in paragraph (a) of this section will be disapproved, under § 314.127(a)(11), and a 505(j)(2)(C) petition described in paragraph (a) of this section will be disapproved, under § 314.93(e)(1)(iv), unless the agency determines that the withdrawal of the listed drug was not for safety or effectiveness reasons.

(d) Certain drug products approved for safety and effectiveness that were no longer marketed on September 24, 1984, are not included in the list. Any person who wishes to obtain marketing approval for such a drug product under an abbreviated new drug application must petition FDA for a determination whether the drug product was withdrawn from the market for safety or effectiveness reasons and request that the list be amended to include the drug product. A person seeking such a determination shall use the petition procedures established in § 10.30 of this chapter. The petitioner shall include in the petition information to show that the drug product was approved for safety and effectiveness and all evidence available to the petitioner concerning the reason that marketing of the drug product ceased.

33. Section 314.125 is amended by revising the section heading, the introductory text of paragraph (a), the introductory text of paragraph (b), paragraphs (b)(7), (b)(9), (b)(10), (b)(12), (b)(14), (b)(15), (b)(16), and (b)(17), and by adding new paragraph (b)(18) to read as follows:

§ 314.125 Refusal to approve an application or abbreviated antibiotic application.

(a) The Food and Drug Administration will refuse to approve the application or abbreviated antibiotic application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300, if:

* * * * *

(b) FDA may refuse to approve an application or abbreviated antibiotic application for any of the following reasons:

* * * * *

(7) The application or abbreviated antibiotic application contains an untrue statement of a material fact.

* * * * *

(9) The application or abbreviated antibiotic application does not contain bioavailability or bioequivalence data required under part 320 of this chapter.

(10) A reason given in a letter refusing to file the application or abbreviated antibiotic application under § 314.101(d), if the deficiency is not corrected.

* * * * *

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application or abbreviated antibiotic application.

* * * * *

(14) The application or abbreviated antibiotic application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated antibiotic application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application or abbreviated antibiotic application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application or abbreviated antibiotic application, subject to the institutional review board regulations in part 58 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(17) The applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application or abbreviated antibiotic application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(18) For a new drug, the application failed to contain the patent information required by section 505(b)(1) of the act.

* * * * *

34. New § 314.127 is added to subpart D to read as follows:

§ 314.127 Refusal to approve an abbreviated new drug application.

(a) FDA will refuse to approve an abbreviated application for a new drug under section 505(j) of the act for any of the following reasons:

(1) The methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to ensure and preserve its identity, strength, quality, and purity.

(2) Information submitted with the abbreviated new drug application is insufficient to show that each of the proposed conditions of use has been previously approved for the listed drug referred to in the application.

(3)(i) If the reference listed drug has only one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredient is the same as that of the reference listed drug;

(ii) If the reference listed drug has more than one active ingredient, information submitted with the abbreviated new drug application is insufficient to show that the active ingredients are the same as the active ingredients of the reference listed drug; or

(iii) If the reference listed drug has more than one active ingredient and if the abbreviated new drug application is for a drug product that has an active ingredient different from the reference listed drug:

(A) Information submitted with the abbreviated new drug application is insufficient to show:

(*1*) That the other active ingredient are the same as the active ingredients of the reference listed drug; or

(*2*) That the different active ingredient is an active ingredient of a listed drug or a drug that does not meet the requirements of section 201(p) of the act; or

(b) No petition to submit an abbreviated application for the drug product with the different active ingredient was approved under § 314.93.

(4)(i) If the abbreviated new drug application is for a drug product whose

route of administration, dosage form, or strength purports to be the same as that of the listed drug referred to in the abbreviated new drug application, information submitted in the abbreviated new drug application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the reference listed drug; or

(ii) If the abbreviated new drug application is for a drug product whose route of administration, dosage form, or strength is different from that of the listed drug referred to in the application, no petition to submit an abbreviated new drug application for the drug product with the different route of administration, dosage form, or strength was approved under § 314.93.

(5) If the abbreviated new drug application was submitted under the approval of a petition under § 314.93, the abbreviated new drug application did not contain the information required by FDA with respect to the active ingredient, route of administration, dosage form, or strength that is not the same as that of the reference listed drug.

(6)(i) Information submitted in the abbreviated new drug application is insufficient to show that the drug product is bioequivalent to the listed drug referred to in the abbreviated new drug application; or

(ii) If the abbreviated new drug application was submitted under a petition approved under § 314.93, information submitted in the abbreviated new drug application is insufficient to show that the active ingredients of the drug product are of the same pharmacological or therapeutic class as those of the reference listed drug and that the drug product can be expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use approved for the reference listed drug.

(7) Information submitted in the abbreviated new drug application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the abbreviated new drug application except for changes required because of differences approved in a petition under § 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers or because aspects of the listed drug's labeling are protected by patent, or by exclusivity, and such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use.

(8)(i) Information submitted in the abbreviated new drug application of any other information available to FDA shows that:

(A) The inactive ingredients of the drug product are unsafe for use, as described in paragraph (a)(8)(ii) of this section, under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug product; or

(B) The composition of the drug product is unsafe, as described in paragraph (a)(8)(ii) of this section, under the conditions prescribed, recommended, or suggested in the proposed labeling because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included.

(ii)(A) FDA will consider the inactive ingredients or composition of a drug product unsafe and refuse to approve an abbreviated new drug application under paragraph (a)(8)(i) of this section if, on the basis of information available to the agency, there is a reasonable basis to conclude that one or more of the inactive ingredients of the proposed drug or its composition raises serious questions of safety. From its experience with reviewing inactive ingredients, and from other information available to it, FDA may identify changes in inactive ingredients or composition that may adversely affect a drug product's safety. The inactive ingredients or composition of a proposed drug product will be considered to raise serious questions of safety if the product incorporates one or more of these changes. Examples of the changes that may raise serious questions of safety include, but are not limited to, the following:

(*1*) A change in an inactive ingredient so that the product does not comply with an official compendium.

(*2*) A change in composition to include an inactive ingredient that has not been previously approved in a drug product for human use by the same route of administration.

(*3*) A change in the composition of a parenteral drug product to include an inactive ingredient that has not been previously approved in a parenteral drug product.

(*4*) A change in composition of a drug product for ophthalmic use to include an inactive ingredient that has not been previously approved in a drug for ophthalmic use.

(*5*) The use of a delivery or a modified release mechanism never before approved for the drug.

(*6*) A change in composition to include a significantly greater content of one or more inactive ingredients than previously used in the drug product.

(*7*) If the drug product is intended for topical administration, a change in the properties of the vehicle or base that might increase absorption of certain potentially toxic active ingredients thereby affecting the safety of the drug product, or a change in the lipophilic properties of a vehicle or base, e.g., a change from an oleaginous to a water soluble vehicle or base.

(B) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for parenteral use to be unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, and antioxidants, in the same concentration as the listed drug, and, if it differs from the listed drug in a preservative, buffer, or antioxidant, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product.

(C) FDA will consider an inactive ingredient in, or the composition of, a drug product intended for ophthalmic or otic use unsafe and will refuse to approve the abbreviated new drug application unless it contains the same inactive ingredients, other than preservatives, buffers, substances to adjust tonicity, or thickening agents, in the same concentration as the listed drug, and if it differs from the listed drug in a preservative, buffer, substance to adjust tonicity, or thickening agent, the application contains sufficient information to demonstrate that the difference does not affect the safety of the drug product and the labeling does not claim any therapeutic advantage over or difference from the listed drug.

(9) Approval of the listed drug referred to in the abbreviated new drug application has been withdrawn or suspended for grounds described in § 314.150(a) or FDA has published a notice of opportunity for hearing to withdraw approval of the reference listed drug under § 314.150(a).

(10) Approval of the listed drug referred to in the abbreviated new drug application has been withdrawn under § 314.151 or FDA has proposed to withdraw approval of the reference listed drug under § 314.151(a).

(11) FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under § 314.161, or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal is for safety or effectiveness reasons, or approval of the reference listed drug has been suspended under

§ 314.153, or the agency has issued an initial decision proposing to suspend the reference listed drug under § 314.153(a)(1).

(12) The abbreviated new drug application does not meet any other requirement under section 505(j)(2)(A) of the act.

(13) The abbreviated new drug application contains an untrue statement of material fact.

(b) FDA may refuse to approve an abbreviated application for a new drug if the applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the abbreviated new drug application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

35. Section 314.150 is revised to read as follows:

§ 314.150 Withdrawal of approval of an application or abbreviated application.

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in §§ 310.6 and 314.151(a) of this chapter and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and under the procedure in § 314.300, if any of the following apply:

(1) The Secretary of Health and Human Services has suspended the approval of the application or abbreviated application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application or abbreviated application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application or abbreviated application was approved, evaluated together with the evidence available when the application or abbreviated application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application or abbreviated application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application or abbreviated application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application or abbreviated application contains any untrue statement of a material fact; or

(v) That the patent information prescribed by section 505(c) of the act was not submitted within 30 days after the receipt of written notice from FDA specifying the failure to submit such information; or

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or abbreviated new drug application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and the procedure in § 314.300, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(k) or 507(g) of the act and § 314.80, § 314.81, or § 314.98, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application or abbreviated application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular, and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under part 320 of this chapter.

(6) The application or abbreviated application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application or abbreviated application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application or abbreviated application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in part 58 of this chapter and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application or abbreviated application, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(9) That the applicant or contract research organization that conducted a bioavailability or bioequivalence study contained in the application or abbreviated application refuses to permit an inspection of facilities or records relevant to the study by a properly authorized officer or employee

of the Department of Health and Human Services or refuses to submit reserve samples of the drug products used in the study when requested by FDA.

(10) That the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application, except for differences approved in the abbreviated new drug application or those differences resulting from:

(i) A patent on the listed drug issued after approval of the abbreviated new drug application; or

(ii) Exclusivity accorded to the listed drug after approval of the abbreviated new drug application that do not render the drug product less safe or effective than the listed drug for any remaining, nonprotected condition(s) of use.

(c) FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section applies to the drug. FDA will consider a written request for a withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application or abbreviated application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application or abbreviated application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under paragraph (b) of this section, but will withdraw approval of the application or abbreviated application in a notice published in the **Federal Register** that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

36. New § 314.151 is added to subpart D to read as follows:

§ 314.151 Withdrawal of approval of an abbreviated new drug application under section 505(j)(5) of the act.

(a) Approval of an abbreviated new drug application approved under § 314.105(d) may be withdrawn when the agency withdraws approval, under § 314.150(a) or under this section, of the approved drug referred to in the abbreviated new drug application. If the agency proposed to withdraw approval of a listed drug under § 314.150(a), the holder of an approved application for the listed drug has a right to notice and opportunity for hearing. The published notice of opportunity for hearing will identify all drug products approved under § 314.105(d) whose applications are subject to withdrawal under this section if the listed drug is withdrawn, and will propose to withdraw such drugs. Holders of approved applications for the identified drug products will be provided notice and an opportunity to respond to the proposed withdrawal of their applications as described in paragraphs (b) and (c) of this section.

(b)(1) The published notice of opportunity for hearing on the withdrawal of the listed drug will serve as notice to holders of identified abbreviated new drug applications of the grounds for the proposed withdrawal.

(2) Holders of applications for drug products identified in the notice of opportunity for hearing may submit written comments on the notice of opportunity for hearing issued on the proposed withdrawal of the listed drug. If an abbreviated new drug application holder submits comments on the notice of opportunity for hearing and a hearing is granted, the abbreviated new drug application holder may participate in the hearing as a nonparty participant as provided for in § 12.89 of this chapter.

(3) Except as provided in paragraphs (c) and (d) of this section, the approval of an abbreviated new drug application for a drug product identified in the notice of opportunity for hearing on the withdrawal of a listed drug will be withdrawn when the agency has completed the withdrawal of approval of the listed drug.

(c)(1) If the holder of an application for a drug identified in the notice of opportunity for hearing has submitted timely comments but does not have an opportunity to participate in a hearing because a hearing is not requested or is settled, the submitted comments will be considered by the agency, which will issue an initial decision. The initial decision will respond to the comments, and contain the agency's decision whether there are grounds to withdraw approval of the listed drug and of the abbreviated new drug applications on which timely comments were submitted. The initial decision will be sent to each abbreviated new drug application holder that has submitted comments.

(2) Abbreviated new drug application holders to whom the initial decision was sent may, within 30 days of the issuance of the initial decision, submit written objections.

(3) The agency may, at its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(4) If there are no timely objections to the initial decision, it will become final at the expiration of 30 days.

(5) If timely objections are submitted, they will be reviewed and responded to in a final decision.

(6) The written comments received, the initial decision, the evidence relied on in the comments and in the initial decision, the objections to the initial decision, and, if a limited oral hearing has been held, the transcript of that hearing and any documents submitted therein, shall form the record upon which the agency shall make a final decision.

(7) Except as provided in paragraph (d) of this section, any abbreviated new drug application whose holder submitted comments on the notice of opportunity for hearing shall be withdrawn upon the issuance of a final decision concluding that the listed drug should be withdrawn for grounds as described in § 314.150(a). The final decision shall be in writing and shall constitute final agency action, reviewable in a judicial proceeding.

(8) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, room. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, promptly upon receipt in that office.

(d) If the agency determines, based upon information submitted by the holder of an abbreviated new drug application, that the grounds for withdrawal of the listed drug are not applicable to a drug identified in the notice of opportunity for hearing, the final decision will state that the approval of the abbreviated new drug application for such drug is not withdrawn.

37. Section 314.152 is revised to read as follows:

§ 314.152 Notice of withdrawal of approval of an application or abbreviated application for a new drug.

If the Food and Drug Administration withdraws approval of an application or abbreviated application for a new drug, FDA will publish a notice in the **Federal Register** announcing the withdrawal of

approval. If the application or abbreviated application was withdrawn for grounds described in § 314.150(a) or § 314.151, the notice will announce the removal of the drug from the list of approved drugs published under section 505(j)(6) of the act and shall satisfy the requirement of § 314.162(b).

38. New § 314.153 is added to Subpart D to read as follows:

§ 314.153 Suspension of approval of an abbreviated new drug application.

(a) *Suspension of approval.* The approval of an abbreviated new drug application approved under § 314.105(d) shall be suspended for the period stated when:

(1) The Secretary of the Department of Health and Human Services, under the imminent hazard authority of section 505(e) of the act or the authority of this paragraph, suspends approval of a listed drug referred to in the abbreviated new drug application, for the period of the suspension;

(2) The agency, in the notice described in paragraph (b) of this section, or in any subsequent written notice given an abbreviated new drug application holder by the agency, concludes that the risk of continued marketing and use of the drug is inappropriate, pending completion of proceedings to withdraw or suspend approval under § 314.151 or paragraph (b) of this section; or

(3) The agency, under the procedures set forth in paragraph (b) of this section, issues a final decision stating the determination that the abbreviated application is suspended because the listed drug on which the approval of the abbreviated new drug application depends has been withdrawn from sale for reasons of safety or effectiveness or has been suspended under paragraph (b) of this section. The suspension will take effect on the date stated in the decision and will remain in effect until the agency determines that the marketing of the drug has resumed or that the withdrawal is not for safety or effectiveness reasons.

(b) *Procedures for suspension of abbreviated new drug applications when a listed drug is voluntarily withdrawn for safety or effectiveness reasons.* (1) If a listed drug is voluntarily withdrawn from sale, and the agency determines that the withdrawal from sale was for reasons of safety or effectiveness, the agency will send each holder of an approved abbreviated new drug application that is subject to suspension as a result of this determination a copy of the agency's initial decision setting forth the reasons for the determination. The initial decision will also be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, room 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

(2) Each abbreviated new drug application holder will have 30 days from the issuance of the initial decision to present, in writing, comments and information bearing on the initial decision. If no comments or information is received, the initial decision will become final at the expiration of 30 days.

(3) Comments and information received within 30 days of the issuance of the initial decision will be considered by the agency and responded to in a final decision.

(4) The agency may, in its discretion, hold a limited oral hearing to resolve dispositive factual issues that cannot be resolved on the basis of written submissions.

(5) If the final decision affirms the agency's initial decision that the listed drug was withdrawn for reasons of safety or effectiveness, the decision will be published in the **Federal Register** in compliance with § 314.152, and will, except as provided in paragraph (b)(6) of this section, suspend approval of all abbreviated new drug applications identified under paragraph (b)(1) of this section and remove from the list the listed drug and any drug whose approval was suspended under this paragraph. The notice will satisfy the requirement of § 314.162(b). The agency's final decision and copies of materials on which it relies will also be filed with the Dockets Management Branch (address in paragraph (b)(1) of this section).

(6) If the agency determines in its final decision that the listed drug was withdrawn for reasons of safety or effectiveness but, based upon information submitted by the holder of an abbreviated new drug application, also determines that the reasons for the withdrawal of the listed drug are not relevant to the safety and effectiveness of the drug subject to such abbreviated new drug application, the final decision will state that the approval of such abbreviated new drug application is not suspended.

(7) Documents in the record will be publicly available in accordance with § 10.20(j) of this chapter. Documents available for examination or copying will be placed on public display in the Dockets Management Branch (address in paragraph (b)(1) of this section) promptly upon receipt in that office.

39. Section 314.160 is revised to read as follows:

§ 314.160 Approval of an application or abbreviated application for which approval was previously refused, suspended, or withdrawn.

Upon the Food and Drug Administration's own initiative or upon request of an applicant, FDA may, on the basis of new data, approve an application or abbreviated application which it had previously refused, suspended, or withdrawn approval. FDA will publish a notice in the **Federal Register** announcing the approval.

40. New §§ 314.161 and 314.162 are added to subpart D to read as follows:

§ 314.161 Determination of reasons for voluntary withdrawal of a listed drug.

(a) A determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made:

(1) Prior to approving an abbreviated new drug application that refers to the listed drug;

(2) Whenever a listed drug is voluntarily withdrawn from sale and abbreviated new drug applications that referred to the listed drug have been approved; and

(3) When a person petitions for such a determination under §§ 10.25(a) and 10.30 of this chapter.

(b) Any person may petition under §§ 10.25(a) and 10.30 of this chapter for a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons. Any such petition must contain all evidence available to the petitioner concerning the reason that the drug is withdrawn from sale.

(c) If the agency determines that a listed drug is withdrawn from sale for safety or effectiveness reasons, the agency will, except as provided in paragraph (d) of this section, publish a notice of the determination in the **Federal Register.**

(d) If the agency determines under paragraph (a) of this section that a listed drug is withdrawn from sale for safety and effectiveness reasons and there are approved abbreviated new drug applications that are subject to suspension under section 505(j)(5) of the act, FDA will initiate a proceeding in accordance with § 314.153(b).

(e) A drug that the agency determines is withdrawn for safety or effectiveness reasons will be removed from the list, under § 314.162. The drug may be relisted if the agency has evidence that marketing of the drug has resumed or that the withdrawal is not for safety or

effectiveness reasons. A determination that the drug is not withdrawn for safety or effectiveness reasons may be made at any time after its removal from the list, upon the agency's initiative, or upon the submission of a petition under §§ 10.25(a) and 10.30 of this chapter. If the agency determines that the drug is not withdrawn for safety or effectiveness reasons, the agency shall publish a notice of this determination in the **Federal Register**. The notice will also announce that the drug is relisted, under § 314.162(c). The notice will also serve to reinstate approval of all suspended abbreviated new drug applications that referred to the listed drug.

§ 314.162 Removal of a drug product from the list.

(a) FDA will remove a previously approved new drug product from the list for the period stated when:

(1) The agency withdraws or suspends approval of a new drug application or an abbreviated new drug application under § 314.150(a) or § 314.151 or under the imminent hazard authority of section 505(e) of the act, for the same period as the withdrawal or suspension of the application; or

(2) The agency, in accordance with the procedures in § 314.153(b) or § 314.161, issues a final decision stating that the listed drug was withdrawn from sale for safety or effectiveness reasons, or suspended under § 314.153(b), until the agency determines that the withdrawal from the market has ceased or is not for safety or effectiveness reasons.

(b) FDA will publish in the **Federal Register** a notice announcing the removal of a drug from the list.

(c) At the end of the period specified in paragraph (a)(1) or (a)(2) of this section, FDA will relist a drug that has been removed from the list. The agency will publish in the **Federal Register** a notice announcing the relisting of the drug.

41. Section 314.200 is amended by revising the introductory text of paragraph (a), paragraphs (b)(1) and (b)(2), the last sentence in paragraph (c)(1), paragraph (c)(3), and the first sentence in paragraph (g)(1) to read as follows:

§ 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* The Director of the Center for Drug Evaluation and Research, Food and Drug Administration, will give the applicant, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6 of this chapter, notice and an opportunity for a hearing on the Center's proposal to refuse to approve an application or to withdraw the approval of an application or abbreviated application under section 505(e) of the act. The notice will state the reasons for the action and the proposed grounds for the order.

* * * * *

(b) * * *

(1) To any person who has submitted an application or abbreviated application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application or abbreviated application.

(2) To any person who has not submitted an application or abbreviated application but who is subject to the notice under § 310.6 of this chapter, by publication of the notice in the **Federal Register**.

(c)(1) * * * The applicant, or other person, may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application, abbreviated application, or other report.

* * * * *

(3) Any other interested person who is not subject to the notice of opportunity for a hearing may also submit comments on the proposal to withdraw approval of the application or abbreviated application. The comments are requested to be submitted within the time and under the conditions specified in this section.

* * * * *

(g) * * *

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or abbreviated application or the withdrawal of approval of the application or abbreviated application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50 of this chapter, showing effectiveness have been identified. * * *

* * * * *

42. Section 314.430 is amended by revising the section heading, paragraphs (a), (b), (c), and (d), the introductory text of paragraph (e), paragraphs (f)(5) and (f)(6), and the introductory text of paragraph (g) to read as follows:

§ 314.430 Availability for public disclosure of data and information in an application or abbreviated application.

(a) The Food and Drug Administration will determine the public availability of any part of an application or abbreviated application under this section and part 20 of this chapter. For purposes of this section, the application or abbreviated application includes all data and information submitted with or incorporated by reference in the application or abbreviated application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70 or § 314.97, reports under § 314.80 or § 314.98, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application or abbreviated application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged. The Center for Drug Evaluation and Research will maintain and make available for public disclosure a list of applications or abbreviated applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application or abbreviated application has not been publicly disclosed or acknowledged, no data or information in the application or abbreviated application is available for public disclosure.

(d) If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application or abbreviated application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications and abbreviated applications, entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," is available from the Government Printing Office, Washington, DC 20402. This list is updated monthly.

* * * * *

(f) * * *

(5) For applications submitted under section 505(b) of the act, the effective date of the approval of the first abbreviated application submitted under section 505(j) of the act which refers to such drug, or the date on which the approval of an abbreviated application under section 505(j) of the act which refers to such drug could be made effective if such an abbreviated application had been submitted.

(6) For applications or abbreviated applications submitted under sections 505(j), 506, and 507 of the act, when FDA sends an approval letter to the applicant.

(g) The following data and information in an application or abbreviated application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61 of this chapter:

* * * * *

43. Section 314.440 is amended by revising the section heading, the introductory text of paragraph (a), and paragraphs (a)(1) and (a)(2) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) Applicants shall send applications, abbreviated applications, and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and directed to the appropriate office identified below:

(1) An application under § 314.50 or § 314.54 submitted for filing should be directed to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. Applicants may obtain folders for binding applications from the Forms and Publications Warehouse, 12100 Parklawn Dr., Rockville, MD 20852. After FDA has filed the application, the agency will inform the applicant which division is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be directed to the appropriate division.

(2) An abbreviated application under § 314.94, and amendments, supplements, and resubmissions should be directed to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Items sent by parcel post or overnight courier service should be directed to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II, 7500 Standish Place, rm. 150, Rockville, MD 20855. Correspondence not associated with an application should be addressed specifically to the intended office or division and to the person as follows: Center for Drug Evaluation and Research, Food and Drug Administration, Attn: [*insert name of person*], MPN II, HFD–[*insert mail code of office or division*], 5600 Fishers Lane, Rockville, MD 20857. The mail code for the Office of Generic Drugs is HFD–600, the mail code for the Division of Chemistry is HFD–630, and the mail code for the Division of Bioequivalence is HFD–650.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

44. Part 320 is amended by revising the table of contents with the authority citation continuing to read as follows:

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

Authority: Secs. 201, 501, 502, 505, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, 357, 371).

45. Section 320.1 is amended by revising paragraphs (a) and (e) to read as follows:

§ 320.1 Definitions.

(a) *Bioavailability* means the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

* * * * *

(e) *Bioequivalence* means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain controlled release dosage forms), certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active

ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

* * * * *

46. Part 320 is amended by revising the heading for subpart B, revising §§ 320.21, 320.22, 320.23, 320.24, 320.30, and 320.31, and by removing the heading for subpart C to read as follows:

Subpart B—Procedures for Determining the Bioavailability or Bioequivalence of Drug Products

§ 320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.

(a) Any person submitting a full new drug application to the Food and Drug Administration (FDA) shall include in the application either:

(1) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or

(2) Information to permit FDA to waive the submission of evidence demonstrating in vivo bioavailability.

(b) Any person submitting an abbreviated new drug application to FDA shall include in the application either:

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b)); or

(2) Information to show that the drug product is bioequivalent to the reference listed drug which would permit FDA to waive the submission of evidence demonstrating bioequivalence as provided in paragraph (f) of this section.

(c) Any person submitting a supplemental application to FDA shall include in the supplemental application the evidence or information set forth in paragraphs (a) and (b) of this section if the supplemental application proposes any of the following changes:

(1) A change in the manufacturing process, including a change in product formulation or dosage strength, beyond the variations provided for in the approved application.

(2) A change in the labeling to provide for a new indication for use of the drug product, if clinical studies are required to support the new indication for use.

(3) A change in the labeling to provide for a new dosage regimen or for an additional dosage regimen for a special patient population, e.g., infants, if clinical studies are required to support the new or additional dosage regimen.

(d) FDA may approve a full new drug application, or a supplemental application proposing any of the changes set forth in paragraph (c) of this section, that does not contain evidence of in vivo bioavailability or information to permit waiver of the requirement for in vivo bioavailability data, if all of the following conditions are met.

(1) The application was under review by FDA on July 7, 1977.

(2) The application is otherwise approvable.

(3) The application agrees to submit, within the time specified by FDA, either:

(i) Evidence demonstrating the in vivo bioavailability of the drug product that is the subject of the application; or

(ii) Information to permit FDA to waive demonstration of in vivo bioavailability.

(e) Evidence demonstrating the in vivo bioavailability and bioequivalence of a drug product shall be obtained using one of the approaches for determining bioavailability set forth in § 320.24.

(f) Information to permit FDA to waive the submission of evidence demonstrating the in vivo bioavailability or bioequivalence shall meet the criteria set forth in § 320.24.

(g) Any person holding an approved full or abbreviated new drug application shall submit to FDA a supplemental application containing new evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application if notified by FDA that:

(1) There are data demonstrating that the dosage regimen in the labeling is based on incorrect assumptions or facts regarding the pharmacokinetics of the drug product and that following this dosage regimen could potentially result in subtherapeutic or toxic levels; or

(2) There are data demonstrating significant intra-batch and batch-to-batch variability, e.g., plus or minus 25 percent, in the bioavailability of the drug product.

(h) The requirements of this section regarding the submission of evidence demonstrating in vivo bioavailability and bioequivalence apply only to a full or abbreviated new drug application or a supplemental application for a finished dosage formulation.

§ 320.22 Criteria for waiver of evidence of in vivo bioavailability or bioequivalence.

(a) Any person submitting a full or abbreviated new drug application, or a supplemental application proposing any of the changes set forth in § 320.21(c), may request FDA to waive the requirement for the submission of evidence demonstrating the in vivo bioavailability or bioequivalence of the drug product that is the subject of the application. An applicant shall submit a request for waiver with the application. Except as provided in paragraph (g) of this section, FDA shall waive the requirement for the submission of evidence of in vivo bioavailability or bioequivalence if the drug product meets any of the provisions of paragraphs (b), (c), (d), or (e) of this section.

(b) For certain drug products, the in vivo bioavailability or bioequivalence of the drug product may be self-evident. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability or bioequivalence of these drug products. A drug product's in vivo bioavailability or bioequivalence may be considered self-evident based on other data in the application if the product meets one of the following criteria:

(1) The drug product:

(i) Is a parenteral solution intended solely for administration by injection, or an ophthalmic or otic solution; and

(ii) Contains the same active and inactive ingredients in the same concentration as a drug product that is the subject of an approved full new drug application.

(2) The drug product:

(i) Is administered by inhalation as a gas, e.g., a medicinal or an inhalation anesthetic; and

(ii) Contains an active ingredient in the same dosage form as a drug product that is the subject of an approved full new drug application.

(3) The drug product:

(i) Is a solution for application to the skin, an oral solution, elixir, syrup, tincture, or similar other solubilized form.

(ii) Contains an active drug ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application; and

(iii) Contains no inactive ingredient or other change in formulation from the drug product that is the subject of the approved full new drug application that may significantly affect absorption of the active drug ingredient or active moiety.

(c) FDA shall waive the requirement for the submission of evidence demonstrating the in vivo bioavailability of a solid oral dosage form (other than an enteric coated or controlled release dosage form) of a drug product determined to be effective for at least one indication in a Drug Efficacy Study Implementation notice or which is identical, related, or similar to such a drug product under § 310.6 of this chapter unless FDA has evaluated the

drug product under the criteria set forth in § 320.32, included the drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations List, and rated the drug product as having a known or potential bioequivalence problem. A drug product so rated reflects a determination by FDA that an in vivo bioequivalence study is required.

(d) For certain drug products, bioavailability or bioequivalence may be demonstrated by evidence obtained in vitro in lieu of in vivo data. FDA shall waive the requirement for the submission of evidence obtained in vivo demonstrating the bioavailability of the drug product if the drug product meets one of the following criteria:

(1) [Reserved]

(2) The drug product is in the same dosage form, but in a different strength, and is proportionally similar in its active and inactive ingredients to another drug product for which the same manufacturer has obtained approval and the conditions in paragraphs (d)(2)(i) through (d)(2)(iii) of this section are met:

(i) The bioavailability of this other drug product has been demonstrated;

(ii) Both drug products meet an appropriate in vitro test approved by FDA; and

(iii) The applicant submits evidence showing that both drug products are proportionally similar in their active and inactive ingredients.

(iv) This subparagraph does not apply to enteric coated or controlled release dosage forms.

(3) The drug product is, on the basis of scientific evidence submitted in the application, shown to meet an in vitro test that has been correlated with in vivo data.

(4) The drug product is a reformulated product that is identical, except for a different color, flavor, or preservative that could not affect the bioavailability of the reformulated product, to another drug product for which the same manufacturer has obtained approval and the following conditions are met:

(i) The bioavailability of the other product has been demonstrated; and

(ii) Both drug products meet an appropriate in vitro test approved by FDA.

(e) FDA, for good cause, may waive a requirement for the submission of evidence of in vivo bioavailability if waiver is compatible with the protection of the public health. For full new drug applications, FDA may defer a requirement for the submission of evidence of in vivo bioavailability if deferral is compatible with the protection of the public health.

(f) FDA, for good cause, may require evidence of in vivo bioavailability or bioequivalence for any drug product if the agency determines that any difference between the drug product and a listed drug may affect the bioavailability or bioequivalence of the drug product.

§ 320.23 Basis for demonstrating in vivo bioavailability or bioequivalence.

(a)(1) The in vivo bioavailability of a drug product is demonstrated if the product's rate and extent of absorption, as determined by comparison of measured parameters, e.g., concentration of the active drug ingredient in the blood, urinary excretion rates, or pharmacological effects, do not indicate a significant difference from the reference material's rate and extent of absorption. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of action.

(2) Statistical techniques used shall be of sufficient sensitivity to detect differences in rate and extent of absorption that are not attributable to subject variability.

(3) A drug product that differs from the reference material in its rate of absorption, but not in its extent of absorption, may be considered to be bioavailable if the difference in the rate of absorption is intentional, is appropriately reflected in the labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug product.

(b) Two drug products will be considered bioequivalent drug products if they are pharmaceutical equivalents or pharmaceutical alternatives whose rate and extent of absorption do not show a significant difference when administered at the same molar dose of the active moiety under similar experimental conditions, either single dose or multiple dose. Some pharmaceutical equivalents or pharmaceutical alternatives may be equivalent in the extent of their absorption but not in their rate of absorption and yet may be considered bioequivalent because such differences in the rate of absorption are intentional and are reflected in the labeling, are not essential to the attainment of effective body drug concentrations on chronic use, and are considered medically insignificant for the particular drug product studied.

§ 320.24 Types of evidence to establish bioavailability or bioequivalence.

(a) Bioavailability or bioequivalence may be determined by several in vivo and in vitro methods. FDA may require in vivo or in vitro testing, or both, to establish the bioavailability of a drug product or the bioequivalence of specific drug products. Information on bioequivalence requirements for specific products is included in the current edition of FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and any current supplement to the publication. The selection of the method used to meet an in vivo or in vitro testing requirement depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Applicants shall conduct bioavailability and bioequivalence testing using the most accurate, sensitive, and reproducible approach available among those set forth in paragraph (b) of this section. The method used must be capable of demonstrating bioavailability or bioequivalence, as appropriate, for the product being tested.

(b) The following in vivo and in vitro approaches, in descending order of accuracy, sensitivity, and reproducibility, are acceptable for determining the bioavailability or bioequivalence of a drug product.

(1)(i) An in vivo test in humans in which the concentration of the active ingredient or active moiety, and, when appropriate, its active metabolite(s), in whole blood, plasma, serum, or other appropriate biological fluid is measured as a function of time. This approach is particularly applicable to dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution within the body; or

(ii) An in vitro test that has been correlated with and is predictive of human in vivo bioavailability data; or

(iii) An in vivo test in animals that has been correlated with and is predictive of human bioavailability data.

(2) An in vivo test in humans in which the urinary excretion of the active moiety, and, when appropriate, its active metabolite(s), are measured as a function of time. The intervals at which measurements are taken should ordinarily be as short as possible so that the measure of the rate of elimination is as accurate as possible. Depending on the nature of the drug product, this approach may be applicable to the category of dosage forms described in paragraph (b)(1)(i) of this section. This method is not appropriate where urinary

excretion is not a significant mechanism of elimination.

(3) An in vivo test in humans in which an appropriate acute pharmacological effect of the active moiety, and, when appropriate, its active metabolite(s), are measured as a function of time if such effect can be measured with sufficient accuracy, sensitivity, and reproducibility. This approach is applicable to the category of dosage forms described in paragraph (b)(1)(i) of this section only when appropriate methods are not available for measurement of the concentration of the moiety, and, when appropriate, its active metabolite(s), in biological fluids or excretory products but a method is available for the measurement of an appropriate acute pharmacological effect. This approach may be particularly applicable to dosage forms that are not intended to deliver the active moiety to the bloodstream for systemic distribution.

(4) Well-controlled clinical trials in humans that establish the safety and effectiveness of the drug product, for purposes of establishing bioavailability, or appropriately designed comparative clinical trials, for purposes of demonstrating bioequivalence. This approach is the least accurate, sensitive, and reproducible of the general approaches for determining bioavailability or bioequivalence. For dosage forms intended to deliver the active moiety to the bloodstream for systemic distribution, this approach may be considered acceptable only when analytical methods cannot be developed to permit use of one of the approaches outlined in paragraphs (b)(1)(i) and (b)(2) of this section, when the approaches described in paragraphs (b)(1)(ii), (b)(1)(iii), and (b)(3) of this section are not available. Ths approach may also be considered sufficiently accurate for determining the bioavailability or bioequivalence of dosage forms intended to deliver the active moiety locally, e.g., topical preparations for the skin, eye, and mucous membranes; oral dosage forms not intended to be absorbed, e.g., an antacid or radiopaque medium; and bronchodilators administered by inhalation if the onset and duration of pharmacological activity are defined.

(5) A currently available in vitro test acceptable to FDA (unusually a dissolution rate test) that ensures human in vivo bioavailability.

(6) Any other approach deemed adequate by FDA to establish bioavailability or bioequivalence.

(c) FDA may, notwithstanding prior requirements for establishing bioavailability or bioequivalence, require in vivo testing in humans of a product at any time if the agency has evidence that the product:

(1) May not produce therapeutic effects comparable to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably;

(2) May not be bioequivalent to a pharmaceutical equivalent or alternative with which it is intended to be used interchangeably; or

(3) Has greater than anticipated potential toxicity related to pharmacokinetic or other characteristics.

§ 320.30 Inquiries regarding bioavailability and bioequivalence requirements and review of protocols by the Food and Drug Administration.

(a) The Commissioner of Food and Drugs strongly recommends that, to avoid the conduct of an improper study and unnecessary human research, any person planning to conduct a bioavailability or bioequivalence study submit the proposed protocol for the study to FDA for review prior to the initiation of the study.

(b) FDA may review a proposed protocol for a bioavailability or bioequivalence study and will offer advice with respect to whether the following conditions are met:

(1) The design of the proposed bioavailability or bioequivalence study is appropriate.

(2) The reference material to be used in the bioavailability or bioequivalence study is appropriate.

(3) The proposed chemical and statistical analytical methods are adequate.

(c)(1) General inquiries relating to in vivo bioavailability requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Biopharmaceutics (HFD–420), 5600 Fishers Lane, Rockville, MD 20857.

(2) General inquiries relating to bioequivalence requirements and methodology shall be submitted to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Bioequivalence (HFD–650), 5600 Fishers Lane, Rockville, MD 20857.

§ 320.31 Applicability of requirements regarding an "Investigational New Drug Application."

(a) Any person planning to conduct an in vivo bioavailability or bioequivalence study in humans shall submit an "Investigational New Drug Application" (IND) if:

(1) The test product contains a new chemical entity as defined in § 314.108(a) of this chapter; or

(2) The study involves a radioactively labeled drug product; or

(3) The study involves a cytotoxic drug product.

(b) Any person planning to conduct a bioavailability study in humans using a drug product that contains an already approved, non-new chemical entity shall submit an IND if the study is one of the following:

(1) A single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(2) A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

(3) A multiple-dose study on a controlled release product on which no single-dose study has been completed.

(c) The provisions of part 312 of this chapter are applicable to any bioavailability or bioequivalence study conducted under an IND.

(d) [Reserved]

(e) [Reserved]

(f) An in vivo bioavailability or bioequivalence study in humans shall be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, and informed consent set forth in part 50 of this chapter, regardless of whether the study is conducted under an IND.

§ 320.32 [Redesignated as § 320.38]

47. Section 320.32 *Retention of bioavailability samples* is redesignated as § 320.38.

§ 320.50 [Removed]

48. Section 320.50 *Purpose* is removed.

§ 320.51 [Redesignated as § 320.32]

49. Section 320.51 is redesignated as § 320.32 in subpart B and is revised to read as follows:

§ 320.32 Procedures for establishing or amending a bioequivalence requirement.

(a) The Food and Drug Administration, on its own initiative or in response to a petition by an interested person, may propose and promulgate a regulation to establish a bioequivalence requirement for a product not subject to section 505(j) of the act if it finds there is well-documented evidence that specific

pharmaceutical equivalents or pharmaceutical alternatives intended to be used interchangeably for the same therapeutic effect:

(1) Are not bioequivalent drug products; or

(2) May not be bioequivalent drug products based on the criteria set forth in § 320.33; or

(3) May not be bioequivalent drug products because they are members of a class of drug products that have close structural similarity and similar physicochemical or pharmacokinetic properties to other drug products in the same class that FDA finds are not bioequivalent drug products.

(b) FDA shall include in a proposed rule to establish a bioequivalence requirement the evidence and criteria set forth in § 320.33 that are to be considered in determining whether to issue the proposal. If the rulemaking is proposed in response to a petition, FDA shall include in the proposal a summary and analysis of the relevant information that was submitted in the petition as well as other available information to support the establishment of a bioequivalence requirement.

(c) FDA, on its own initiative or in response to a petition by an interested person, may propose and promulgate an amendment to a bioequivalence requirement established under this subpart.

§ 320.52 [Redesignated as § 320.33]

50. Section 320.52 is redesignated as § 320.33 in subpart B, and the section heading and the introductory paragraph are revised to read as follows:

§ 320.33 Criteria and evidence to assess actual or potential bioequivalence problems.

The Commissioner of Food and Drugs shall consider the following factors, when supported by well-documented evidence, to identify specific pharmaceutical equivalents and pharmaceutical alternatives that are not or may not be bioequivalent drug products.

* * * * *

§ 320.53 [Removed]

51. Section 320.53 *Types of bioequivalence requirements* is removed.

§ 320.54 [Removed]

52. Section 320.54 *Contents of a petition to establish a bioequivalence requirement* is removed.

§§ 320.55 and 320.56 [Redesignated as §§ 320.34 and 320.35]

53. Section 320.55 *Requirements for batch testing and certification by the Food and Drug Administration* and § 320.56 *Requirements for in vitro testing of each batch* are redesignated as §§ 320.34 and 320.35 in subpart B, respectively.

§ 320.57 [Removed]

54. Section 320.57 *Requirements for the conduct of in vivo bioequivalence testing in humans* is removed.

§ 320.58 [Removed]

55. Section 320.58 *Requirements for marketing a drug product subject to a bioequivalence requirement* is removed.

§ 320.59 [Removed]

56. Section 320.59 *Bioequivalence requirements based on data voluntarily submitted* is removed.

§ 320.60 [Removed]

57. Section 320.60 *Bioequivalence requirements for a drug product subject to an old drug monograph* is removed.

§ 320.61 [Removed]

58. Section 320.61 *Requirements for in vivo testing of a drug product not meeting an in vitro bioequivalance standard is removed.*

§ 320.62 [Redesignated as § 320.36]

59. Section 320.62 *Requirements for maintenance of records of bioequivalence testing* is redesignated as § 320.36 in subpart B.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

60. The authority citation for 21 CFR part 433 continues to read as follows:

Authority: Secs. 502, 505, 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 355, 357).

§ 433.1 [Amended]

61. Section 433.1 *Exemption of antibiotic drugs for human use from batch certification requirements* is amended in paragraph (d)(2) by removing "§ 314.55" and replacing it with "§ 314.94".

Dated: July 17, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 92-9320 Filed 4-27-92; 8:45 am]

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Federal Register

Tuesday
April 28, 1992

Part III

Securities and Exchange Commission

17 CFR Parts 230 and 240

Penny Stock Transactions; Final Rules, Proposed Rule, and Notice

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34-30608]

RIN 3235-AE21

Penny Stock Disclosure Rules

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission is adopting seven rules ("Rules") under the Securities Exchange Act of 1934 ("Exchange Act") requiring broker-dealers engaging in transactions in low-priced, over-the-counter securities, often referred to as "penny stocks," with or for their customers to provide to those customers certain specified information. Unless one of various exemptions is available, the Rules require broker-dealers effecting customer transactions in penny stocks, as defined by the Rules, to provide the customers with: A risk disclosure document; disclosure of market quotations, if any; disclosure of the compensation of the broker-dealer and its salesperson in the transaction; and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotation and compensation information must be provided prior to effecting the transaction and must be contained on the customer's confirmation. These Rules are being adopted pursuant to the requirements of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Act").

EFFECTIVE DATE: Sections 240.3a51-1 and 240.15g-1 will be effective on April 28, 1992. The effective date for §§ 240.15g-2 and 240.15g-100 is July 15, 1992. The effective date for §§ 240.15g-3, 240.15g-4, 240.15g-5, and 240.15g-6 is January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Robert L. D. Colby, Chief Counsel; John M. Ramsay, Branch Chief (with respect to Rules 15g-5 and 15g-6); Belinda Blaine, Attorney (with respect to Rules 3a51-1 and 15g-1); or Alexander Dill, Attorney (with respect to Rule 15g-2 and Schedule 15G, Rule 15g-3, and Rule 15g-4); all at (202) 504-2418, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5-1, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

The Commission is adopting the Rules in order to implement certain provisions of the Penny Stock Act and section 15(g) [1] of the Exchange Act. Rules concerning these matters were proposed in Securities Exchange Act Release No. 29093 (April 17, 1991), 56 FR 19165 (the "Proposing Release"). The Commission has determined not to adopt at this time proposed Rule 15g-7, which would have required disclosure of the status of a broker-dealer as a sole market maker in connection with penny stock transactions. Specific provisions of each of the adopted Rules are summarized below.

[1] 15 U.S.C. 78o(g).

Rule 3a51-1—Definition of "Penny Stock"

Rule 3a51-1 implements the provisions of section 3(a)(51) of the Exchange Act by defining the term "penny stock" to exclude certain equity securities. In general, Rule 3a51-1 excludes from the definition of penny stock any security that is a "reported security," [2] except that a security that is registered on the American Stock Exchange, Inc. ("Amex") pursuant to the listing criteria of the Emerging Company Marketplace ("ECM") is considered to be a "penny stock" solely for purposes of section 15(b)(6) of the Exchange Act. Securities listed on the New York Stock Exchange, Inc. ("NYSE") and Amex (other than ECM securities), as well as securities that meet NYSE or Amex listing standards but that are listed only on the regional exchanges, are reported securities for purposes of the rule. In addition, securities quoted on the National Association of Securities Dealers, Inc.'s ("NASD") automated quotation system ("NASDAQ") that are designated as National Market System ("NMS") securities are reported securities pursuant to Rule 11Aa3-1 of the Exchange Act.

Paragraph (e) of Rule 3a51-1 also excludes from the definition of penny stock for most purposes any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available pursuant to Rule 11Aa3-1, provided that: (1) Current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange; and (2) the security is purchased or sold in a transaction on or through the facilities of a national securities exchange, or as part of a distribution of the security. The rule contains a similar provision excluding any security that is authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ. This exclusion is subject to the condition that current price and volume information with respect to transactions in that security must be reported and be made available to vendors pursuant to the rules of the NASD.

Rule 3a51-1 further defines the term "penny stock" to exclude securities that have a price of five dollars or more (including any share of any unit that has

[2] *I.e.*, securities for which last sale reports are collected and made available pursuant to an effective transaction reporting plan.

an independent exercise price), as determined either on a per transaction basis or, in the absence of a transaction, on the basis of the inside bid quotation for the security displayed on an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act or any other system that is designated by the Commission for purposes of the rule ("Qualifying Electronic Quotation System"). If there is no such inside bid quotation, price is determined by the average of three or more interdealer bid quotations at specified prices displayed in an interdealer quotation system, as defined in Rule 15c2–7(c)(1), by three or more market makers in the security.

Paragraph (g) of Rule 3a51–1 excludes from the definition of penny stock securities whose issuer has either (1) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years; or (2) average revenue of at least $6 million for the last three years.[3] The required level of net tangible assets or revenues must be demonstrated by current, audited financial statements that the broker-dealer has reviewed and has a reasonable basis for believing are accurate.

Finally, Rule 3a51–1 excludes from the definition of penny stock securities that are issued by an investment company registered under the Investment Company Act of 1940 and put and call options issued by the Options Clearing Corporation ("OCC").

Rule 15g–1—Exemptions

Rule 15g–1 exempts certain transactions from the broker-dealer disclosure requirements of Rules 15g–2 through 15g–6. First, Rule 15g–1 exempts transactions in penny stocks by broker-dealers that derive less than 5% of their revenues from sales of penny stocks during a specified period, unless they are acting as a market maker in the penny stock that is the subject of the transaction. Second, transactions in which the customer is an institutional accredited investor are exempt from Rules 15g–2 through 15g–6. Third, the rule exempts transactions that meet the requirements of Regulation D, or that are exempt from the registration requirements of the Securities Act of 1933 ("Securities Act") pursuant to section 4(2) of that Act. Fourth, transactions in which the customer is the issuer, or a director, officer, general partner, or direct or indirect beneficial owner of more than 5% of any class of equity security of the issuer, of the penny stock that is the subject of the transaction, are exempt from the Rules. Finally, the rule exempts transactions that are not recommended by the broker or dealer. Rule 15g–1 also contains a provision giving to the Commission the authority to exempt by order any other transactions or persons from the Rules, if such an exemption would be consistent with the public interest and the protection of investors.

Rule 15g–2—Risk Disclosure Document

Rule 15g–2 makes it unlawful for a broker-dealer to effect transactions in penny stocks without providing to the customer a standardized disclosure document as contained in Schedule 15G prior to such transactions. The first part of Schedule 15G is a one-page summary of the essential items required to be disclosed under section 15(g)(2). The remainder explains the required information in greater detail: The risks of investing in penny stocks in both public offerings and secondary trading; terms important to an understanding of the functioning of the penny stock market, such as "bid" and "offer" quotes, a dealer's "spread," and broker-dealer compensation; the broker-dealer's duties to its customers, including the disclosures required by the other penny stock disclosure rules, and the customer's rights and remedies in cases of fraud in penny stock transactions; and the NASD's toll-free number and the central number of the North American Securities Administrators Association ("NASAA") for information on the disciplinary history of broker-dealers and their associated persons.

Rule 15g–3—Bid-Offer Quotations

Rule 15g–3 makes it unlawful for a broker-dealer to effect a transaction in any penny stock without first disclosing and subsequently confirming to the customer current quotation prices or similar market information.

For transactions effected on a principal basis, the broker-dealer must provide the inside bid and offer quotations for a penny stock appearing on a Qualifying Electronic Quotation System. If this quotation information is unavailable, the rule requires that a broker-dealer effecting principal transactions in a penny stock must disclose its own bid and offer quotes in the stock to a customer if the broker-dealer has effected at least three *bona fide* interdealer transactions consistently at these bid or offer prices over the previous five business days, no less than 75% of these transactions have occurred consistently at such quotes, and the broker-dealer reasonably believes that such quotes accurately reflect the prices at which it is prepared to trade with other dealers. If the dealer cannot validate its own quotations in accordance with this procedure, the dealer must disclose that it has not traded consistently at its quotes, and it must disclose the price at which it last purchased the penny stock from, or sold the penny stock to, another dealer in a *bona fide* transaction.

In transactions effected on an agency or riskless principal basis, the broker-dealer must disclose the best interdealer bid and offer prices for the penny stock that the broker-dealer can obtain through reasonable diligence. For all transactions in penny stocks to which Rule 15g–3 applies, the broker-dealer must also disclose the number of shares for which the bid and offer prices are firm quotations.

Rule 15g–4—Broker-Dealer Compensation

Rule 15g–4 makes it unlawful for a broker-dealer to effect a penny stock transaction for a customer unless the broker-dealer discloses to the customer, both prior to effecting the transaction and at the time of confirming the transaction, the aggregate amount of any compensation received in connection with such transaction. "Compensation" is defined in the rule as: (1) in the case of an agency transaction, the amount of any remuneration received or to be received from a customer in connection with the transaction; (2) in the case of a "riskless principal" transaction, the difference between the price to the customer and the contemporaneous purchase or sale price to the broker-dealer; and (3) otherwise in the case of a principal transaction, the difference between the price to the customer and the prevailing market price in the security. This release contains a discussion of the criteria to be used for determining "prevailing market price."

In addition, Rule 15g–4 provides an alternative method of calculating compensation in principal transactions, permitting market makers to use an "active and competitive market" standard in calculating prevailing market price solely for purposes of Rule 15g–4, provided that the aggregate volume of transactions effected by the market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate amount of all transactions in the penny stock reported on a Qualifying Electronic Quotation System. However, this option would not be

[3] *I.e.*, total revenue of at least $18 million by the end of three years.

available to market makers until last sale reporting is included on such a quotation system.

Rule 15g–5—Associated Person Compensation

Rule 15g–5 makes it unlawful for a broker-dealer to effect a transaction in any penny stock for a customer unless the broker-dealer first discloses and subsequently confirms to the customer specified information with respect to any associated person, other than a person whose functions are solely clerical or ministerial, that has communicated with the customer concerning the transaction at or prior to the receipt by the broker-dealer of the customer's order. This information includes the aggregate amount of cash compensation that the associated person of the broker-dealer has received or will receive from any source in connection with the transaction and that is determined at or prior to the transaction, as well as separate disclosure of the source and amount of any compensation that is paid by persons other than the broker-dealer. In addition, if the associated person may receive contingent compensation that is not disclosed prior to the transaction because the amount of such compensation is not determined at or prior to the transaction, the written confirmation disclosure must describe the basis upon which such additional compensation is calculated.

Rule 15g–6—Monthly Account Statements

Rule 15g–6 requires a broker-dealer that has sold penny stocks to a customer in transactions that are not exempted by Rule 15g–1 to provide to that customer monthly account statements concerning these securities. The status of a security as a penny stock for purposes of this rule is determined on the last trading day of the month. The statement must be sent within ten days following the end of the month to which it pertains.

Each statement must disclose the identity and number of shares of each penny stock held in the customer's account and the estimated market value of the security, based on the highest inside bid quotation displayed on a Qualifying Electronic Quotation System or recent purchases by the broker-dealer, if available. The statement also must contain a standardized legend that provides certain disclosures relating to the estimated market value shown on the statement.

Rule 15g–6 exempts a security from the monthly account statement requirement following a particular quarter, if the security consistently (during all but five trading days) trades at a price of at least five dollars per share during the quarter. In addition, if the broker-dealer has not effected any penny stock transactions for the customer for six consecutive months, the rule permits account statements to be provided on a quarterly basis.

II. Introduction

The Penny Stock Act and the Rules are part of a comprehensive effort by the Congress and the Commission to reduce fraud and manipulation in the penny stock market and to provide investors with important information concerning that market. Although speculation in penny stocks, often fueled by fraudulent sales practices, has long existed in the United States, advances in communications technology have contributed to substantial growth in these activities in recent years. False representations and manipulative trading patterns, often by repeat offenders, have been facilitated by the absence of a visible market and a lack of investor information and education.[4]

In response to these developments, the Commission, along with other federal departments and agencies, the NASD, and state authorities have increased enforcement activities, promoted investor education, and adopted regulatory changes.[5] To date, the primary regulatory response by the Commission has been the adoption of Rule 15c2–6,[6] which became effective on January 1, 1990.[7] In general, that rule requires that a broker-dealer effecting transactions for customers in designated securities make a documented determination that the transactions are suitable for those customers and obtain the customers' written agreement to the transactions.

The Penny Stock Act contains provisions designed to target abuses in the penny stock market in a variety of ways, including, among others, the expansion of the Commission's enforcement authority with respect to persons associated with penny stock offerings, promoting the development of automated quotation systems for penny stocks, restrictions on "blank check" offerings, and broker-dealer disclosure requirements.[8] The disclosure provisions are contained in section 15(g) of the Exchange Act, which requires the Commission to adopt rules: (i) Governing the content and form of a risk disclosure document required to be provided by broker-dealers to their customers prior to effecting transactions in penny stocks with those customers; (ii) requiring broker-dealers to disclose, prior to each penny stock transaction and on the customer's confirmation, information concerning bid and ask prices and compensation to be paid to the broker-dealers and their associated persons; and (iii) requiring broker-dealers to provide to customers monthly statements showing the market value of penny stocks held in customer accounts. Section 15(g)(4) provides the Commission with authority to exempt classes of persons or transactions from these disclosure requirements or to adopt additional regulations not mandated by statute.

Pursuant to the Penny Stock Act, in the Proposing Release, the Commission proposed rules defining the term penny stock, covering each of the disclosure areas described above, and providing certain exemptions. In addition, the Commission proposed requiring disclosure of a broker-dealer's role as a sole market maker in a penny stock when effecting transactions in the security for customers.

The Commission solicited comment in the Proposing Release relating to a variety of matters, including the effectiveness of the proposed rules in deterring fraud in the penny stock market, the value of the information required to be furnished to investors, and the costs and operational difficulties that would be faced by broker-dealers subject to the rules. In addition, the Commission was particularly concerned with the potential effect of the proposed rules on the ability of legitimate small issuers to obtain capital needed for growth.

The Commission received 73 written comments relating to the proposed rules.[9] In addition, members of the Commission's staff spoke directly to various broker-dealers, lawyers, and other securities market participants with respect to compliance issues and the potential impact of the proposed rules on small business capital formation.[10]

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[4] *See* Proposing Release, 56 FR 19168–19169.

[5] *Id.* at 19169–70.

[6] 17 CFR 240.15c2–6.

[7] Securities Exchange Act Release No. 27160 (August 22, 1989), 54 FR 35468 ("Rule 15c2–6 Release").

[8] *See generally* House Comm. on Energy and Commerce, *Report to accompany the Penny Stock Reform Act of 1990*, H.R. Rep. No. 617, 101st Cong. 2d Sess. (July 23, 1990) (reporting H.R. 4497) (hereinafter, "House Report"). The Commission is also today adopting new rules, pursuant to the Penny Stock Act, applicable to blank check offerings.

[9] A detailed comment summary has been prepared by the staff and placed in the Commission's public files, together with all comment letters received. *See* File No. S7–8–91.

[10] Memoranda summarizing the staff's contacts with 15 broker-dealers are contained in File No. S7–8–91.

The overwhelming majority of comments voiced general support for the need to prevent fraud in the penny stock market and for the Commission's efforts in this regard. However, the comments were sharply divided over the scope of the proposed rules, in terms of the classes of securities and transactions that would be covered, the comprehensiveness of the information required to be disclosed, and the manner and frequency with which it would be provided. One group of comments, submitted primarily by state regulatory authorities and consumer groups, supported the proposed rules in this respect or suggested that proposed definitional exclusions or transactional exemptions, or other provisions, would unduly limit the effectiveness of the rules.[11]

A much larger group of comments claimed that the application of the proposed rules was too broad, or that they would pose unworkable compliance burdens on broker-dealer firms in one or more particular respects. The largest single objection raised by these comments was the inclusion of securities quoted on NASDAQ, other than NMS securities, within the penny stock definition. Many of these and other comments suggested that the proposed rules would significantly limit the ability of companies covered by the rules to raise capital in the securities markets and would negatively affect the existing market for the stock of these issuers, because of the compliance burdens caused by the rules, the unwillingness of broker-dealer firms to effect transactions in these securities, or the negative connotation of being classified as a penny stock.

The Rules adopted by the Commission today reflect its concern that the Rules not stifle the formation of capital for legitimate small companies or eliminate a viable secondary market for their securities. The Commission recognizes the important economic function served by small companies and recently has proposed to ease certain filing requirements and limitations applicable to limited offerings by small issuers and increase the percentage of investment company assets that may consist of illiquid assets, such as the securities of small issuers.[12]

Many of the new provisions incorporated in the Rules are intended to maintain the access of small ventures to capital markets where this may be accomplished consistent with the Commission's primary charter to protect investors. In considering this issue, the Commission also recognizes that fraudulent sales practices, which have occurred disproportionately in this market, may themselves hinder economic growth, because they cause the loss of the productive use of investor funds and discourage further investment by those who have been defrauded.[13] Legitimate small business is thus harmed by the diversion of substantial capital to unscrupulous promoters and broker-dealers. Moreover, issuers of penny stocks that are fraudulently traded may themselves be victimized by this activity.[14]

The Commission has also considered, in reviewing the Rules, certain recent developments, including increases in listing and maintenance standards applicable to NASDAQ securities[15] and the NASD's proposal, which has been approved,[16] to apply to non-NMS NASDAQ securities transaction reporting requirements similar to those already applicable to NMS securities.[17] The Commission believes that these developments significantly lessen the potential that NASDAQ securities will be subject to fraudulent sales practices.[18] In addition, the Commission has noted the experience of the NASD in operating its OTC Bulletin Board, which provides automated quotations by market makers in penny stocks ("Bulletin Board").[19] The Commission believes that the Bulletin Board may presage the evolution of a more transparent and reliable market for the shares of promising small companies that are not quoted on NASDAQ or traded on a national securities exchange.

After considering these factors and the comments it has received, the Commission is adopting the Rules with modifications to certain provisions contained in the proposed rules. These changes are intended to limit potential negative effects of the Rules on small business capital formation by (i) modifying the definitional and exemptive provisions in order to limit the application of the Rules to those securities and transactions involving the greatest potential for abuse and (ii) streamlining certain operational aspects of the Rules in order to simplify compliance responsibilities for broker-dealer firms. Among the changes reflected in the Rules are the following: (i) The effective exclusion from the application of the Rules of non-NMS NASDAQ securities at the point in time when last sale reporting requirements are in place for such securities; (ii) an exclusion from the penny stock definition for securities of issuers with specified net tangible assets or revenues; (iii) an exemption for private placement and Regulation D offerings; (iv) expanded availability of the exemption for broker-dealers doing a *de minimis* business in penny stocks; (v) various changes to individual Rules designed to ameliorate compliance burdens, including the use of quotations on the NASD's Bulletin Board, where available, to satisfy various pricing provisions of the Rules; and (vi) deferral of action on proposed Rule 15g–7, requiring disclosure of a firm's status as a sole market maker, which was not mandated by the Penny Stock Act. The Commission believes that these changes will implement the Congressional directive contained in the Penny Stock Act while maintaining the ability of viable small companies to obtain equity capital.

III. The Rules

A. Rule 3a51–1: Definition of Penny Stock

New section 3(a)(51)(A) of the Exchange Act defines the term "penny stock" as any equity security[20] other

[11] A comment supporting the proposed rules and opposing less stringent requirements also was submitted by the Hon. Edward J. Markey, Chairman of the Subcommittee on Telecommunications and Finance of the U.S. House of Representatives.

[12] Securities Act Release No. 6924 (March 11, 1992), 57 FR 9768; Securities Act Release No. 6926 (March 12, 1992), 57 FR 9825; Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828.

[13] *See* House Report 10–12; Proposing Release, n. 9. In a recent penny stock fraud case, a federal court expressed the point in these terms: "Defendants' contemptible conduct did more than harm their clients; their actions destroy investor confidence, pollute the environment for securities transactions, and bring disgrace and shame upon Wall Street." *SEC v. Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502, at 92,237, 92,239 (S.D.N.Y. 1992).

[14] Proposing Release, 56 FR 19169.

[15] Securities Exchange Act Release No. 29636 (August 30, 1991), 56 FR 44108.

[16] Securities Exchange Release No. 30569 (April 10, 1992).

[17] Securities Exchange Act Release No. 30392, (February 21, 1992), 57 FR 6880.

[18] *See* discussion at section III.A.2.a, *infra*.

[19] *See* discussion at section III.A.3.b below.

[20] The term "equity security" is defined in section 3(a)(11) of the Exchange Act (15 U.S.C. 78c(a)(11)) as:

Any stock or similar security; or any security convertible, with or without consideration, into such a security, or carrying any warrant or right to subscribe to or purchase such a security; or any such warrant or right; or any other security which the Commission shall deem to be of similar nature and consider necessary or appropriate, by such rules and regulations as it may prescribe in the public interest or for the protection of investors, to treat as an equity security.

Rule 3all–1 (17 CFR 240.3all–1) further defines "equity security" to include:

Any stock or similar security, certificate of interest or participation in any profit sharing agreement, preorganization certificate or

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than a security that is: (1) Registered, or approved for registration, and traded on a national securities exchange that meets criteria prescribed by the Commission; (2) authorized for quotation on an automated quotation system sponsored by a registered securities association, if such system was established and in operation before January 1, 1990, and meets criteria prescribed by the Commission; (3) issued by an investment company registered under the Investment Company Act of 1940; or (4) excluded or exempted, on the basis of exceeding a minimum price, net tangible assets of the issuer, or other relevant criteria, from the definition of the term "penny stock" by rule or regulation prescribed by the Commission. Section 3(a)(51)(A) determines the extent of the Commission's authority under section 15(b)(6)(A) of the Exchange Act to censure, suspend, bar, or restrict the activities of persons participating in an offering of penny stock. This section also defines the Commission's authority to adopt rules under section 15(g) of the Exchange Act imposing additional broker-dealer disclosure requirements or other obligations with respect to penny stocks and to prescribe rules under section 7(b) of the Securities Act governing registration statements of blank check companies. [21]

The Commission is adopting Rule 3a51–1 to implement the provisions of section 3(a)(51) of the Act. Rule 3a51–1 excludes from the definition of penny stock any equity security that is: (1) A "reported" security; (2) a put or call option issued by the OCC; (3) priced at five dollars or more, as determined (a) on a per transaction basis, or (b) on the basis of the inside bid quotation displayed on a Qualifying Electronic Quotation System, or if there is no such inside bid quotation, the average of at least three interdealer bid quotations displayed in an interdealer quotation system; (4) subject to last sale reporting and (a) registered, or approved for registration upon notice of issuance, on a national securities exchange and purchased or sold in a transaction executed on the exchange or in a distribution, or (b) authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ; or (5) whose issuer has (a) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years, or (b) average revenue of at least $6 million for the last three years. The most significant change from the proposed rule is the exclusion, subject to certain limitations, of regional exchange-listed and NASDAQ securities from the definition of penny stock. [22] As discussed further below, the rule contains several other modifications from the proposed rule that are designed to address the suggestions made in the comments.

1. Reported Securities

As adopted, Rule 3a51–1 excludes from the definition of penny stock any equity security that is a reported security—that is, any exchange-listed or NASDAQ security for which transaction reports are required to be made on a real-time basis pursuant to an effective transaction reporting plan. [23] The proposed rule also contained an exclusion for reported securities. In the Proposing Release, the Commission concluded that reported securities should be excluded from the penny stock rules because they are subject to rules of the self-regulatory organizations ("SROs") that set specific standards for inclusion, promote efficient pricing and transaction execution procedures, and generate public price information for evaluation by professional securities analysts and the financial press. [24]

The comments generally agreed with this conclusion, [25] and so Rule 3a51–1 continues to exclude reported securities from the definition of penny stock. Thus, securities listed on the NYSE, certain regional exchange-listed securities that meet NYSE or Amex original listing criteria, as well as NASDAQ NMS securities, are not considered penny stocks under paragraph (a) of the rule. [26]

As reported securities, securities that are listed on Amex pursuant to Amex's original and junior tier, or ECM, listing criteria [27] also are not considered penny stocks for purposes of the Rules. Securities listed on Amex as part of the ECM, however, continue to be deemed "penny stocks" solely for purposes of section 15(b)(6) of the Exchange Act. Although ECM securities are subject to real-time reporting requirements, they are not required to meet the same stringent listing and maintenance criteria as required for securities listed on Amex under the exchange's regular standards. In fact, the requirements for listing on the ECM are comparable to the current eligibility requirements for NASDAQ (non-NMS) securities. As discussed further below, securities that are quoted on NASDAQ are excluded from the definition of penny stock, except for purposes of Section 15(b)(6) of the Exchange Act.

The Commission believes that Amex's ECM securities should be treated in the same manner under the Rules as NASDAQ (non-NMS) securities. Excluding ECM securities from the definition of penny stock for all purposes would be unwarranted in view of the fact that the listing criteria for ECM and NASDAQ issuers are similar, and potentially could provide Amex's ECM with an unfair competitive advantage. The Commission therefore has determined to subject Amex's ECM securities to the same condition as is applicable to NASDAQ securities, discussed below, by including them in the definition of penny stock solely for purposes of Section 15(b)(6) of the Exchange Act.

2. Other NASDAQ and Exchange-Listed Securities

a. *Last sale reporting.* Although proposed Rule 3a51–1 excluded reported securities from the definition of penny stock, it did not exclude non-reported securities, such as securities that are quoted on NASDAQ but that are not designated as NMS securities. [28] The

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subscription, transferable share, voting trust certificate or certificate of deposit for an equity security, limited partnership interest, interest in a joint venture, or certificate of interest in a business trust; or any security convertible, with or without consideration into such a security, or carrying any warrent or right to subscribe to or purchase such a security; or any such warrant or right; or any put, call, straddle, or other option or privilege of buying such a security from or selling such a security to another without being bound to do so.

[21] *See* 15 U.S.C. 77g(b)(3) (defining "blank check company" as any development stage company that is issuing a penny stock, as defined in section 3(a)(51) of the Exchange Act, and that either has no specific business purpose or has indicated that its business plan is to merge with an unidentified company).

[22] Under the proposed rules, these securities were not excluded from the definition of penny stock, but instead were exempted from certain disclosure requirements pursuant to Rule 15g–1. Rule 15g–1, as adopted, is discussed in section III.B of this release.

[23] See the definition of "reported security" in 17 CFR 240.11Aa3–1(a)(4).

[24] See 56 FR 19172–19173.

[25] In Amex's view, "[b]y utilizing last sale reporting, a marketplace can generate the type of detailed surveillance runs which are best able to deter would-be wrongdoers or lead to their ready detection and ultimate prosecution."

[26] In general, as reported securities, securities admitted to unlisted trading privileges on an exchange also are excluded under this provision.

[27] The Commission recently approved Amex's proposal to create a new "Emerging Company Marketplace," or ECM, to enable certain companies traded in the over-the-counter ("OTC") market that are too small to meet Amex's regular listing criteria to register their securities on the exchange. Securities Exchange Act Release No. 30445 (March 5, 1992), 57 FR 8693.

[28] In lieu of excluding these securities from the definition, under Rule 15g–1, the Commission

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Commission reasoned that persons investing in these securities could benefit from the disclosure provided by the penny stock rules because, unlike reported securities, these securities are not traded in a market that is subject to a comprehensive regulatory scheme requiring real-time transaction reporting, nor are they required to meet the same minimum qualification and maintenance criteria.[29] The Commission requested comment on whether the definition of penny stock nevertheless should be narrowed in order to avoid unnecessarily inhibiting small business capital formation.

As discussed above, the majority of the comments on the proposed rules objected to the inclusion of securities quoted on NASDAQ in the definition of penny stock.[30] These comments argued that the rules of the NASD, particularly the increased listing and maintenance standards for issuers of NASDAQ securities and the requirement that market makers in NASDAQ securities display firm bid and ask quotations, provide an adequate substitute for the protections afforded by the penny stock rules. Many of these comments also stated that there was insufficient evidence of fraud in the NASDAQ market to include NASDAQ securities in the scope of the Rules; in any case, they believed that the NASD's surveillance capabilities were sufficient to address any existing fraud in that market.

The Commission approved a NASD proposal to increase the listing and maintenance standards for NASDAQ securities in August of 1991.[31] These new standards ensure that securities that are quoted on NASDAQ represent companies that have generated significant shareholder interest and that have a demonstrated financial history and minimum pricing levels. In addition, the Commission today approved the NASD's proposal to amend Schedule D to the NASD By-laws to implement last sale price and volume reporting requirements for NASDAQ securities.[32] Under this rule proposal, NASD members will be required to report to the NASD the execution price and the number of shares of each trade within 90 seconds after execution. This information will then be validated by the NASD and be made available to information vendors for dissemination to the investment community and the public. In the NASD's view, the "resulting dissemination of real-time trade and volume data during market hours will significantly benefit investors by providing the same high degree of market visibility and more efficient price discovery for all * * * NASDAQ issues that currently exists for NMS and major exchange listed securities." Moreover, rather than relying on end-of-the-day statistics as the primary source of surveillance information for trades in NASDAQ securities, the NASD will have access to trading data through its equity audit trail, which currently integrates last sale, clearing, and inside quotation data for reported securities. The NASD's ability to detect and deter manipulative or abusive trading practices in the NASDAQ market thereby will be significantly enhanced.

The NASD also has filed a rule proposal to require all NASDAQ market makers to display minimum quotation sizes of five hundred shares.[33] If approved by the Commission, this rule change will provide investors with further information about the liquidity and depth of the market for NASDAQ securities. As the NASD stated in its comment letter, all of these rule changes will increase the transparency and liquidity of the market for NASDAQ securities, thus reducing the need for the additional disclosure provided by the penny stock rules.

In light of these comments and the NASD's rule changes, the Commission has amended Rule 3a51–1 to exclude from the definition of penny stock any security that is authorized, or approved for authorization upon notice of issuance,[34] for quotation on NASDAQ, provided that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the NASD.[35] In the Proposing Release, the Commission emphasized that many of the abuses occurring in the penny stock market are a direct result of the lack of publicly available information about the market in general and about the price and trading volume of particular penny stocks. The Commission believes that the NASD's proposal to implement last sale reporting for NASDAQ securities will increase the transparency of the market for NASDAQ securities. This rule change, combined with the NASD's increased listing criteria for NASDAQ issuers and its surveillance of the NASDAQ market, will provide sufficient protection to investors to substitute for the disclosure provided by the penny stock rules. Therefore, when the NASD implements last sale reporting pursuant to the terms of its proposal, all NASDAQ securities will be excluded from the definition of penny stock under paragraph (f) of Rule 3a51–1.[36]

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proposed to exempt transactions in NASDAQ and exchange-listed securities from the requirements of Rules 15g–2, 15g–3, and 15g–6.

[29] *See* Proposing Release, 56 FR 19173, n. 58, and accompanying text.

[30] *E.g.*, NASD. A small number of comments, primarily submitted by state regulatory authorities and consumer groups, believed that the definition should cover all non-reported securities. See discussion, *infra*.

[31] Securities Exchange Act Release No. 29638 (August 30, 1991), 56 FR 44106. For instance, the initial listing requirements for issuers were increased from $2 million in total assets and $1 million in capital and surplus, to $4 million in total assets and $2 million in capital and surplus. The rule change also added a minimum initial price requirement of $3.00 per share and increased the number of market makers required for continued quotation in the system from one to two.

[32] Securities Exchange Act Release No. 30569 (April 10, 1992); and Securities Exchange Act Release No. 30392 (February 21, 1992), 57 FR 6880. Anticipating this rule change, six comments specifically suggested that, in lieu of applying the penny stock rules to non-reported securities, the Commission should address any perceived problems in the NASDAQ OTC market by extending real-time transaction reporting requirements to NASDAQ securities.

[33] Securities Exchange Act Release No. 29859 (October 25, 1991), 56 FR 56258.

[34] One comment suggested that securities underwritten on a best efforts basis should be considered "approved for authorization upon notice of issuance" on NASDAQ, even when NASD approval is contingent upon the amount of proceeds raised by the offering. Schedule D to the NASD's By-laws, however, provides that a new issue offered on a best efforts basis will be considered for inclusion under NASD rules only upon the closing of the offering if the issuer is relying on the proceeds of that offering to satisfy the NASDAQ financial authorization criteria. Accordingly, under Rule 3a51–1(f), securities underwritten on a best efforts or contingency basis will not be considered to be "approved for authorization upon notice of issuance" in the NASDAQ system if NASD approval is contingent in whole or in part upon the amount of proceeds raised by the offering.

In contrast, under the rules of the NASD, a new issue offered on a firm commitment basis will be considered for inclusion in the NASDAQ system when the registration statement is declared effective by the Commission or other appropriate regulatory authority. Therefore, if prior contingent approval has been received from the NASD, securities that are offered on a firm commitment basis will be considered to be "approved for authorization upon notice of issuance" in the NASDAQ system under Rule 3a51–1 at the time the registration statement becomes effective, provided that the NASDAQ financial authorization criteria are satisfied at that time. See NASD Schedules to the By-Laws, Schedule D, pt. II section 1, *NASD Manual* (CCH) ¶ 1803 (1990).

This position is consistent with the Commission staff's interpretation of the analogous provisions of Rule 15c2–6. See *Rechargeable Battery Corporation*, [1990–1991] Fed. Sec. L. Rep. (CCH) ¶ 79,638, at 77,893 (May 7, 1990).

[35] This provision, together with the provision excluding exchange-listed securities, discussed below, replaces the exclusion in proposed Rule 3a51–1 for securities that are registered and traded on a national securities exchange or quoted on an automated quotation system that has the authority to delist the securities of an issuer with less than $2 million in net tangible assets or stockholders' equity.

[36] As discussed above, NASDAQ NMS securities are excluded pursuant to paragraph (a) of the rule.

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For similar reasons, Rule 3a51–1 as adopted provides an exclusion in paragraph (e) for any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange, [37] provided that current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange.[38] Securities that are listed on the regional exchanges also are subject to general reporting requirements under the rules of those exchanges. Investors therefore have a greater ability to evaluate and to monitor the market price of listed securities without having to rely exclusively on the representations of their broker-dealer. In addition, issuers of these securities are required to meet minimum qualification and maintenance standards for listing on the exchange. The Commission believes that these requirements, together with comprehensive exchange surveillance, also make the protections provided by the penny stock rules less necessary for securities listed and traded on the regional exchanges.[39]

The exclusion in paragraph (e) of Rule 3a51–1 is limited to exchange-listed securities that actually are purchased or sold through the facilities of the exchange or in a distribution. This restriction is intended to address Congress' concern that securities that would otherwise be considered penny stocks because they are primarily traded in the non-NASDAQ OTC market nevertheless may be able to avoid the requirements of the Rules by becoming listed on an exchange.[40] By limiting the exclusion in paragraph (e) to specific transactions, the rule ensures that the information required under the Rules will be provided to customers in transactions executed by dealers as principal away from the exchange market, where the dealers' quotations generally are not made public and electronic surveillance is less effective.[41]

b. *Section 15(b)(6).* Paragraphs (e) and (f) of Rule 3a51–1 generally remove exchange-listed and NASDAQ securities from the definition of penny stock for purposes of section 15(g) of the Exchange Act and section 7(b) of the Securities Act and the rules promulgated thereunder. These securities nevertheless continue to be deemed penny stocks for purposes of section 15(b)(6) of the Exchange Act.[42]

Section 15(b)(6) gives the Commission the authority to prohibit any person that has engaged in unlawful conduct while participating in a distribution of penny stock, as defined in Rule 3a51–1, from associating with a broker-dealer or participating in a distribution of penny stock, if the Commission finds that such a restriction would be in the public interest. Under this section, broker-dealers also are prohibited from allowing such persons to participate in a distribution of penny stock without the Commission's consent. According to the House Report, subparagraph (6)(A) was added to section 15(b) to enable the Commission to prohibit persons from participating in penny stock activities through remote affiliations with issuers and broker-dealers and to give the Commission broader prescriptive authority to address patterns of recidivism in the penny stock market.[43]

In the Proposing Release, the Commission solicited comment on whether the exclusions from the definition of penny stock would provide particular opportunities for persons with a disciplinary history to become involved, as promoters or other associated persons of an issuer or broker-dealer, in offerings of penny stock. In response, several state securities regulators, NASAA, and the Consumer Federation of America ("CFA") argued that regional exchange-listed and NASDAQ securities should be included in the definition of penny stock in part to prevent persons with an established record of fraudulent activity in the low-priced securities market from associating with issuers of those securities and their broker-dealers.[44]

Although the Commission recognizes that last sale reporting and SRO supervision will address many of the problems that the penny stock disclosure rules are designed to remedy, the Commission believes that the markets for low-priced securities listed or quoted on the regional exchanges, Amex's ECM, and NASDAQ would be strengthened by protecting them from

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Securities that are quoted on the NASD's Bulletin Board, however, are not excluded from the definition of penny stock.

[37] This exclusion is conditioned on the national securities exchange making transaction reports available for at least some securities pursuant to Rule 11Aa3–1. Exchanges that currently qualify for this exclusion are the NYSE, Amex, the Boston Stock Exchange, the Cincinnati Stock Exchange, the Midwest Stock Exchange, the Pacific Stock Exchange, the Philadelphia Stock Exchange, and the Chicago Board Options Exchange, which was authorized to provide transaction reports for equity securities other than options in Securities Exchange Act Release No. 28808 (January 22, 1991), 56 FR 3124. *Cf.* n. 34, *supra.*

[38] These exchange-listed securities do not need to be reported pursuant to the Restated Consolidated Tape Association Plan to satisfy the requirements of this provision.

[39] In addition, because put and call options issued by the OCC are already subject to special disclosure requirements, they are separately excluded from the definition of penny stock in paragraph (c) of Rule 3a51–1. See, *e.g.*, 17 CFR 240.9b–1; CBOE Rules, Rules 9.1–9.23, *CBOE Guide* (CCH) ¶¶ 2301–23; and NASD Rules of Fair Practice, appendix E, *NASD Manual* (CCH) ¶ 2184.

Trans Canada Options Inc. ("TCO") argued that, like OCC options, Canadian put and call options issued by TCO should be excluded from the coverage of Rule 3a51–1. According to TCO, these securities generally have not been the subject of fraudulent activities because they are traded in markets that are subject to comprehensive regulation, and because they are subject to the same risk disclosure scheme as options issued by the OCC. The Commission believes that most foreign securities, such as options issued by TCO, that are traded in markets other than NASDAQ or a national securities exchange will be exempt from the coverage of the Rules based on the five dollar price or the net tangible assets/revenue exclusion in Rule 3a51–1. The Commission, however, has specifically retained exemptive authority under paragraph (f) of Rule 15g–1 for foreign securities that do not qualify for these exemptions but that are otherwise subject to alternative, comprehensive disclosure schemes. See discussion, *infra.*

[40] The House Report stated that:

[t]he Committee is aware that certain securities that should properly be categorized as penny stocks may be able to gain registration on regional exchanges. Once registered on an exchange, most of the trading activity in these securities may be directed to the non-NASDAQ over-the-counter market, where a lack of trading or quotation information, higher spreads and markups, and other factors may operate to the disadvantage of public investors. Similarly, the fact that a security is authorized for quotation on NASDAQ would not preclude a market maker in the security from effecting transactions in the security without entering quotations in NASDAQ. Therefore, if exchange registration or NASDAQ authorization provided a complete exemption from the penny stock definition, investors effecting transactions in these securities with dealers in the non-NASDAQ over-the-counter market could be disadvantaged.

House Report at 27.

[41] Similarly, the exclusion in paragraph (f) for NASDAQ securities is conditioned on the NASD implementing last sale reporting for NASDAQ securities. As discussed above, under the NASD's last sale reporting proposal, transactions in NASDAQ securities generally will be required to be reported to the NASD on a real-time basis, regardless of the market in which they are effected.

[42] In addition, although securities listed on Amex pursuant to Amex's junior tier, or ECM, listing criteria are not considered penny stocks for purposes of the Rules and section 7(b) of the Securities Act, they are deemed penny stocks solely for purposes of section 15(b)(6) of the Exchange Act. See discussion of Rule 3a51–1(a), *supra.*

[43] House Report at 28.

[44] The Securities Division of the State of Delaware, for instance, commented that the definition of penny stock should be broad because "[s]elling securities at greatly inflated prices is such a lucrative operation that the individuals behind these firms are not likely to abandon their unscrupulous practices merely because of regulatory efforts aimed at the non-NASDAQ OTC market. Rather, it is more likely that they will seek to infiltrate the low end of the NASDAQ market and to continue to engage in market manipulation and excessive price mark-ups, albeit in a more selective and less transparent manner."

persons with a history of penny stock abuse.[45]

The Commission therefore has retained the authority under section 15(b)(6)(A) of the Exchange Act to restrict such persons from becoming involved in those markets by excluding regional exchange-listed, ECM, and NASDAQ securities only from the requirements of section 15(g) of the Exchange Act and section 7(b) of the Securities Act. Specifically, paragraphs (e)(2) and (f) of Rule 3a51–1 provide that exchange-listed and NASDAQ securities that are not otherwise excluded from the definition of penny stock are considered to be penny stocks solely for purposes of section 15(b)(6) of the Exchange Act. As discussed above, under paragraph (a) of Rule 3a51–1, securities that are registered on Amex pursuant to its ECM listing criteria also are included in the definition of penny stock for purposes of section 15(b)(6).

3. Price of the Security

a. *Transactions.* As adopted, Rule 3a51–1(d) excludes from the definition of penny stock securities that are priced at five dollars or more. In most cases, the price of a security for purposes of the rule will be the price at which it is purchased or sold in a particular transaction, excluding the amount of any broker-dealer commission, commission equivalent, mark-up, or mark-down.

The proposed rule contained a similar exclusion for securities priced at five dollars. The comments were sharply divided on whether the five dollar price threshold was appropriate. Several comments supported the five dollar price threshold on the ground that lower-priced securities are more susceptible to manipulation. In contrast, other comments argued that the five dollar price was arbitrary, and suggested alternative prices, ranging from one cent to three dollars, which they believed would more accurately reflect the common understanding of the term "penny stock." The Regional Investment Brokers, Inc. recommended that the price threshold be entirely eliminated because, by itself, it does not provide an accurate indication of the quality of a company.[46]

The Commission has determined to retain a five dollar price threshold in Rule 3a51–1 for several reasons. First, as noted in the Proposing Release, securities priced above five dollars are less frequently the vehicle for manipulation and high pressure sales campaigns because the percentage price spreads at that level are much lower. In contrast, securities selling for under five dollars are often used in manipulative schemes due to the potential for immediate profits from large percentage spreads.[47] A broker-dealer, for instance, can sell a large volume of securities priced below three dollars by representing to unwary customers that small absolute price increases constitute large returns in relation to the purchase price.[48] The higher the price of the security, however, the harder it is for a broker-dealer to maintain large percentage spreads or to tout a security based on small price increases; that is, it becomes more difficult to sell a large volume of securities solely for the purpose of generating rapid profits.[49] Thus, the Commission has included a five dollar price threshold in the rule because it believes that manipulation and sales practice abuses are less likely to occur at that level. The five dollar threshold, however, is not intended to provide any indication of the inherent worth of a company.[50]

Second, the five dollar price threshold is consistent with the Uniform Limited Offering Registration ("ULOR") project developed by the State Regulation of Securities Committee of the American Bar Association and NASAA to provide a short-form registration procedure for small business offerings priced above five dollars.[51] The price threshold also is consistent with a number of other existing price standards.[52]

Finally, the minimum price threshold serves an important function by mitigating the impact of the penny stock rules on legitimate small business capital formation. The Commission's experience with a similar threshold in Rule 15c2–6, confirmed by discussions with a number of broker-dealers, indicates that the price threshold will allow small issuers to respond to the Rules by setting the initial offering price for their securities at five dollars or more, or by engaging in reverse stock splits to raise the price of their existing shares. Although a higher price structure reduces the number of shares of smaller issuers available for trading in the secondary market, it appears that, at a five dollar price level, this reduction does not substantially impede the liquidity of the market for those securities. Moreover, as discussed further below, the list of exempt transactions under Rule 15g–1 has been expanded to provide relief for legitimate small issuers attempting to raise capital. Accordingly, many small issuers will be able to avoid the requirements of the Penny Stock Act by relying on a transactional exemption from the disclosure rules.[53]

For the foregoing reasons, subparagraph (d)(1)(i) of the adopted rule excludes securities that are purchased or sold in a transaction at a price of five dollars or more. In order to prevent broker-dealers from charging excessive mark-ups to inflate the price of a penny stock above five dollars, the rule has been amended to provide that, in both agency and principal transactions, the price of a security is the price exclusive of the broker-dealer's remuneration.[54]

[45] See, *e.g.*, *SEC* v. *Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502 (S.D.N.Y. 1992) (abusive sales practices involving NASDAQ securities); and cases cited in the Proposing Release at 56 FR 19173, n. 64.

[46] In this connection, a few comments expressed concern that the Rules will apply to all issuers whose securities are priced below five dollars, even issuers that have substantial assets. The Commission notes that the securities of issuers with substantial assets will be excluded from the Rules by virtue of paragraph (g), discussed below.

[47] Proposing Release, 56 FR 19174. In fact, in a dominated and controlled market, the per share profit to the broker-dealer may be much higher than the spread. See Rule 15c2–6 Release, 54 FR at 35469, n.14.

[48] The broker-dealer, however, typically will not explain that a large spread will undermine the investor's ability to later resell the security at a profit. See Rule 15c2–6 Release, 54 FR 35470.

[49] See Rule 15c2–6 Release, 54 FR 35469, 35475; and House Report at 12.

[50] See, generally, Proposing Release, 56 FR 19174.

[51] Specifically, ULOR (also known as Small Company Offering Registration, or SCOR) provides a streamlined state registration procedure for small businesses raising less than $1 million in offerings that are exempt from registration under Rule 504 of Regulation D [17 CFR 230.504]. In order to prevent abuses in the secondary market in securities issued pursuant to ULOR, as a general rule, issuers may only apply for ULOR registration if the offering price of their common stock, or the exercise or conversion price of any warrants, options, rights, or convertible securities included in the offering, is at least five dollars. See Rule 15c2–6 Release, 54 FR 35475; NASAA Reports (CCH) ¶ 5057, at 5198 (instructions to SCOR form); and Emshwiller, SCOR Funding Provides Short Form for Going Public, Wall St. J., Jan. 21, 1992, at B.2. See also Securities Act Release No. 6924 (March 11, 1992), 57 FR 9768.

[52] See, *e.g.*, 17 CFR 240.15c2–6; 12 CFR 220.17(a)(2) (five dollars per share requirement for inclusion on the list of OTC margin stocks); NASD Schedules to the By-Laws, Schedule D, pt. III, section 2, NASD Manual (CCH) ¶ 1809 (five dollars per share requirement for designation as a NMS security); Washington Administrative Code section 460–17A–030(2)(d), Blue Sky Law Reporter (CCH) ¶ 61,585C (five dollars per share requirement for offerings pursuant to ULOR); and Securities Exchange Act Release No. 30354 (February 18, 1992), 57 FR 5920 (five dollar offering price requirement for registration of "U–7," or ULOR, securities on the Pacific Stock Exchange, Inc.).

[53] In addition, some small issuers may be able to rely on the exclusion for reported securities under paragraph (a) of Rule 3a51–1, or the new exclusion under paragraph (g) for securities issued by issuers that meet certain financial criteria. See the discussion of Amex's ECM, *supra*.

[54] The proposed rule would have differentiated between agency and principal transactions in

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b. *Bid quotations.* As indicated above, the price of a security typically will be determined by the price at which it is purchased or sold in a particular transaction. In the absence of a transaction,[55] however, Rule 3a51–1(d)(1)(ii) provides that the five dollar price may be based on the inside bid quotation for the security displayed on a Qualifying Electronic Quotation System (*i.e.*, an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act or any other system that is designated by the Commission for purposes of the rule).[56] The term "inside bid quotation" is defined in the rule as the highest bid quotation for the security displayed by a market maker in the security on such Qualifying Electronic Quotation System, provided that at the same time there are at least two market makers contemporaneously displaying in such system bid and offer quotations for the security.

Where there is no such inside bid quotation, subparagraph (d)(1)(ii) of Rule 3a51–1 provides that the average of at least three interdealer bid quotations at specified prices displayed in an interdealer quotation system [57] by three or more market makers in the security must be five dollars or more. The rule requires that the price be based on at least three bid quotations because quotations for low-priced securities that are traded in the non-NASDAQ OTC market, such as the pink sheets, frequently are the subject of negotiation and may not accurately reflect the prevailing market price.

The rule does not require a broker-dealer to conduct an independent investigation into whether the inside bid quotation or the three bid quotations upon which it is relying for purposes of the rule are *bona fide*. A broker-dealer, however, may not rely on quotations if it knows, or if it has reason to know, that those quotations have been entered into the interdealer quotation system by broker-dealers for the purpose of circumventing the requirements of the rule.[58]

As proposed, Rule 3a51–1 did not include a provision allowing broker-dealers to calculate the five dollar price based on the inside bid quotation displayed on a Qualifying Electronic Quotation System. This provision was added in response to the NASD's comment that the average price provision would be difficult for broker-dealers to comply with and for the Commission and the SROs to enforce. The Commission believes that permitting broker-dealers to determine the price of a security based on the inside bid quotation displayed on an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the Exchange Act will facilitate compliance with the rule because, as discussed below, such information is readily available to broker-dealers.

Currently, no automated quotation system satisfies all of the requirements of section 17B(b)(2).[59] The Commission anticipates, however, that the Bulletin Board operated by the NASD may substantially meet those requirements by the effective date of the penny stock disclosure rules.[60] The NASD has made several enhancements to the Bulletin Board since it was first approved in May of 1990.[61] Specifically, NASD rules now require that quotations for domestic securities entered into the system by registered market makers must be firm for one unit of trading.[62] The NASD also calculates and distributes an inside quotation for each domestic security quoted in the Bulletin Board for which there are at least two registered market makers displaying firm two-sided quotations. Other changes have been made to the Bulletin Board to make the system more responsive to the operational needs of NASD member firms.[63] All of these changes are consistent with section 17B of the Exchange Act and, assuming that the Bulletin Board meets the requirements of section 17B(b)(2) by the effective date of the penny stock disclosure rules,[64] will facilitate broker-dealer compliance with Rule 3a51–1(d)(1)(ii) by providing readily available quotations upon which to calculate the five dollar price.

Finally, the NASD and the Securities Traders Association suggested that Rule 3a51–1(d) should be modified to account for price fluctuations occurring as a result of temporary market or economic conditions. Rather than complicate the five dollar price calculation in the definitional provision of Rule 3a51–1(d)(1)(ii) by taking into account temporary price fluctuations, the Commission has amended Rule 15g–6 to exempt from the monthly account statement requirement securities that are consistently priced above five

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determining the five dollar price. Specifically, under the proposed rule, the price of a security in an agency transaction or a contemporaneous offsetting purchase and sale principal transaction was the price exclusive of any broker-dealer commission, commission equivalent, mark-up, or mark-down. The price in all other principal transactions, however, was the price inclusive of the broker-dealer's mark-up or mark-down. The rule has been amended in response to the suggestion in several comments that the price should be calculated by excluding the broker-dealer's remuneration in all transactions. The State of Florida, for example, stated that "[e]xperience tells us that lower tiered stocks can be inflated by compensation above the five dollar threshold without much difficulty."

The Commission does not believe that this will create compliance problems because, under Rule 15g–4 (which requires disclosure of mark-ups and mark-downs for transactions in penny stocks), firms must establish procedures to quantify mark-ups and mark-downs in trades that potentially are subject to the Rules. See discussion at section III.E, *infra*.

[55] For instance, promoters, consultants, or other associated persons of a broker-dealer or issuer that have been barred pursuant to section 15(b)(6) of the Exchange Act from participating in penny stock transactions may rely on subparagraph (d)(1)(ii) to determine whether a particular security would be deemed to be a penny stock for purposes of section 15(b)(6). See also discussion of Rule 15g–6, *infra*.

[56] Section 17B(b) of the Exchange Act [15 U.S.C. 78q–2(b)] directs the Commission to facilitate the wide-spread dissemination of reliable and accurate last sale and quotation information with respect to penny stocks, with a view toward establishing one or more automated quotation systems to collect and disseminate information regarding penny stocks. See discussion, *infra*.

[57] "Interdealer quotation system" is defined in 17 CFR 240.15c2–7(c)(1) as "any system of general circulation to brokers and dealers which regularly disseminates quotations of identified brokers or dealers but shall not include a quotation sheet prepared and distributed by a broker or dealer in the regular course of his business and containing only quotations of such broker or dealer." This definition includes the Bulletin Board and other published quotation media of general circulation, such as the National Daily Quotation Service (the "pink sheets").

[58] NASD rules specifically prohibit NASD members from publishing any notice quoting a bid or offer price for a security, unless the member believes that such quotation represents a *bona fide* bid or offer. NASD Rules of Fair Practice, Art. III, § 5, NASD Manual (CCH) ¶ 2155. For further discussion of *bona fide* and independent quotations, see section III.G, *infra*.

[59] Although the NASD's system for quotation of NASDAQ NMS securities meets the requirements of section 17B, it is not an "automated quotation system for penny stocks" because NASDAQ NMS securities are not "penny stocks" under Rule 3a51–1.

[60] As discussed in section II above, the Bulletin Board is an automated system operated by the NASD that collects and displays quotation information for non-NASDAQ securities.

[61] Securities Exchange Act Release No. 27975 (May 1, 1990), 55 FR 19124.

[62] Securities Exchange Act Release No. 29261 (May 31, 1991), 56 FR 29297.

[63] See Securities Exchange Act Release No. 29713 (September 30, 1991), 56 FR 49500.

[64] If the Bulletin Board does not meet the requirements of section 17B(b)(2) by that date, the Commission will consider designating it or another system as a Qualifying Electronic Quotation System for purposes of compliance with the Rules.

In determining whether a particular system should be designated as a Qualifying Electronic Quotation System, the Commission will consider whether the system: (i) Is operated by or under the auspices of a SRO, or subject to comparable Commission review and oversight; (ii) collects and disseminates quotation and volume information; (iii) has effective surveillance capabilities and procedures; and (iv) makes widely available, on an electronic basis, bid and offer quotations of participating broker-dealers (or comparably accurate and reliable pricing information), including firm bid or offer quotations for at least such minimum number of shares or dollar amounts as the Commission and the SRO may require.

dollars during any quarterly period.[65] Amending subparagraph (d)(1)(ii) of Rule 3a51–1 to account for price fluctuations could create investor confusion as to whether a security is a penny stock at a given point in time and would be difficult for broker-dealers, the Commission, and the SROs to monitor.

c. *Unit pricing.* Paragraph (d)(2) of Rule 3a51–1 further provides that, in the case of a unit composed of different securities, the price divided by the number of shares of the unit that are not warrants, options, rights, or similar securities, must be five dollars or more, as determined in accordance with paragraph (d)(1) of the rule, and the exercise price of any warrant, option, or right, as well as the conversion price of any convertible security, included in the unit must be five dollars or more.[66] Merrill Lynch, Pierce, Fenner & Smith Inc. and the Securities Industry Association ("SIA") suggested that this provision should be eliminated from the rule because it could create confusion, especially when one of the securities in a unit is a "blue chip" stock, or when a derivative security that is a penny stock is convertible into a non-penny stock. The Commission notes, however, that these securities usually would be excluded under paragraphs (e), (f), or (g) of Rule 3a51–1.[67] In addition, the Commission believes that a customer who is buying separately traded securities (such as warrants) in the non-NASDAQ OTC market that are priced below five dollars and issued by a company with less than $2 million in net tangible assets or $6 million in three-year average revenues would benefit from the disclosure provided by the Rules.

4. *Issuer financial standards.* Finally, a new paragraph (g) has been added to Rule 3a51–1, which excludes any security issued by an issuer that has (1) net tangible assets in excess of $2 million, if that issuer has been in continuous operation for at least three years, or $5 million, if the issuer has been in continuous operation for less than three years, or (2) average revenue of at least $6 million for the last three years. As proposed, Rule 15g–1 contained a similar transactional exemption based on issuer net tangible assets.[68] The Proposing Release particularly solicited comment on whether the higher $5 million net tangible assets standard should apply to all issuers, regardless of their number of years in business.

The comments were divided on whether a two-tier standard for issuer net tangible assets was appropriate. While several comments responded that a single $2 million standard would be sufficient, NASAA and the State of Virginia indicated that the standard should either be eliminated, or raised to $5 million for all issuers. Four comments stated that Rule 15g–1 should not include any transactional exemption based on net tangible assets because such a standard is vague and easy to circumvent. In particular, one commenter believed that a net tangible assets standard would be unfair to certain industries (or companies within an industry) because accounting measurements may be evaluated differently depending on whether the industry of the issuer is oriented towards manufacturing or services. Several other comments, on the other hand, argued that the transactional exemption based on issuer net tangible assets should be replaced with a similar exclusion from the definition of penny stock so that securities that are issued by companies with substantial assets will not be considered "penny stocks."

In response to these comments, the Commission has amended Rule 3a51–1 to add an exclusion for securities issued by an issuer with either $2 million or $5 million in net tangible assets, depending on whether the issuer has been in operation for three years or less. Including a definitional exclusion based on issuer net tangible assets, rather than a transactional exemption, will simplify the Rules and be more consistent with Rule 15c2–6.[69] In addition, to address the comment that the standard is vague, the term "net tangible assets" is defined in the rule as total assets minus intangible assets and total liabilities. For purposes of the rule, intangible assets include, among other assets, goodwill, patents, licenses, and trademarks.[70] The rule continues to impose a separate higher standard for start-up companies in order to prevent the types of abusive activities described in the Proposing Release that have occurred both prior to and since the adoption of Rule 15c2–6 in August of 1989.[71]

Rule 3a51–1, however, also includes a new alternative revenue standard. Specifically, paragraph (g)(2) of the rule excludes any transaction in a penny stock issued by an issuer that has average revenues of $6 million for the prior three years. In other words, to satisfy the requirements of this provision, an issuer must have had total revenues of $18 million or more by the end of the three-year period.[72] The Commission believes that providing an alternative exclusion based on issuer revenue will ensure that the rule does not discriminate among issuers by industry, and will provide another basis upon which the securities of small issuers may be excluded from the application of the penny stock rules. The three-year revenue standard was selected over other standards,[73] because

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[65] Because Rule 15g–6 is the only penny stock disclosure rule that is not specifically linked to transactions, it is the only rule that uses the calculation in subparagraph (d)(1)(ii) of Rule 3a51–1. In other words, to ascertain whether a monthly account statement would be required for a particular stock based on its price, a broker-dealer would need to determine whether the security has a price of five dollars or more under subparagraph (d)(1)(ii). To determine whether that same security would be subject to the requirements of Rules 15g–2 through 15g–5, however, the broker-dealer would look at the price at which the security was purchased or sold in a transaction; *i.e.*, the broker-dealer would calculate the price of the security pursuant to subparagraph (d)(1)(i) of Rule 3a51–1.

For further discussion of the amendments to Rule 15g–6, *see* discussion at section III.C, *infra*.

[66] For example, a unit composed of five shares of common stock and five warrants would satisfy the requirements of this paragraph only if the unit price was twenty-five dollars or more, and the warrant exercise price was five dollars or more. Once the components of the unit begin trading separately on the secondary market, they must each be separately priced at five dollars or more. See Proposing Release, 56 FR 19174, n. 72, and the NASD's Special Notice to Members No. 90–18, part B, Questions #17 and 18 (March 19, 1990).

[67] In most cases, a warrant or an option on a non-penny stock would be excluded from the definition of penny stock pursuant to the exclusion for securities whose issuers have a minimum level of net tangible assets or average revenue. See discussion of Rule 3a51–1(g), *infra*.

[68] Specifically, proposed Rule 15g–1(b) included an exemption for transactions in penny stocks issued by an issuer that has been in continuous operation for three or more years and has net tangible assets of at least $2 million, or that has been in continuous operation for less than three years and has net tangible assets of $5 million.

[69] As discussed further below, this modification also will expand the *de minimis* revenue exemption under Rule 15g–1(a).

[70] Categories in the issuer's financial statements that may include intangible assets, such as "Other Assets," also must be subtracted unless the broker-dealer determines that they consist only of tangible assets. The definition of intangible assets is discussed in further detail in Accounting Principles Board Opinion No. 17 (August, 1970).

[71] See 56 FR 19176. In addition, a two-tier standard has been adopted in several other contexts involving issuer qualification standards. *See, e.g.*, NASD Schedules to the By-Laws, Schedule D, pt. III, section 2, NASD Manual (CCH), ¶ 1809; and Amex Rules, part 10, section 1003, *Amex Guide* (CCH), ¶ 10,377.

[72] The exclusion therefore only applies to operating companies with a demonstrated three-year history of revenues.

[73] For example, Paulson Investment Company, Inc. suggested that the net tangible assets standard should be replaced with a standard that would require issuers to have had $2 million in cash investment in equity securities in the past five years. The Commission has not adopted this suggestion because cash investments cannot be easily ascertained from an issuer's financial statements. A paid-in capital standard also was rejected because it can be changed merely by increasing the par value of the issuer's shares.

it not only provides an indication of the financial history of a small company, but also because it can be readily derived from an issuer's income statement.

The $6 million revenue level was chosen because the Commission believes that, as a general rule, companies historically subject to penny stock manipulations and sales practice abuses have not achieved this level of revenue.[74] Like the exclusion based on issuer net tangible assets, however, this exclusion is not designed to give investors an indication of the investment merits of an issuer. Rather, it is intended only to exclude companies whose financial condition makes them less likely to be vehicles for abusive market activities even though their securities are traded outside of a transparent market at prices below five dollars.

The rule further provides that, for domestic issuers, the required level of net tangible assets or revenues must be demonstrated by financial statements that are dated less than fifteen months prior to the date of the related transaction and that have been audited and reported on by an independent accountant in accordance with Regulation S–X.[75] For foreign private issuers, the rule requires that net tangible assets or revenues be reflected in financial statements that are dated less than fifteen months prior to the date of the related transaction, and that have been filed with or furnished to the Commission pursuant to Rule 12g3–2(b).[76] If the foreign private issuer has not been required to file or furnish financial statements during the previous fifteen months, however, the financial statements may be prepared and audited in compliance with generally accepted accounting principles of the country of incorporation and reported on by an accountant registered and in good standing in accordance with the regulations of that jurisdiction. To demonstrate compliance with the rule, broker-dealers are required to keep copies of the domestic or foreign issuer's financial statements for at least three years following the date of the related transaction, the first two of which must be in an easily accessible place.[77]

In all cases, the broker-dealer must review the financial statements and have a reasonable basis for believing that they were accurate as of their date and that the issuer's financial condition has not substantially weakened by the date of the related transaction. A few comments argued that this requirement would impose a higher standard of review on broker-dealers than is required for auditors who report on the issuer's financial statements. These comments suggested that the Commission should rephrase the language of the rule to require that broker-dealers have "no reason to believe the statements are not accurate."

The Commission has not adopted this suggestion because, as noted in the Proposing Release, the existing standard does not require the type of "due diligence" investigation typically required of an underwriter or an auditor.[78] Rather, the rule requires broker-dealers to obtain audited financial statements from a reliable source, such as the issuer or the Commission, and to review those statements to ascertain whether the amount of the issuer's net tangible assets or revenues are in compliance with the rule. Ordinarily, if the issuer's audited balance sheet shows net tangible assets equaling either $2 million or $5 million (depending on the number of years the issuer has been in operation), or if its audited income statement shows average revenues of at least $6 million for the past three years, the broker-dealer will be entitled to rely on those statements to establish an exclusion under the rule.[79] Therefore, in most cases, the broker-dealer need not inquire about or independently verify any of the information contained in the issuer's financial statements. Only if materially inconsistent or inaccurate information appears on the face of the financial statements, or if the broker-dealer becomes aware, in the course of its review, of material inconsistencies between the statements and information in the broker-dealer's possession, would the broker-dealer need to satisfy itself that the information contained in the financial statements is accurate and complete.[80] The way in which a broker-dealer may satisfy itself as to the accuracy of an issuer's financial statements under the rule will vary according to the circumstances.[81] The Commission emphasizes, however, that under no circumstances would the rule require the type of "due diligence" investigation typically conducted by an underwriter.

B. Rule 15g–1: Exempt Transactions

In the Proposing Release, the Commission recognized that the rules proposed pursuant to section 15(g) of the Exchange Act potentially could affect legitimate small business capital formation. The Commission therefore proposed Rule 15g–1, which exempted certain transactions from the disclosure requirements of Rules 15g–2 through 15g–6. As originally proposed, the rule was organized in two parts: paragraph (a) exempted certain transactions from Rules 15g–2 through 15g–6, while paragraph (b) exempted transactions in securities listed on a national securities exchange or quoted on NASDAQ from Rules 15g–2, 15g–3, and 15g–6. Because exchange-listed and NASDAQ securities are now excluded from the definition of penny stock under Rule 3a51–1, paragraph (b) has been deleted from the final rule. In addition, as discussed below, the list of transactions that are exempt from Rules 15g–2 through 15g–6

[74] *See, e.g., SEC* v. *Hasho*, [Current] Fed. Sec. L. Rep. (CCH) ¶ 96,502 (S.D.N.Y. 1992); *SEC* v. *Phoenix Aviation, Inc.*, Litigation Release No. 12483 (May 22, 1990); and *SEC* v. *San Marino Securities, Inc.*, Litigation Release No. 12660 (Oct. 9, 1990).

This standard is higher than the minimum income requirement for quotation on NASDAQ. Unlike the NASDAQ market, however, the non-NASDAQ OTC market lacks last sale reporting and the accompanying automated SRO surveillance systems. In view of the lower transparency of this market, the Commission believes that the protections of the Rules should apply to the securities of somewhat larger issuers than those satisfying the minimum requirements for quotation on NASDAQ.

[75] 17 CFR 210.2–02.

[76] 17 CFR 240.12g3–2(b). Securities Exchange Act Release No. 28889 (February 22, 1991), 56 FR 7424, provides a list of foreign issuers that have submitted the information required by Rule 12g3–2(b) to date.

[77] See 17 CFR 240.17a–4(b).

[78] 56 FR 19176. Moreover, Rule 15c2–6, which contains a similar standard, has not been interpreted to require such an extensive review. See Rule 15c2–6 Release, 54 FR 35475, n. 45.

[79] Once a broker-dealer has reviewed the issuer's most recent audited financial statements and determined that the issuer qualifies for this exemption, the issuer will continue to qualify until the earlier of the following: (i) Fifteen months after the date as of which those financial statements reflect the issuer's financial condition; (ii) when the issuer produces more recent audited financial statements; or (iii) when the broker-dealer ceases to have a reasonable basis for believing that the financial statements reflect the current financial condition of the issuer.

[80] Rule 15c2–11 (17 CFR 240.15c2–11), which governs the submission and publication of quotations by broker-dealers for non-NASDAQ OTC securities, contains a similar standard. For further discussion of what constitutes a "reasonable basis for believing" that information is accurate, see Securities Exchange Act Release No. 29094 (April 25, 1991), 56 FR 19148, adopting amendments to Rule 15c2–11. This release discusses the types of "red flags" that generally should call into question information that has been provided to a broker dealer.

[81] For example, the broker-dealer may deem it appropriate to directly consult with the issuer or its accountant. The broker-dealer, however, may not rely on information from any outside source, such as the issuer, to establish an exclusion under the rule if the issuer's audited financial statements indicate that the issuer does not have the required amount of net tangible assets or average revenue at the date of the financial statements.

has been expanded to include certain transactions identified by the comments as being less in need of the protections provided by the penny stock disclosure rules.

1. Limited Broker-Dealer Activity in Penny Stocks

Section 15(g)(4) of the Exchange Act, which gives the Commission the authority to exempt any person or transactions from the rules adopted pursuant to section 15(g), requires the Commission to include an exemption for brokers-dealers that derive only an insignificant percentage of their total revenue from transactions in penny stocks. Accordingly, paragraph (a) of Rule 15g–1 exempts from Rules 15g–2 through 15g–6 transactions in penny stocks by broker-dealers that derive less than 5% of their total revenue from purchases and sales of penny stocks, except when they are acting as a market maker in the penny stock that is the subject of the transaction.

As adopted, the *de minimis* exemption differs from the proposed exemption in two significant respects. The 5% revenue calculation under the proposed rule was based on transactions in penny stocks, as defined in proposed Rule 3a51–1. A few comments pointed out that this would require broker-dealers to include in their 5% calculation transactions in low-priced securities that are issued by well-capitalized domestic and foreign issuers.[82] As a result, they indicated that the exemption would be too limited to be of much use to broker-dealers, even those broker-dealers that typically are not in the business of effecting transactions in penny stocks. In lieu of a transactional exemption, these comments recommended that the definition of penny stock include an exception based on the net tangible assets of the issuer.

As discussed above, to address the concerns expressed in these comment letters and to simplify the Rules, the Commission has amended the definition of penny stock in Rule 3a51–1 to exclude any security issued by an issuer that meets the financial standards set forth in paragraph (g) of that rule. Transactions in those securities therefore are not required to be included in the 5% revenue calculation for purposes of Rule 15g–1(a).[83] In addition, the rule has been revised to give broker-dealers the option of calculating their revenue over a six month period, rather than on a monthly basis.[84]

A few comments objected to the provision in Rule 15g–1(a)(2) that would preclude market makers from relying on the exemption because they believed that it would create a strong disincentive for securities firms to make markets in lower-priced securities.[85] The Commission, however, has determined to retain this provision because it believes that market making constitutes a level of involvement in the penny stock market inconsistent with the use of a *de minimis* exemption. The rationale for the *de minimis* exemption is that there is less risk of abuse from firms whose business is not concentrated on the penny stock market because they have less incentive or opportunity to manipulate the price of a penny stock. Conversely, much of the abuse in the penny stock market has involved market makers, because their ability to control the prices of the securities in which they make a market gives them the opportunity to generate large profits.[86] The Commission thus believes that it is appropriate to limit the *de minimis* exemption to firms that are not acting as market makers in penny stocks. This limitation is supported by fairness considerations; allowing larger firms to use the *de minimis* exemption while making markets in penny stocks potentially could provide them with an unfair competitive advantage over their smaller counterparts.[87] Therefore, regardless of their percentage of revenue from penny stock transactions, market makers in a penny stock are not exempt under Rule 15g–1 with respect to transactions in that particular penny stock.[88]

The Commission recognizes that broker-dealers relying on the *de minimis* exemption will need a period of time after the effective date of the Rules to modify their data retrieval systems in order to determine whether their revenue from penny stock transactions exceeds the 5% level.[89] The rule therefore includes a note indicating that broker-dealers may calculate their 5% revenue based on "designated securities," as defined in Rule 15c2–6(d)(2) (as of April 15, 1992), rather than "penny stocks," as defined in Rule 3a51–1, for a period of twelve months following the publication of this release in the **Federal Register**.

2. Institutional Accredited Investors

Proposed Rule 15g–1 provided an exemption for transactions with institutional accredited investors, as defined in Regulation D of the Securities Act.[90] No comments stated any

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[82] This is because, while transactions in such securities would have been exempt from the disclosure requirements of the rules, the securities would not have been excluded from the definition of penny stock in Rule 3a51–1.

[83] Two comments also recommended that the *de minimis* revenue exemption be expanded to reflect all revenues received by a broker-dealer. Conversely, one comment suggested that the exemption should be limited to commissions from agency trades. The Commission believes that the rule appropriately focuses on total sales-related revenue because it better identifies broker-dealers that have less incentive to engage in manipulative penny stock sales conduct. Thus, the rule as adopted applies to commissions, commission equivalents, mark-ups, and mark-downs.

Further, two other comments recommended exempting (or excluding) transactions effected by a broker-dealer acting as a dealer-manager or a financial advisor for an exchange offer, recapitalization, or restructuring. The Commission believes that most broker-dealers engaging in these activities may be exempt from the penny stock rules under the amended *de minimis* exemption. In this connection, the Commission emphasizes that advisory fees that are not contingent on the total volume of shares sold are not required to be included in the 5% revenue calculation for purposes of the rule.

[84] Specifically, subparagraph (a)(1) of the rule exempts transactions by a broker-dealer whose commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, *or* during the immediately preceding six months, did not exceed 5% of its total commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months.

[85] The CFA, on the other hand, strongly supported this provision.

[86] For further discussion of price manipulation by market makers in thinly traded markets, see Proposing Release, 56 FR 19175; Rule 15c2–6 Release, 54 FR 35477; and House Report at 11–12.

[87] For this reason, two comments opposed the *de minimis* revenue exemption in principle.

[88] For the reasons discussed above, however, broker-dealers will now be able to act as market makers in securities whose issuers meet the financial standards set forth in Rule 3a51–1(g), without jeopardizing their ability to rely on the *de minimis* exemption.

[89] In particular, broker-dealers may need to modify their systems to take into account the fact that the *de minimis* exemption under Rule 15g–1 is different from the analogous exemption under Rule 15c2–6 because it is based on transactions in "penny stocks," as defined in Rule 3a51–1, rather than transactions in "designated securities," as defined in subparagraph (d)(2) of Rule 15c2–6. Specifically, the exemption under Rule 15g–1 is broader than the exemption under Rule 15c2–6 in that it allows broker-dealers to exclude from their 5% calculation securities priced below five dollars. In addition, unlike Rule 15c2–6, which permits broker-dealers to exclude transactions in securities if the issuer has $2 million in net tangible assets, Rule 15g–1 only allows broker-dealers to exclude those transactions if the issuer has been in business for at least three years. Rule 15g–1, however, allows broker-dealers to exclude transactions based on average revenues of the issuer. Finally, because the penny stock disclosure rules apply to both purchases and sales of penny stocks, the *de minimis* revenue exemption under Rule 15g–1 includes mark-downs in the 5% calculation.

[90] 17 CFR 230.501(a)(1), (2), (3), (7), or (8). Under these provisions, an "accredited investor" is defined as:

Any bank as defined in section 3(a)(2) of the [Securities] Act, or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Act whether acting in its individual

Continued

objection to this provision. Therefore, for the reasons stated in the Proposing Release, the Commission has determined to include the exemption in paragraph (c) of the adopted rule.[91]

3. Private Offerings

Although proposed Rule 15g–1 included an exemption for transactions with institutional accredited investors, it did not provide a similar exemption for individual accredited investors.[92] The Proposing Release specifically requested comment on whether transactions with individual accredited investors also should be exempt from the penny stock disclosure rules. In response, several comments argued that there are insufficient grounds for distinguishing between institutional and individual accredited investors, especially in light of the fact that the two types of investors are treated in the same manner under Regulation D of the Securities Act. They therefore suggested exempting all accredited investors from the Rules.

The Commission has determined not to provide a general exemption for transactions with individual investors based solely on their net worth or income. Unlike institutional investors, which generally do not purchase penny stocks, individual accredited investors are frequently the target of high pressure sales efforts involving speculative equity securities. Given the lack of publicly available information about the price and trading volume of particular penny stocks and the penny stock market in general, these investors often have few means of independently evaluating the market for the stock in question or the financial interest of the broker-dealer in the transaction. In the absence of this information, many individual investors of considerable financial means have been convinced through abusive sales practices to purchase penny stocks without sufficiently understanding the nature of the market. The penny stock disclosure rules are designed to give individual investors the information they need to make an independent and informed evaluation of a broker-dealer's recommendation to invest in low-priced securities that are not traded in a visible public market.[93]

The Commission recognizes, however, that many of the sales practice abuses that occur in the secondary market for penny stocks do not occur in initial private offerings. In general, private offerings are limited to a small number of investors who are familiar with the broker-dealer involved in the transaction and who have access to information about the issuer of the securities.[94] In addition, securities that are sold in private placements are subject to certain restrictions on resale.[95] As a result, the market for these securities is limited and the securities typically are not used as vehicles for the types of market manipulation and broad scale sales efforts characteristic of fraudulent penny stock activities.

Accordingly, the list of transactions that are exempt under Rule 15g–1 has been expanded to include an exemption for transactions that meet the requirements of Regulation D under the Securities Act,[96] as well as transactions by an issuer not involving any public offering pursuant to section 4(2) of the Securities Act.[97] Assuming that the requirements of either of those provisions have been met, this exemption applies even if the particular customer involved is not an accredited investor.

4. Insider Transactions

Under proposed Rule 15g–1, transactions by issuers repurchasing or redeeming their own securities were exempt on the basis that corporations have sufficient access to information about the market for their own securities to deal with broker-dealers without the additional disclosure provided by the Rules. Several comments suggested that, in addition to the issuer of the penny stock, officers, directors, and controlling shareholders of the issuer should be exempt from the Rules because, as insiders, they also have sufficient knowledge about the issuer to be aware of the risks of their investment. As one broker-dealer stated, "insiders would have a * * * better knowledge of the intrinsic value of the security than any market-maker, and should not require the protection of this rule." [98] The Commission agrees with these comments and therefore has expanded the issuer exemption in Rule 15g–1 to also exempt from Rules 15g–2 through 15g–6 transactions in which the customer is a director, officer, general partner, or direct or indirect beneficial owner of more than 5% of any class of equity security,[99] of the issuer of the penny stock that is the subject of the transaction.

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or fiduciary capacity; any broker or dealer registered pursuant to section 15 of the Securities Exchange Act of 1934; any insurance company as defined in section 2(13) of the Act; any investment company registered under the Investment Company Act of 1940 or a business development company as defined in section 2(a)(48) of that Act; any Small Business Investment Company licensed by the U.S. Small Business Administration under section 301(c) or (d) of the Small Business Investment Act of 1958; any plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of $5,000,000; any employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 if the investment decision is made by a plan fiduciary, as defined in section 3(21) of such Act, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of $5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors;

Any private business development company as defined in section 202(a)(22) of the Investment Advisers Act of 1940;

Any organization described in section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000;

Any trust, with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in 230.506(b)(2)(ii); and

Any entity in which all of the equity owners are accredited investors.

For further discussion of the definition of accredited investor, see Securities Act Release No. 6825 (March 20, 1989), 54 FR 11369.

[91] See 56 FR 19177.

[92] The term "individual accredited investor" is defined in 17 CFR 230.501(a)(4), (5), and (6) as:

Any director, executive officer, or general partner of the issuer of the securities being offered or sold, or any director, executive officer, or general partner of a general partner of that issuer;

Any natural person whose individual net worth, or joint net worth with that person's spouse, at the time of his purchase exceeds $1,000,000; or

Any natural person who had an individual income in excess of $200,000 in each of the two most recent years or joint income with that person's spouse in excess of $300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year.

[93] See Proposing Release, 56 FR 19177, n. 101. As the State of Missouri pointed out in its comment letter, "[t]he information reported on a weekly basis in a few major newspapers is not sufficient disclosure for the average investor in penny stocks in this state, who is often a first-time investor, almost always unsophisticated * * *." Rules 15g–2 through 15g–6 are specifically designed to redress this information imbalance by requiring broker-dealers to disclose information regarding the risks involved in investing in the penny stock market, quotations and other relevant market information, including monthly account statements, and the amount of compensation received by the broker-dealer and any associated persons of the broker-dealer in connection with the penny stock transaction. See discussion at sections III.C–G, *infra*.

[94] *See SEC* v. *Ralston Purina Co.*, 346 U.S. 119 (1953) (in determining whether a distribution was a private offering exempt under section 4(2) of the Securities Act, the Supreme Court focused on the offerees' need for the protections of the Securities Act—namely, whether they were able to "fend for themselves" and had access to the same kind of information that usually is disclosed through registration).

[95] See, *e.g.*, 17 CFR 230.502(d).

[96] 17 CFR 230.501 through 230.508.

[97] 15 U.S.C. 77d(2).

[98] Herzog, Heine, Geduld, Inc.

[99] The 5% figure is derived from Rule 13d–1(a) [17 CFR 240.13d-1(a)] of the Exchange Act.

5. Non-Recommended Transactions

Proposed Rule 15g–1 contained an exemption for transactions in penny stocks that are not recommended by a broker-dealer. All of the comments that addressed this provision supported the concept of an exemption for non-recommended transactions. Several comments, however, requested that the Commission clarify the scope of the exemption by distinguishing between retail broker-dealers who actively recommend stocks to individual investors and wholesale market makers who maintain lists of the types or specifications of stocks in which certain active investors have expressed an interest. These comments argued that the activities of wholesale broker-dealers should be considered "non-recommended" because the customers of those broker-dealers make their own investment decisions once they are alerted to the existence of a stock that meets their specifications.[100] Two commenters believed that the exemption would be clearer if it applied to non-solicited, rather than non-recommended, transactions.

The Commission has determined to retain the exemption for non-recommended transactions in paragraph (e) of Rule 15g–1. To be consistent with Rule 15c2–6, the exemption continues to apply to "non-recommended" rather than "non-solicited" trades.[101] Accordingly, the exemption is limited to situations in which a broker-dealer acts as an order taker for the customer, with little or no incentive to engage in manipulative sales tactics. The rule does not exempt situations in which a broker-dealer brings a penny stock to the attention of an investor because, in most cases, this action is intended, and is understood by the customer, as an implicit recommendation to buy the penny stock. Moreover, as a practical matter, the Commission believes that it would be difficult to determine whether a broker-dealer "brought a penny stock to the attention of a customer," or whether it actively promoted the merits of that penny stock. In any case, wholesale market makers who maintain lists of stocks that they bring to the attention of institutional investors generally will be able to rely on the exemption for transactions with institutional accredited investors under paragraph (b) of Rule 15g–1.[102]

6. Exemptive Authority

Finally, as in the proposed rule, Rule 15g–1 includes a provision giving the Commission the authority to exempt by order any transaction or persons or class of persons from Rules 15g–2 through 15g–6 if it determines that an exemption would be consistent with the public interest and the protection of investors. The Commission believes that this provision will give it the necessary flexibility to exempt transactions and persons that are subject to alternative disclosure requirements that are comparable to the requirements of the Penny Stock Act.[103]

C. Rule 15g–2: Penny Stock Risk Disclosure Document

Section 15(g)(2) of the Exchange Act requires a broker-dealer to provide to each of its customers, prior to effecting any transaction in any penny stock, a document that discloses the risks of investing in the penny stock market. The statute enumerates the following specific items that broker-dealers must include in the disclosure document: (i) A description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading; (ii) a description of the broker-dealer's duties to the customer and of the customer's rights and remedies; (iii) a brief, clear, narrative description of a dealer market, including 'bid' and 'ask' prices for penny stocks and the significance of the spread between the bid and ask prices; (iv) the NASD's toll-free telephone number for inquiries on disciplinary actions; and (v) definitions of significant terms.[104] The statute grants the Commission specific rulemaking authority with respect to the language and the type size and format to be used in the risk disclosure document.[105] In enacting section 15(g)(2), Congress recognized that basic information about the nature of the penny stock market, its depth and liquidity, and the risks of investing, is largely unavailable to many investors.[106]

1. Description of the Rule

Pursuant to this statutory authority, the Commission is adopting Rule 15g–2. The rule makes it unlawful for a broker-dealer to effect a transaction in a penny stock with or for the account of a customer unless the broker-dealer distributes to the customer, prior to effecting a transaction in a penny stock,[107] a two-part document, as set forth in Schedule 15G.

The first part of the risk disclosure document, entitled "Important Information on Penny Stocks" (the "Summary Document"), summarizes on a single page the items required to be disclosed pursuant to section 15(g)(2). The preamble urges investors to read the risk disclosure document before purchasing a penny stock. The first section of the Summary Document, entitled "Penny stocks can be very risky," briefly defines "penny stock" and identifies certain risks of investing in penny stocks. The second section, entitled "Information you should know," describes the penny stock market and

[100] In Mayer & Schweitzer, Inc.'s view, "[t]he trader does not recommend such security to the customer. The trader is merely telling the customer that such stock is available and asks whether the customer has any interest in such security."

[101] The Commission's interpretation of the "non-recommended" transaction exemption under Rule 15c2–6 therefore applies to the exemption in paragraph (e) of Rule 15g–1. Under this interpretation, neither exemption would apply to situations in which a broker-dealer recommends a penny stock by sending promotional literature directly to a particular investor. For further discussion of what constitutes a "recommended" transaction, see Rule 15c2–6 Release, 54 FR 35477.

[102] In addition, two comments suggested that the exemption should be expanded to include sales or other transactions that primarily are effected to avoid customer losses, such as "liquidating transactions." The Commission has not adopted this suggestion because it believes that in most cases it would be difficult to determine whether a transaction was effected solely to avoid customer losses—especially when one penny stock is sold in exchange for another penny stock. Moreover, the information provided by the penny stock rules, particularly Rule 15g–3 (disclosure of quotation information), will assist investors in determining whether to sell a penny stock to avoid a loss.

[103] The Commission also has the authority under section 15(g)(4) of the Exchange Act to exempt any person or transaction from the disclosure requirements by rule or regulation.

[104] 15 U.S.C. 78*o*(g)(2).

[105] See 15 U.S.C. 78*o*(g)(2)(F).

[106] Section 15(g)(2) reflects the Congressional finding that broker-dealers in the penny stock market have sold stock to investors with little sophistication or understanding of that market. See Proposing Release, 56 FR 19180.

[107] As noted in the Proposing Release, in practice, the broker-dealer probably would send the disclosure document to a potential customer through the mail after preliminary telephone contact; however, the document also could be provided to a potential investor in the course of a meeting, before the investor agrees to the penny stock trade. In any event, a broker-dealer would be obligated to ensure that each customer has received the document before effecting the first transaction in a penny stock with the customer. "Effecting" in this context means agreement, oral or otherwise, to the terms of the transaction.

In response to one comment requesting clarification whether the risk disclosure document must be provided prior to effecting every transaction in a penny stock, the Commission notes that, by its terms, the Penny Stock Act only requires provision of the document to the customer prior to a broker-dealer's effecting *any* transaction in a penny stock. Thus, once the customer has received the document prior to the first transaction, in any subsequent transaction by the broker-dealer with that customer, the broker-dealer will be in compliance with the rule. However, broker-dealers are encouraged to provide a new copy of the risk disclosure document to the customer prior to effecting another transaction if a substantial amount of time has elapsed since the previous transaction.

terminology important to an understanding of that market. The final section, entitled "Brokers' duties and customers' rights and remedies," informs customers who have questions or who have been defrauded that they may have rights or remedies under federal and state law, and provides a toll-free telephone number of the NASD and the central number of NASAA for information on the background and disciplinary history of the firms and salespersons with whom they are dealing, and the Commission's complaint number.

The remainder of Schedule 15G (the "Explanatory Document") supplements and explains in greater detail the information provided in the Summary Document. The Explanatory Document begins with a section entitled "Further Information," [108] which provides a non-technical definition of "penny stock," and gives several warnings to investors concerning the penny stock market, including warnings against making a hurried investment decision, that salespersons are not impartial advisers, that investors should compare information from the salesperson with other information on the penny stock, and that salespersons may not legally state that a stock will increase in value or guarantee against loss. This section also discusses "shell" corporations, the high risks of initial public offerings, the speculative nature of penny stocks and the potential for significant losses, and suggests contacting the NASD and NASAA to obtain information on salespersons and broker-dealers and reading the prospectus in a public offering before making an investment. Investors are further informed that they do not have to transfer their stock if their salesperson leaves the firm and that they have the right to physical possession of their stock certificates.

The next section of the Explanatory Document, entitled "Your Rights," informs investors about their rights and the broker-dealer's duties under the new penny stock rules, including the particular disclosures that must be made to them under each rule, and of the timing requirements for such disclosures. The section also informs customers generally of their rights under section 29(b) of the Exchange Act, as amended by the Penny Stock Act, which may allow a rescission of the purchase contract for broker-dealer transactions in violation, *inter alia*, of the disclosure rules under section 15(g) of the Exchange Act. Customers also are informed of the availability of private litigation if they believe they have been defrauded or their rights otherwise violated, and the use of arbitration procedures, if they are subject to an arbitration agreement, and that they can report their grievances to regulatory authorities, including the Commission, the NASD, and their state securities administrator.

The final section of the Explanatory Document, entitled "Market Information," provides an overview of important aspects of the market for low-priced securities. The first two paragraphs provide a general description of the non-NASDAQ market and an explanation of important concepts associated with that market, such as the role of brokers, dealers, and market makers, and the ability of firms in the penny stock market to dominate the market in a penny stock and to control its prices. The next three paragraphs provide a detailed explanation of the relationship between mark-ups, mark-downs, the dealer's spread, and broker-dealer compensation, and discuss the reason why the bid price of a low-priced stock purchased by a customer generally must rise substantially before the customer may profitably resell that stock. The final two paragraphs explain the initial public offering, warn investors of the especially high risk in such a market, and provide the Commission's address for investors who want additional information concerning penny stocks.

Schedule 15G contains instructions for production of the document by the broker-dealer. The instructions set forth the criteria for type size and typeface, so that the document will be uniform among broker-dealers, and so that the type will be sufficiently large to be legible to the average reader. [109]

Schedule 15G may be reproduced by photographic copying, so long as the copy is clear, complete, and meets the minimum type size requirements set forth for a printed document. In addition, the instructions prohibit the broker-dealer from omitting, adding to, or altering the language of Schedule 15G in any way and from providing supplementary materials to the customer intended to detract from, rebut, or contradict Schedule 15G. Broker-dealers may not charge customers a fee for receipt of Schedule 15G. In addition, broker-dealers are required to distribute the Summary Document as the first page of the risk disclosure document, and on one page only.

2. Schedule 15G as Proposed

Schedule 15G as originally proposed consisted of a three-part document, entitled "Penny Stock Disclosure Document," that outlined the items broker-dealers are required to disclose pursuant to the Penny Stock Act. The document defined a penny stock, provided several brief warnings to investors, discussed the disclosures required by the proposed penny stock disclosure rules and the available legal remedies under the section entitled "Your Rights," and, under the caption "Important Market Information," explained the functioning of the penny stock market. Specific features of the proposed rule are discussed below in connection with the comments.

3. Simplification

In the Proposing Release, the Commission requested comment whether the language of Schedule 15G as proposed accurately and concisely communicated the information required by the Penny Stock Act. While nearly all comments expressed general agreement with the philosophy of providing a risk disclosure document to customers in penny stock transactions, many comments also said that the schedule was too complicated for the average investor to read and comprehend. [110] Along the same line, some comments argued that a one-page document would achieve the purpose of a risk disclosure document more effectively. Three comments pointed to the risk disclosure document required under the

[108] Included at the beginning of the Explanatory Document is a statement that the Commission has not approved or disapproved the securities being sold or offered for sale, and has not passed upon the fairness or merits of the transaction or the accuracy or adequacy of the information contained in any prospectus or otherwise provided by a broker-dealer. This proposed statement is similar to notices required by Rule 13e-3 under the Exchange Act (17 CFR 240.13e-3(e)(3)(ii) (A) and (B)), Item 431 of Regulation C under the Securities Act (17 CFR 230.481(b)(1)), and Item 501 of Regulation S-K under the Securities Act (17 CFR 229.501(c)(5)). See also, e.g., Regulation A, 17 CFR 230.610a, Item 1, part (e), and Division I, Item 2, of Schedules A, B, C and D to Regulation B, 17 CFR 230.300-346.

[109] The fonts required by the Schedule are consistent with those used for other documents required to be produced under the Securities Act and Exchange Act. See, *e.g.*, the printing instructions set forth in Regulation S-K under the Securities Act, 17 CFR 229.501(c)(5), and Rule 13e-3 under the Exchange Act, 17 CFR 240.13e-3(e)(3)(ii)(A) and (B).

[110] One comment stated that proposed Schedule 15G required a level of sophistication that the average penny stock investor lacks, and that the document should not exceed the average adult reading comprehension level in this country. Other comments pointed to specific portions of the document, stating that they should be rewritten, either to clarify or to simplify the language.

Commodity Exchange Act,[111] which informs investors of the risks involved in trading commodity futures contracts in five brief paragraphs, as a good example.

In response to the comments, the Commission has revised Schedule 15G to make it more straightforward and comprehensible to the average reader. First, the Commission has added the new Summary Document to summarize the essential information. The Commission believes that a brief, one-page document, which succinctly states the main required items, would more effectively attract the average investor's attention.

Second, the Commission has revised Schedule 15G as proposed, which has become the Explanatory Document as described above. Changes from proposed Rules 3a51–1 and 15g–1 through 15g–6 are reflected in the Explanatory Document. Where possible, without altering significantly the meaning of Schedule 15G as proposed, shorter, more commonly understood words have been substituted. Most paragraphs have been shortened; however, to incorporate some of the comments noted below, the Commission has expanded other sections.

4. Strengthening the Risk Disclosure Document

The Commission has accepted several suggestions proposed in the comment letters intended to strengthen the risk disclosure document. In response to one recommendation, the Commission has revised the discussion of the relationship between the bid and offer quotation prices, the spread, and the compensation of a broker-dealer.[112] Investors are warned that, in order to sell their stock at a profit, the bid price must rise above both the original offer price (constituting the dealer's spread), and the compensation to the broker-dealer, consisting of the mark-up in the original transaction and the mark-down in the sales transaction.

The Commission also has included the Commission's own telephone number for reporting complaints and NASAA's central telephone number in addition to the NASD toll-free telephone number. Investors may call the latter two numbers for the disciplinary history of broker-dealers and their salespersons.[113]

Several comments suggested broadening the description of the penny stock market to include the Bulletin Board, and other local or regional interdealer quotation services. The Commission has added the Bulletin Board to the description of the quotation media in which information about penny stocks may be obtained.

One comment suggested that prior to a transaction, investors should be required to sign and return a form to the broker-dealer stating that they had read the risk disclosure document. The Commission believes that the burden on broker-dealers of imposing such a requirement would be too high, both in terms of the delay in effecting a transaction, and the additional paperwork involved. Instead, compliance with the rule may be monitored by review of the broker-dealer's internal procedures, and, if necessary, by contacting the clients of the broker-dealer.

Similarly, the Commission also has decided against requiring the firm to provide the risk disclosure document to all investors in penny stocks, including those investing in transactions exempted by Rule 15g–1,[114] as proposed by one comment. For the reasons stated in the Proposing Release, the Commission believes that such a requirement is not warranted.[115] Under the definition of a penny stock as set forth in Rule 3a51–1 as adopted, transactions in a stock registered and executed on a national securities exchange or quoted on NASDAQ are excluded from Rule 15g–2, in addition to the other penny stock disclosure rules being adopted today.[116] The availability of price and volume information in these markets enhances the ability of investors to investigate the accuracy of their broker-dealer's or salesperson's representations. Moreover, SRO rules impose certain restrictions on these quotations designed to protect investors.[117] The Commission believes that investors would not receive significantly greater protection from receiving a risk disclosure document in such transactions.

Several representatives from the industry felt that the risk disclosure document casts the penny stock market in an unduly pejorative light.[118] One broker-dealer stated that the term "penny stock" should not be used because its negative connotation may taint all securities that technically fall within that category. However, the objective of the risk disclosure document, as reflected in the Penny Stock Act and its legislative history, is to disclose the risks present in this market as well as the incidence of fraud that has been demonstrated. After reviewing the risk disclosure document, and making the revisions described above, the Commission believes that this document, which is necessarily a warning notice, achieves this objective in a measured way.[119]

D. Rule 15g–3: Broker-Dealer Disclosure of Quotations and Other Information Relating to the Penny Stock Market

The Penny Stock Act requires the Commission to adopt a rule requiring broker-dealers to disclose to each customer, prior to effecting any transaction in, and at the time of confirming any transaction with respect to any penny stock, the bid and ask prices for the penny stock, and the

[111] See 17 CFR 1.55. Rule 1.55, adopted by the Commodity Futures Trading Commission under the Commodity Exchange Act, 7 U.S.C. 1 *et seq.*, requires futures commissions merchants and introducing brokers, before opening an account, to receive from their customer a signed and dated acknowledgment that the customer has received and understood a risk disclosure statement that contains only the language set forth in the rule.

[112] A substantial portion of the Summary Document is devoted to this subject.

[113] The Commission has not included a description of the type of disciplinary history available from the NASD and NASAA, as some comments had suggested. The Commission believes that such a specific explanation might be confusing to the ordinary investor. The Summary Document simply indicates that "additional information" may be obtained from NASAA.

[114] See Section III.B of this release. In contrast, another comment suggested that the obligation to deliver the document be restricted to purchasers of a penny stock, because of the limited benefits of providing the document to customers who are only selling penny stocks. However, the Commission notes that the Penny Stock Act does not distinguish between purchasers and sellers in a penny stock transaction. In addition, the document contains important warnings not only to purchasers, but also to sellers, of penny stocks.

[115] See Proposing Release, 56 FR 19178.

[116] See paragraphs (e) and (f) of Rule 3a51–1.

[117] See, *e.g.*, NASD Rules of Fair Practice, Art. III, Section 5, *NASD Manual* (CCH) ¶ 2155 (NASD member prohibited from publishing any notice quoting a bid or offer price for a security, unless it believes that such quotation represents a *bona fide* bid or offer).

[118] One comment argued that the language in proposed Schedule 15G would lead investors to believe that there was no legitimate penny stock activity. Another comment said that the schedule concluded that a dominated market is inherently a fraudulent market.

[119] In this connection, instructions to proposed Schedule 15G stated that no language of the document may be omitted, added to, or altered in any way. Some comments requested clarification whether the document nonetheless may be supplemented by additional materials. One comment strongly encouraged that such a practice be permitted, and that the prohibition on changes be restricted only to the document itself.

In response, the Commission has included specific language warning broker-dealers against supplementing Schedule 15G with any material intended in any way to detract from, rebut, or contradict the risk disclosure document. The Commission believes that supplementary materials intended to reduce the impact of the risk disclosure document potentially could undermine the purpose of the risk disclosure document to alert investors to the high pressure and abusive sales tactics in the penny stock market, as reflected in Congressional findings and in Commission proceedings.

number of shares to which such bid and ask prices apply.[120] If information is not available on bid and ask prices, broker-dealers must provide customers with other useful and reliable information relating to prices of penny stock, and other comparable information relating to the depth and liquidity of the market for the stock.[121]

1. Description of the Rule

Pursuant to this statutory requirement, Rule 15g–3 requires a broker-dealer that effects a transaction in any penny stock with or for the account of a customer to disclose to its customers, prior to effecting the transaction, and in the written confirmation,[122] certain information relating to prices and quotations. Procedures for disclosing quotations derived from interdealer bid and offer prices are treated separately in principal transactions on the one hand, and riskless principal and agency transactions, on the other.

The rule sets forth three levels of disclosure in principal transactions, other than riskless principal transactions,[123] depending on the availability and reliability of price information. First, paragraph (a)(1) of Rule 15g–3 requires a broker-dealer effecting a transaction in a penny stock to provide the inside bid and offer quotations for the penny stock appearing on a Qualifying Electronic Quotation System, such as the Bulletin Board, on which there is both an inside bid and offer quotation for the security.[124]

Second, if an inside quotation, as defined, is not available, the rule requires disclosure of the broker-dealer's own quotations. For principal transactions other than riskless principal transactions, a broker-dealer is required to disclose its own bid and offer prices if, during the previous five business days, the dealer has effected at least three *bona fide* sales to, in the case of its current offer quotation, or purchases from, in the case of its current bid quotation, other dealers consistently at these respective bid or offer quotations at the time of those transactions.[125] In addition, the dealer must reasonably believe in good faith at the time of the transaction with the customer that its respective bid or offer price accurately reflects the price at which it is willing to sell to or buy from other dealers.[126]

In order for a quotation to be disclosed under this second procedure, no less than 75% of a broker-dealer's *bona fide* interdealer purchases or sales must have occurred consistently at the currently quoted price over the previous five-day period. At a minimum, dealers must have effected three *bona fide* transactions with other dealers. If only three interdealer transactions have occurred in the interdealer market, all three such transactions must have occurred at the dealer's currently quoted bid or offer price, as the case may be.

Finally, if the dealer's own bid and offer prices differ from its interdealer transaction prices over the previous five days, the rule requires the dealer to disclose that it has not consistently effected interdealer purchases or sales of the penny stock at its bid or offer price. The dealer also must disclose to the customer the price at which it last purchased the penny stock from, or sold the penny stock to, respectively, another dealer in a *bona fide* transaction.

In this situation, the dealer must state, in a clear manner, the price of its last transaction and its lack of trades consistent with its quotes. The Commission believes that under such circumstances it generally would be misleading to customers for dealers to provide, in addition, their own purported market quotations, since the broker-dealer's own quotes would not reflect the prices at which it is trading. If the dealer nonetheless chooses to provide additional quotations, such quotations must be *bona fide*, and the dealer must communicate clearly the nature of those quotations, without rendering the required disclosures ineffectual.[127]

In the case of a sole market maker in a penny stock, the market maker would be required to disclose its quotations, if validated by its trades, as required by the rule. Otherwise, it must disclose its last relevant trade price, and the fact that its trades and quotes were not consistent. In other instances where it has not been possible for a dealer to effect transactions consistently with other dealers over a five-day period, as, for example, during the first few days of an initial public offering, a dealer would be required to disclose to the customer that it has not effected previous, consistent interdealer purchases or sales. In the case of an initial public offering, the broker-dealer could explain that no trading market existed prior to the offering. This information should indicate to the customer that the market for the securities may be inactive or untested, because an interdealer market has not yet been established for the securities.

The rule provides for a separate procedure for disclosing transactions effected by a broker on an agency basis, or by a broker-dealer on a riskless principal basis. In these trades, the rule requires a broker-dealer to disclose the best interdealer bid and offer prices for the penny stock that the broker-dealer obtains through reasonable diligence. The Commission believes that the "reasonable diligence" standard would require the broker-dealer acting as agent or riskless principal, at a minimum, to follow standards set forth by the NASD, and generally accepted as industry practice, by presenting to the customer the best of three quotations obtained from market makers in the security. Quotations from all market makers

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[120] 15 U.S.C. 78o(g)(3)(A)(i), (ii).

[121] *Id.*

[122] The timing and procedure of disclosure are discussed at Section III.G of this release.

[123] Riskless principal transactions are discussed below in this section in connection with the comments to Rule 15g–3 and in Section III.E in connection with Rule 15g–4. For purposes of these rules, riskless principal transactions are those trades for which the dealer has both a buy and a sell commitment at the time of the trade with the customer.

[124] The Penny Stock Act provides that the Commission shall facilitate the development of automated quotation systems that collect and disseminate information regarding penny stocks. A "Qualifying Electronic Quotation System" is defined in paragraph (c)(5) of the rule. See the discussion of this system below in this section.

[125] Under this validation procedure, the broker-dealer is required under the rule to disclose to the customer both its bid and offer quotations for a penny stock. However, the Commission wishes to clarify that in order to do so, the validation procedure under Rule 15g–3 does not require the dealer to have effected both three sale and three purchase transactions in the previous five days. It is sufficient that only one side, *i.e.*, either the bid or the offer side, be validated. For example, a dealer may have effected only three sales, and no purchases, of a penny stock during the relevant period. Nevertheless, provided that the other elements of the validation procedure have been satisfied, the dealer would give its own bid and offer quotations to the customer in satisfaction of the requirements of Rule 15g–3.

However, if any transaction(s) has occurred on the other side in the relevant five-day period, the dealer must have effected such transaction(s) at its quoted price at the time of such transaction(s), and the 75% standard would apply. The three transaction requirement would not apply in determining consistency of transactions at the quoted price on this other side.

[126] In reviewing the quotations disseminated by dealers under the rule that are validated by interdealer transactions, the Commission intends to consider the context in which such interdealer transactions have occurred to determine whether the interdealer transactions are *bona fide*, *i.e.*, whether such transactions are arms-length and otherwise determined by market forces.

[127] When making such additional quotations under paragraph (a)(2)(i)(C) of Rule 15g–3, the dealer must, at a minimum, communicate clearly to the customer that the dealer has not consistently effected such interdealer purchases or sales at its bid or offer for the number of shares to which the bid and offer apply and that the dealer's quotations under these conditions are potentially unreliable.

would have to be provided if there are fewer than three.[128]

Finally, paragraph (a)(3) of the rule requires broker-dealers to disclose the number of shares to which the bid and offer prices apply.[129]

2. Comments on Rule 15g–3

The Commission requested comment concerning the procedure for validating quotations of broker-dealers, specifically, the adequacy and appropriateness of the provision of the proposed rule requiring that at least 75% of a dealer's purchase or sales transactions during the previous five-day period occur at its bid or offer price. Six comments supported the manner in which the rule requires disclosure of quotations.[130] However, representatives of industry generally were critical of the validation process, stating that it posed substantial compliance and operational problems.[131] In particular, these comments asserted that it would be unduly burdensome for broker-dealers to determine whether quotations were "consistent" during the five-day period prior to effecting the penny stock transaction. The NASD stated that the 75% figure was too high, and would be ineffective without a minimum number of trades. The NASD preferred a process of validation based on *Alstead, Dempsey & Company, Inc.* ("*Alstead*"),[132] which permits use of properly validated quotations in the absence of contemporaneous transactions, without quantifying the percentage of trades required to validate the quotations.

In response to these comments, the Commission has concluded that broker-dealers should have available an objective procedure that would assist them in complying with the Penny Stock Act's requirement of disclosure of bid and offer quotations. In section 17B of the Exchange Act, Congress directed the Commission to facilitate the "wide-spread dissemination of reliable and accurate last sale and quotation information with respect to penny stocks," which would provide, among other things, bid and offer quotations of participating broker-dealers, or other comparably accurate and reliable pricing information. The Commission has incorporated the standards enumerated in section 17B in the specifications of an automated quotation system for purposes of disclosure under Rule 15g–2.[133] The Commission believes that the use of such a quotation system will substantially ease the costs to broker-dealers of complying with the bid-offer disclosure requirement of the Penny Stock Act.

The rule requires use of the highest firm inside bid quotation and the lowest firm inside offer quotation displayed on a Qualifying Electronic Quotation System, when available.[134] Under paragraphs (c)(3)–(4) of the rule, in order for an "inside bid quotation" and an "inside offer quotation" to exist, at least two market makers in the security must contemporaneously be displaying on a Qualifying Electronic Quotation System bid and offer quotations for the security at specified prices.[135] Consequently, broker-dealers will provide these publicly disseminated quotations in the pre-trade disclosure and in the confirmation by drawing these quotes electronically from an external data source. The Commission believes that broker-dealers should be able to derive the inside quotes from an electronic system like the Bulletin Board in an efficient and straightforward manner, and that this will provide useful information to investors.

In its comment letter, the ABA hypothesized a situation where a broker-dealer has consistently effected *bona fide* sales to other dealers at its offer price, but has not effected purchases consistently at its bid price. The letter argued that this "unfairly" required the broker-dealer to disclose the unreliability of its quotations to its customers. However, one of the principal reasons for requiring broker-dealers to disclose bid as well as offer quotations is so that investors understand the problems that they may face when they attempt to sell a penny stock. A consistent bid price, validated by actual trades, evidences an active, liquid secondary market in the stock, and, therefore demonstrates that the customer may readily find a broker-dealer to repurchase that stock.

3. Validation of Quotations in Principal Transactions

Where qualifying inside quotations are not available, however, the Commission has retained the proposed validation procedure, while modifying certain features in accordance with the comments. The Commission believes that outside of an electronic quotation environment with multiple displayed quotations, quotations in the non-NASDAQ OTC market are not sufficiently reliable to require broker-dealers to give them to customers without a validation process. Moreover, as an operational matter, based on the comment letters and discussions with a number of broker-dealers, it appears that market makers generally are aware whether they are trading at their quoted prices. Although the Commission considered using a non-quantified validation standard, as suggested by the NASD, the Commission believes that a validation standard provides clearer

[128] See Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2151.03, Interpretation D, at 2037–3. Interpretation D reads as follows:

In any transaction for or with a customer pertaining to the execution of an order in a non-NASDAQ security (as defined in Schedule H to the By-Laws), a member or person associated with a member, shall contact and obtain quotations from three dealers (or all dealers if three or less) to determine the best inter-dealer market for the subject security.

The Commission notes that in any transaction in which a broker-dealer is acting in an agency or riskless principal capacity, the firm generally would have at least one *bona fide* quote to provide to a customer. In such transactions, the broker-dealer would obtain the security contemporaneously from another broker-dealer at a quoted price, and thus would be able to provide that quote to its customer. Therefore, the rule does not contain a provision requiring a broker-dealer in agency or riskless principal transactions to disclose the unreliability of quotation information. In contrast, in principal transactions not effected on a riskless principal basis, a dealer may sell the security from its inventory when no readily ascertainable quote is available. In such instances, the rule requires disclosure of the unreliability of unvalidated quotes.

[129] The Commission believes that the general antifraud provisions of the federal securities laws would prohibit the dealer from providing a quotation, such as for a round lot of shares, without further explanation if the broker-dealer is aware that this quotation in fact would mislead the customer with respect to the value actually paid or received by the customer in a transaction resulting from such a quotation.

[130] According to one comment, the rule as proposed would contribute substantially to the investor's ability to make an informed choice about the advisability of investing in a penny stock.

[131] One comment stated that the validation procedure would render automated back office services useless for processing penny stock transactions, but did not specify how this would be the case.

Some comments queried whether the bid and offer information required at the time of confirmation is the quotation information disclosed at the time of the pre-trade disclosure, or at the time of the confirmation. In the post-trade confirmation, the bid and offer quotation information would be the same bid and offer information disclosed pursuant to the pre-trade disclosure requirement.

[132] 47 S.E.C. 1034 (1984).

[133] See section III.A of this release for a discussion of the anticipated future compliance of the Bulletin Board with the requirements of section 17B(b)(2) of the Exchange Act by the effective date of the Rule. Where these external quotes are available, the broker-dealer may not use its own quotes, even if validated.

[134] A Qualifying Electronic Quotation System is defined in paragraph (c)(5) of Rule 15g–3 as "an automated quotation system that has the characteristics set forth in section 17B(b)(2) of the [Exchange] Act, or such other automated quotation system designated by the Commission" for purposes of compliance with the rule.

[135] This use of inside bid and offer quotations is consistent with the pricing provisions of Rule 3a51–1. At present, no automated quotation system satisfies all the requirements of section 17B(b)(2).

guidance to broker-dealers in complying with the rule.

The Commission also believes that the proposed 75% standard is a fair gauge of the reliability of a broker-dealer's quotes in the penny stock market. Given that there are often few trades in a penny stock, a figure lower than 75% would not accurately characterize the trading for a penny stock as "consistent." [136] The Commission agrees with the NASD that the rule would be more effective if, in determining whether it has "consistently" traded at its offer or bid price to the customer, the dealer has effected a minimum number of transactions in the security during the relevant time period. Therefore, paragraph (a)(2)(i) of the rule as adopted now requires that there must have been at least three *bona fide* interdealer transactions in the security in the five days preceding the transaction with the customer. As a logical matter, if, in fact, the dealer has effected only three transactions, all three transactions must have occurred at its offer or bid price, as the case may be.

For those principal transactions that do not have qualifying inside bid and offer quotations displayed on a Qualifying Electronic Quotation System, and also cannot be properly validated, a dealer must disclose to customers that the dealer has not consistently effected interdealer purchases or sales of the penny stock at its bid or offer price. However, the Commission does not believe this requirement to be unduly burdensome, particularly in view of the benefits it would produce in terms of customer protection. [137] The alternative would be to tell the customer nothing. The Commission believes that this result would not comply with the mandates of the Penny Stock Act, as reflected in the legislative history, which underscored the importance that investors understand the nature of quotations in the penny stock market. [138]

[136] The Commission wishes to note that the 75% requirement, like the other requirements under the rule, is intended to apply only to transactions under Rule 15g–3.

[137] See the discussion *supra* in this section of the ABA comment that it would be unfair to require a dealer to disclose that it has not consistently effected purchases at its bid price although its sales transactions have been consistent.

[138] In adopting the bid-ask provisions of the Penny Stock Act, the House Report pointed to the fear that,

[w]hile the Committee believes that the disclosure of bid and ask quotations to customers will provide an additional source of useful information for customers to assess the relative merits of a particular investment, the Committee notes that quotations for such securities frequently are the subject of negotiation and may not accurately reflect the actual price a customer would pay or receive for the securities.

House Report, at 29.

E. Rule 15g–4: Compensation of Brokers or Dealers

Section 15(g)(3)(A) of the Penny Stock Act requires the Commission to adopt a rule requiring broker-dealers to disclose to each customer, both prior to effecting any transaction in, and at the time of confirming any transaction with respect to, any penny stock, "the amount and description of any compensation that the broker or dealer * * * will receive or has received in connection with such transaction." [139] In enacting this provision, Congress was concerned that customers in the penny stock market have little notion of the often excessive compensation that broker-dealers obtain in penny stock transactions. [140]

1. Description of the Rule

In accordance with the Penny Stock Act, Rule 15g–4 requires disclosure of aggregate broker-dealer compensation to any customer [141] both prior to effecting any transaction in, and at the time of confirming any transaction [142] with respect to, any penny stock. [143]

Rule 15g–4 defines compensation of broker-dealers with respect to three separate types of transactions. First, the rule defines the compensation of a broker-dealer that is engaged in an agency transaction in a penny stock for a customer as the amount of any remuneration received or to be received by it from the customer. Compensation in agency transactions generally consists of a commission. The amount of remuneration to be received from the customer in agency transactions currently must be disclosed to the customer on the confirmation pursuant to Rule 10b–10(a)(7)(ii) [144] under the Exchange Act. Rule 15g–4 incorporates Rule 10b–10's general standard for agency transactions.

Second, Rule 15g–4 defines compensation of a broker-dealer, other than a dealer acting as a market maker, that executes a "riskless principal" transaction in a penny stock as the difference between the price to the customer and the contemporaneous purchase or sale that is made in connection with such transaction. A riskless principal transaction is a transaction in which a broker-dealer, after receiving (or receiving the commitment for) a buy or sell order, makes a purchase or sale of the penny stock as principal from or to another person to offset the sale or purchase as principal to or from the first person. Thus, riskless principal trades would be those trades in which there is a commitment on both the buy and the sell sides of a transaction at the time of the principal trades.

Third, Rule 15g–4 defines compensation of a dealer that executes principal transactions, other than riskless principal transactions, as the difference between the price to the customer charged by the dealer and the prevailing market price. The preamble to the rule refers broker-dealers to the standards for determining compensation in the Commission's *Alstead* [145] decision, which Congress, in its House Report on the Penny Stock Act, endorsed as the "leading case" establishing the principles for calculating mark-ups. [146]

Paragraph (d) of the rule provides an alternative standard for use by market makers in calculating compensation, once last sale reporting becomes available in a Qualifying Electronic Quotation System, as defined in paragraph (c)(5) of Rule 15g–3. At that time, solely for purposes of Rule 15g–4, a market maker may use an "active and competitive market" standard in determining prevailing market price if the aggregate number of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate number of all transactions in the penny stock reported on a Qualifying Electronic Quotation System. Rule 15g–4 provides that there is no presumption that a market is not "active and competitive" solely because a market maker does not meet the conditions specified therein.

2. Alstead Standard

The Commission's general principles for calculating compensation in principal trades, enunciated in its decision in *Alstead*, provide guidance in determining prevailing market price. [147] Through administrative and judicial proceedings, the Commission has maintained the long-standing position that undisclosed excessive mark-ups

[139] 15 U.S.C. 78*o*(g)(3)(A).

[140] See Proposing Release, 56 FR 19184.

[141] Pursuant to Rule 15g–1, a broker or dealer is not a customer.

[142] The timing and procedure of disclosure are discussed at Section III.G of this release.

[143] 15 U.S.C. 78*o*(g)(3)(A).

[144] 17 CFR 240.10b–10(a)(7)(ii).

[145] 47 S.E.C. 1034 (1984).

[146] House Report, at 30.

[147] The Proposing Release provided a summary of the standards in *Alstead* for determining prevailing market price. Proposing Release, 56 FR 19185–19186. For convenience of reference, that summary is repeated here. None of the commenters disputed the essential accuracy of the summary in the Proposing Release.

and mark-downs [148] violate the antifraud provisions of the federal securities laws, [149] and has set forth the appropriate methods for calculating dealer mark-ups. In addition, since 1943, the NASD has deemed it inconsistent with just and equitable principles of trade under its Rules of Fair Practice for a member to enter into any securities transaction with a customer at a price not reasonably related to the current price of the security. [150]

The Commission and the courts consistently have held in mark-up cases that, absent countervailing evidence, the prevailing market price is the price paid by a dealer in actual contemporaneous transactions with other dealers. [151] This standard, and a variation for certain dealer transactions, has been described most succinctly in the Commission's 1984 decision in *Alstead*. [152] The standards under *Alstead* as summarized in this release are intended to provide a framework for broker-dealers to use in calculating compensation when acting as principal in transactions in penny stocks. The Commission wishes to emphasize that this summary is not intended in any way to modify the standards of *Alstead*. Broker-dealers are encouraged to refer to that case in conjunction with this release for a statement of the Commission's standards regarding calculation of compensation.

The Commission in *Alstead* first reiterated the general contemporaneous cost standard. In one of the situations presented by the case, several market makers in an equity security were listed in the "pink sheets," and the firm in question, Alstead, Dempsey & Co., also entered quotations in regional interdealer quotation sheets. Nonetheless, the Commission held that except for the prices Alstead, Dempsey & Co. charged another dealer in two transactions, the best evidence of prevailing market price was the price paid by Alstead, Dempsey & Co. in contemporaneous transactions, in view of the unreliability of Alstead, Dempsey & Co.'s offer quote. [153]

However, in *Alstead*, [154] and in other decisions, [155] the Commission modified the contemporaneous cost standard for certain principal trades in active and competitive markets. A dealer trading in such a market, that is acting as a market maker rather than effecting a riskless principal trade, would be able to use its own contemporaneous interdealer sales price or the sales prices of other dealers, if known, in actual transactions as the basis for computing mark-ups. [156] In the absence of actual, contemporaneous interdealer sales by the market maker or other dealers, the market maker's own lowest offer quote, or the lowest offer quote of other market makers, may be used as evidence of prevailing market price in sale transactions. [157] However, in

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[148] When a dealer as principal sells a security to a customer, it generally will include, as compensation, a mark-up over the prevailing market price. Similarly, when a dealer purchases a security from a customer, it will calculate a mark-down from the prevailing market price and effect the transaction at that lower price. In this release, the terms "mark-ups" and "mark-downs" will sometimes be used in lieu of "compensation" for discussion purposes, but "mark-ups" and "mark-downs" are included in the meaning of "compensation" as defined under Rule 15g–4.

[149] The Commission and the courts have stated for over 50 years that a broker-dealer, by holding itself out as a securities professional with special knowledge and ability, impliedly represents that it will deal fairly, honestly, and in accordance with industry standards with the public investor. "[A] dealer may not exploit the ignorance of his customer to extract unreasonable profits resulting from a price which bears no reasonable relation to the prevailing market price." *Duker & Duker*, 6 S.E.C. 386, 389 (1939). Specifically, a broker-dealer impliedly represents that the prices it charges bear a reasonable relation to the prevailing market price. Charging an excessive mark-up is inconsistent with that implied representation. Under this theory, the courts have found violations of Section 17(a) of the Securities Act, 15 U.S.C. § 77q(a), and Section 10(b) of the Exchange Act, 15 U.S.C. 78j(b), and Rule 10b–5 thereunder, 17 CFR 240.10b–5. *See generally Charles Hughes & Co.* v. *SEC*, 139 F.2d 434 (2d Cir.), *cert. denied*, 321 U.S. 786 (1943); *SEC* v. *Great Lakes Equities Co.*, [1990–1991] Fed. Sec. L. Rep. (CCH) ¶ 95,685, at 98,201 (E.D. Mich. September 4, 1990); *Trost & Co., Inc.*, 12 S.E.C. 531 (1942). See also Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575 (principles as applied to zero coupon securities market).

[150] Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2154, at 2056. The NASD generally will consider mark-ups and mark-downs on equity securities greater than 5% above the prevailing market price to be unfair or unreasonable. However, the determination of the fairness of mark-ups and mark-downs must be based on a consideration of all the relevant factors, of which the percentage is only one. *Id.* at 2055, 2057. See *Gerald M. Greenberg*, 40 S.E.C. 133, 136–37 (1960).

The Commission consistently has held that undisclosed mark-ups and mark-downs of more than 10% are fraudulent in equity securities. See, *e.g., Peter J. Kisch*, 47 S.E.C. 802, 808 (1982); *Staten Securities Corp.*, 47 S.E.C. 766, 767 (1982); *Powell & Assocs.*, 47 S.E.C. 746, 748 (1982); *Charles Michael West*, 47 S.E.C. 39, 42 n.12 (1979). The Commission has applied the 10% standard in decisions involving the penny stock market as well. See *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767; *James E. Ryan*, 47 S.E.C. 759 (1982); *First Pittsburgh Securities Corp.*, 47 S.E.C. 299 (1980); *Costello, Russotto & Co.*, 42 S.E.C. 798 (1965); *J.A. Winston & Co.*, 42 S.E.C. 62, 69 (1964).

In addition, both the Commission and the NASD have held that compensation below the stated percentages with respect to equity securities may be excessive under certain circumstances. See *Shearson, Hammill & Co.*, 42 S.E.C. 811, 837 (1965) (Commission found markups of 5.4%, 5.7%, and 6.3% excessive and in violation of the anti-fraud laws); *Thill Securities Corp.*, 42 S.E.C. 89, 92–95 (1964) (mark-downs as low as 3.9% found to be inconsistent with NASD Rules of Fair Practice).

[151] See, *e.g., Barnett* v. *United States*, 319 F.2d 340, 344 (8th Cir. 1963). For Commission rulings, see, *e.g., First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980); *DMR Securities, Inc.*, 47 S.E.C. 180, 182 (1979); *Maryland Securities Co., Inc.*, 40 S.E.C. 443, 446 (1960); *Samuel B. Franklin & Co.*, 38 S.E.C. 908, 910 n.4, *aff'd, Samuel B. Franklin & Co.* v. *SEC*, 290 F.2d 719 (9th Cir.), *cert. denied*, 368 U.S. 889 (1961).

[152] 47 S.E.C. 1034 (1984). The Commission has applied the *Alstead* principles in decisions involving the debt securities markets. See, *e.g.*, Amicus Brief of the Securities and Exchange Commission, *Elysian Federal Savings Bank* v. *First Interregional Equity Corp.*, 713 F. Supp. 737 (D.N.J. 1989) (No. 88–3528), at 15 n.20, 20 n.27. In an interpretive statement concerning the zero-coupon securities market, the Commission stated that the best evidence of the prevailing market price would generally be the broker-dealer's contemporaneous retail purchase price, adjusted to reflect the mark-down inherent in such customer transactions. Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575. Zero-coupon securities are often a proprietary product of a broker-dealer, who is usually the sole market maker in the interdealer market, if there is one.

[153] *Alstead*, at 1038. The NASD's policy in determining prevailing market price in calculating mark-ups and mark-downs is in accord with this position. The NASD's interpretation of its mark-up policy, reads, in relevant part:

> Since the adoption of the "5% Policy" the Board has determined that * * * [T]he mark-up over the prevailing market price is the significant spread from the point of view of fairness of dealings with customers in principal transactions. In the absence of other bona fide evidence of the prevailing market, a member's own contemporaneous cost is the best indication of the prevailing market price of a security.

Interpretation of the Board of Governors, *NASD Manual* (CCH) ¶ 2154, at 2056.

[154] *Alstead*, at 1035–36.

[155] *See, e.g., Peter J. Kisch*, 47 S.E.C. 802, 808–809 (1982); *General Investing Corp.*, 41 S.E.C. 952, 954–55 (1964).

[156] *Alstead*, at 1036; *See also LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767 (NASD properly computed mark-ups in certain transactions on basis of price that the firm charged another dealer); *Peter J. Kisch*, 47 S.E.C. 802, 808 (1982) (market maker's own actual contemporaneous sales to other broker-dealers should be used in computing mark-ups); *Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 194 (1966) (evidence showed that contemporaneous prices at which NASD member effected sales constitute appropriate basis for computing mark-ups). Interdealer transactions should be reasonably related to the best available quotations (*i.e.*, highest bid and lowest offer) regardless of whether such quotations are the market maker's own. Memorandum of the Division of Market Regulation to the Commission, In the Matter of Alstead, Strangis & Dempsey Inc., Administrative Proceeding File No. 3–6135 (April 8, 1983) (hereinafter referred to as "Division Memorandum"), at 21 n. 47.

[157] Quotations for NASDAQ securities that are actively traded, have narrow spreads, and have significant trading independent of the market maker in question are an example of acceptable quotations under the circumstances set forth in this release. Division Memorandum at 23.

However, the Commission cautions that quotations may be employed only in certain limited situations. The Commission stated in *Alstead*, in relevant part:

> Where there is an active, independent market for a security, and the reliability of quoted offers can be tested by comparing them with actual inter-dealer transactions during the period in question, such

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order to use an offer quote, the reliability of the market maker's offer prices generally must be validated over time by comparing them with actual interdealer transactions. Although such transactions need not be contemporaneous, they would have to occur with some frequency, and consistently be effected at prices at or around the offer quotes.[158] In the absence of both actual interdealer sales and validated offer quotes, the market maker's contemporaneous cost must be employed as a basis for the mark-up computation. Contemporaneous cost is based on the market maker's purchase that is closest in time prior to the transaction.[159]

In a market dominated by a market maker to such an extent that it controls wholesale prices for a security,[160] market makers are required to apply the contemporaneous cost standard in calculating mark-ups. Where a market maker dominates the trading market for a security, it may be free to control both the quotation spreads and the trading occurring in that market. As a result, neither the market maker's offer quotations or interdealer sales may be indicative of an independent prevailing market price. Accordingly, in those situations, a market maker must use its contemporaneous purchase price in transactions with other dealers as evidence of the prevailing market price in calculating mark-ups. In the absence of actual interdealer purchases, the market maker must use its contemporaneous purchase price from retail customers, adjusted for the mark-down to such customers. This mark-down adjustment should not exceed the amount generally accepted under the NASD's mark-up rule.[161]

3. Changes From Proposed Rule

In the Proposing Release, the Commission requested comments on the proposed rule's definition of compensation[162] and the articulation in the Proposing Release of the appropriate manner of determining prevailing market price in the penny stock dealer market. The comments generally argued that the requirement in the proposed rule that dealers use the *Alstead* standards in determining prevailing market price was inappropriate, because these standards were too subjective and technically difficult to be applied effectively. Specifically, comments argued that the *Alstead* standards unfairly forced a market maker to choose between deeming a market active and competitive at the risk of a subsequent enforcement action, or using contemporaneous cost as the prevailing market price, thus disclosing compensation received by the market maker for the risk incurred in carrying an inventory position in addition to the retail component of compensation. In addition, the comments asserted that calculation of mark-ups based on contemporaneous cost would be difficult because many penny stock firms do not price their inventory on an historical basis, resulting in substantial reprogramming costs.

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quotations may provide a proper basis for computing markups. Thus, if inter-dealer sales occur with some frequency, and on the days when they occur they are consistently effected at prices at or around the quoted offers, it may properly be inferred that on other days such offers provide an accurate indication of the prevailing market.

Alstead, at 1036–37.

The Commission traditionally has believed that actual transactions are a more reliable indicator of the prevailing market price than quotations. Division Memorandum at 32. Offer quotes by OTC market makers generally are negotiable. In less active markets, market makers often purchase securities at prices higher than their bid and sell at prices lower than their offer quotes, which may even be higher than the best bid or lower than the best offer. *Id.* at 8. As the Commission further stated in *Alstead*, "quotations for obscure securities with limited interdealer trading activity may have little value as evidence of the current market." *Alstead*, at 1036. The Commission reaffirmed the lack of reliability of quotations for thinly traded securities most recently in *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767. See *also Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 193 (1966) ("[s]ince such offers were not generally tested in the market place by sales by the member to dealers or by other interdealer sales, they were not a reliable guide to market price."); *C.A. Benson & Co., Inc.*, 42 S.E.C. 952, 954 (1966) (firms did not sell a single share to another dealer at inside offer; thus NASD properly disregarded offering price in sheets).

[158] The Commission generally has required strong evidence that offer quotes accurately reflect prevailing market price because of the lack of reliability of quotations in the OTC market. See, *e.g.*, *Alstead*, at 1036–37; *Gateway Stock and Bond, Inc.*, 43 S.E.C. 191, 193 (1966); *Naftalin & Co., Inc.*, 41 S.E.C. 823, 826–28 (1964). Moreover, the Commission has long held that a broker-dealer in enforcement proceedings has the burden of bringing forth evidence that the use of contemporaneous cost is not appropriate for computing mark-ups or mark-downs. *See James E. Ryan*, 47 S.E.C. 759, 762 (1982) (in the absence of countervailing evidence, a dealer's contemporaneous cost is best evidence of current market price). *See also Barnett* v. *United States*, 319 F.2d 340, 344 (8th Cir. 1963); *Powell & Assocs., Inc.*, 47 S.E.C. 746, 747 (1982) (burden is on dealer to establish that contemporaneous cost is not "true market price"); *First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980) (dealer had burden to show costs did not represent mark-up); *Charles Michael West*, 47 S.E.C. 39, 41–42 (1979) (dealer has burden to establish that contemporary cost is not reliable indicator of prevailing market price).

[159] The Commission believes that same day purchases are the best indication of contemporaneous cost. However, the Commission recently has held that, absent some showing of a change in the market, contemporaneous cost may be based on interdealer purchases for a period up to five business days prior to a particular transaction. See *LSCO Securities, Inc.*, Securities Exchange Act Release No. 28994 (March 21, 1991), 48 SEC Doc. 767. See also *First Pittsburgh Securities Corp.*, 47 S.E.C. 299, 306 (1980) (contemporaneous cost not limited to same-day cost but prices paid by dealer should be "closely related in time" to its retail sales); *Advanced Research Assocs., Inc.*, 41 S.E.C. 579, 611–12 (1963) ("substantially contemporaneous" purchase prices are calculated during period with little fluctuation in purchase and sales prices). In cases of multiple purchases during the day of sale, contemporaneous cost is based on the purchase price closest in time to the sale. The average of prices during that day or any particular period of time cannot be used. *See Century Securities Co.*, 43 S.E.C. 371, 378 (1967), *aff'd sub nom, Nees* v. *SEC*, 414 F.2d 211 (9th Cir. 1969) (average cost is not appropriate evidence of market price); *Hamilton Bohner, Inc.*, Securities Exchange Act Release No. 27232 (September 9, 1989), 44 SEC Doc. 1297 (transactions over a period of time cannot be lumped together for purposes of determining fairness of mark-downs or mark-ups).

[160] In *Alstead*, the Commission found that Alstead, Dempsey & Co. dominated the market in a particular security where it had been the underwriter of that security on a "best efforts" basis and sold 95.7% of the offering to its own customers. Alstead, Dempsey & Co. became a market maker in the security, and during the period at issue, its transactions with other dealers and customers amounted to more than 297,000 shares out of a total volume of 345,000 shares, or 86% of the volume. Alstead, Dempsey & Co. effectively controlled the supply of the security since most of it was held by the registrant's customers. Only two other dealers were market makers in the stock, and their combined transactions amounted to only 7,750 shares, 2.2% of the total trading volume. The Commission consequently used Alstead, Dempsey & Co.'s contemporaneous cost of the stock in computing mark-ups. *Alstead*, at 1037.

[161] The Commission wishes to emphasize that even when disclosure of compensation is properly made under Rule 15g–4, a broker-dealer remains subject to the general antifraud provisions of the federal securities laws.

The Commission cautions that even if it fully meets the disclosure requirements of the antifraud provisions of the federal securities laws, an NASD member that charges substantial mark-ups could violate Article III, section 4 of the NASD Rules of Fair Practice, which require NASD members to "buy or sell at a price which is fair," and could violate the NASD's mark-up policy adopted under that section. Article III, section 4, *NASD Manual*, Rules of Fair Practice (CCH) ¶ 2154, at 2054. The NASD rules apply to virtually all penny stock broker-dealers. Pursuant to section 15(b)(8) of the Exchange Act, registered broker-dealers that effect securities transactions must be members of a national securities association. Currently, the NASD is the only national securities association. Only registered broker-dealers that effect securities transactions as a member of, and solely on, a national securities exchange, are not required to be NASD members. 15 U.S.C. § 78*o*(b)(8). See also Securities Exchange Act Release No. 24368 (May 5, 1987), 52 FR 15575, at 15576 n.8 (rules of just and equitable principles of trade prohibit mark-ups which are unfair in light of all other relevant circumstances, even if disclosed); *Hamilton Bohner, Inc.*, Securities Exchange Act Release No. 27232 (September 9, 1989), 44 SEC Doc. 1297 (disclosure to customers of amount of broker-dealer's profit does not in itself justify unfair profits).

[162] In the rule as proposed and in the Proposing Release, it was not clear that the amount of compensation to be disclosed is the aggregate amount of compensation to the broker-dealer in connection with a transaction. To clarify this point, the Commission has inserted the word "aggregate" before the words "amount of compensation" in paragraph (a) of Rule 15g–4.

The Commission has determined to continue to require disclosure of compensation in principal trades based on the difference between the price to the customer and the prevailing market price, as determined in accordance with the *Alstead* standards. The *Alstead* standards, developed on the basis of the Commission's long-standing precedent in matters involving excessive mark-ups, most accurately reflect the compensation received by dealers in various types of market conditions.

On the basis of the comments received and staff interviews with broker-dealers, the Commission believes that the standards enunciated in *Alstead* do not depart significantly from actual industry practice. In contrast to the *Alstead* standards, several comments suggested the use of average inventory price as the basis for calculating compensation in dominated and controlled markets. However, depending on the trend of market prices, use of average inventory pricing would result in disclosure of varying amounts of compensation. In declining markets, too little compensation would be disclosed; in rising markets, too much compensation would be disclosed.[163] Furthermore, although it appears that many broker-dealers calculate average inventory cost at the end of the day, they do not all have this information on an intra-day basis, as would be necessary to provide it to potential customers before effecting a transaction. In contrast, most traders will know their most recent acquisition cost or interdealer sales price at the time of disclosure of compensation.

In view of the stong Congressional intent that customers in the penny stock market be clearly informed of the often high compensation that broker-dealers may obtain in penny stock transactions, the Commission believes that use of the most accurate compensation standard is necessary, and that the *Alstead* standards represent the most practicable means of disclosing compensation in penny stock markets that are relatively illiquid.[164] For penny stocks that have a more developed market, broker-dealers should be able to use the safe harbor described above.

As an alternative to using *Alstead*, some comments suggested an objective standard, such as a threshold percentage of penny stock market-making, for determining when a market is "active and competitive" and "dominated and controlled." Comments referred to the quotation, last sale, and volume reporting requirements under section 17B of the Exchange Act,[165] added by the Penny Stock Act, as the source of a system for computing the percentage of total volume of a penny stock dealt in by the penny stock market maker. Another alternative suggested by comments was a cap on compensation to a broker-dealer effecting a transaction in a penny stock.[166]

After a careful review of the comment letters, the Commission agrees that a numerical standard should be available to allow a market maker to treat its market in a penny stock as "active and competitive" solely for purposes of disclosing compensation in principal transactions in the stock. Therefore, the Commission has adopted a provision permitting market makers that effect less than 20% of the transactions reported on a Qualifying Electronic Quotation System to use the "active and competitive market" standard in calculating the compensation to be disclosed under Rule 15g–4.[167] The Commission believes that allowing these market makers to determine the prevailing market price based on the "active and competitive market" standard will facilitate compliance with the rule.

As a result, therefore, once last sale reporting begins for penny stocks quoted on a Qualifying Electronic Quotation System, a market maker in a penny stock may use interdealer sales prices or properly validated offer quotations, rather than contemporaneous cost, as the prevailing market price in calculating compensation, provided that the aggregate volume of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than 20% of the aggregate amount of all transactions in the penny stock reported on the Qualifying Electronic Quotation System. Specifically, as discussed previously, a market maker would be able to use its own contemporaneous interdealer sales price or the sales prices of other dealers, if known, in actual transactions as the basis for computing mark-ups and mark-downs if, at the time of its trade, the conditions of paragraph (d) are satisfied. In the absence of contemporaneous interdealer sales by the market maker or other dealers, the market maker's own lowest offer quote, or the lowest offer quote of other market makers, validated in accordance with the standards of *Alstead*, may be used as evidence of prevailing market price. In the absence of interdealer transactions and validated offer quotes, a market maker would have to use contemporaneous cost as the prevailing market price even though the 20% standard under paragraph (d) is satisfied.

Comments also pointed to the difficulty of determining the "riskless principal" status of a principal transaction in some instances.[168] The Proposing Release had stated that determination whether the purchase or sale of penny stock is an off-setting riskless principal transaction can only be established on a case-by-case basis.[169] Comments generally were critical of the uncertainty that such a "facts and circumstances" standard creates for dealers.[170]

The Commission agrees that dealers should have a more objective criterion for determining riskless principal status. Therefore, for purposes of Rule 15g–4, dealers could deem a transaction to be a riskless principal transaction only where commitments on both the buy and the sell sides of a transaction have been made at the time of the trade with the customer.[171] The compensation

[163] In declining markets, average cost would be more than "contemporaneous cost," the standard under *Alstead* in dominated and controlled markets, thus resulting in disclosure of less compensation than otherwise would result under *Alstead*. In rising markets, where average cost would be less than contemporaneous cost under *Alstead*, a broker-dealer would have to disclose more compensation than under *Alstead*.

[164] See Proposing Release at 56 FR 19184.

[165] 15 U.S.C. 78q–2.

[166] The ABA argued for an exemption, where investors receive a prospectus or other disclosure document prior to effecting a transaction, especially when the prospectus prominently sets forth compensation to be paid to the broker-dealer by the issuer or selling shareholder.

[167] The Commission emphasizes that it is using the Qualifying Electronic Quotation System only as a reasonable means of facilitating compliance by broker-dealers with the disclosure requirements of the Penny Stock Act. A Qualifying Electronic Quotation System may not be used to protect participants in the penny stock market otherwise engaged in fraudulent activities.

[168] Two comment letters representative of the industry criticized the inclusion of agency and riskless principal compensation in the prior trade disclosure requirement of the rule as proposed, because such information is already generally required under Rule 10b–10, and the potential for abuse in such transactions has not been demonstrated. The Commission notes that Congress, in enacting the Penny Stock Act, made no distinction in the type of compensation required to be disclosed. The Commission believes that making such an exception could enable broker-dealers more easily to engage in fraudulent activity by mischaracterizing the capacity in which they effect transactions with customers.

[169] Proposing Release, 56 FR 19185 n. 152.

[170] As an example, one comment pointed to the requirement in the proposed rule that at the time of the trade, the dealer would have to disclose the difference between the price to the customer and the counterparty price. Thus, the dealer would have to effect the other side of the transaction prior to agreeing to a trade with its customer, thereby incurring the market risk on the other side.

[171] This standard would be used in lieu of the longer one-day period, generally used at present for

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disclosure to the customer prior to the trade would be based on the price of the corresponding off-setting transaction.

In addition, the Commission understands the risk that would be imposed on market makers in making determinations of riskless principal status. Market makers already are excluded from making such a determination under Rule 10b–10.[172] Therefore, in paragraph (c)(2) of Rule 15g–4, the Commission has excluded market makers' transactions from the definition of riskless principal trades.

F. Rule 15g–5: Salesperson Compensation

As noted above, section 15(g)(3)(A)(iii) requires that the Commission adopt rules requiring brokers and dealers to disclose, prior to effecting and at the time of confirming any transaction in a penny stock, "the amount and a description of any compensation that the broker or dealer and the associated person thereof will receive or has received in connection with such transaction." High interdealer spreads and markups, which often have been found to exist in penny stock transactions, provide the potential for extraordinarily high compensation to broker-dealers and salespersons who buy and sell penny stocks. This compensation provides a strong incentive to recommend the purchase of penny stocks to customers. In enacting the provision quoted above, Congress determined that investors in penny stocks should be informed, on a transaction-by-transaction basis, of this financial incentive.[173]

Pursuant to this requirement, the Commission is adopting Rule 15g–5, which makes it unlawful for a broker-dealer to effect a nonexempt transaction in a penny stock with a customer unless the broker-dealer discloses to the customer the aggregate amount of cash compensation that certain associated persons [174] of the broker-dealer will receive, to the extent that compensation is determined at or prior to the time that the transaction is effected. Information concerning any compensation that is paid to the associated person by someone other than the broker-dealer must be separately disclosed. The rule applies to any associated person of the broker-dealer, other than a person whose functions are solely clerical or ministerial, who is a natural person and has communicated with the customer concerning the transaction at or prior to the time that the customer orders the purchase or sale of the security.

The information must be furnished orally or in writing prior to effecting the transaction, and in writing at or prior to sending the written confirmation required by Rule 10b–10. In addition, this written disclosure must disclose the existence of any contingent payments related to the transaction that are not determined at the time of the trade. The broker-dealer is required to maintain a record of the pre-trade disclosure for the period specified in 17 CFR 240.17a–4(b).

Rule 15g–5 as proposed applied to each associated person who "communicates with the customer in connection with the transaction." The Commission stated in the Proposing Release that the rule was intended to reach "those individuals who regularly solicit or recommend penny stock transactions, or otherwise communicate with customers in connection with those transactions and on whom customers are likely to rely in making investment decisions." [175] Several comments objected that the broad wording of the provision would have unintended results. In particular, these comments indicated that the rule could apply to communications by branch managers or other principals exercising ordinary supervisory responsibilities.[176] On the other hand, another comment argued that the rule should apply to "all persons who affect decision-making." [177]

As adopted, the rule applies to associated persons who "communicat[e] with the customer concerning the transaction at or prior to the customer's transaction order." [178] In addition, the rule does not apply to persons whose function is solely clerical or ministerial.[179] The Commission believes that these modifications will ensure that the rule applies to sales-related communications.[180]

The proposed rule would have permitted the broker-dealer to disclose compensation on either an aggregate or per share basis. In response to a specific request for comment, some comments favored requiring disclosure of both aggregate and per share compensation for each transaction.[181] The final rule requires disclosure only of the aggregate compensation received by the salesperson for the transaction. The Commission has determined that the form in which compensation is shown should be consistent among firms and that reflecting compensation in aggregate dollar amount will be the simplest and most easily understood form in which to present this information.[182]

The Commission noted in the Proposing Release that in some circumstances, salespersons may receive compensation directly from issuers or others.[183] As adopted, the rule requires that separate disclosure be provided with respect to any compensation that is received from sources other than the broker-dealer. This change was endorsed by several persons in response to a specific request for comment.[184] The Commission

confirmation disclosure purposes under Rule 10b–10. For similar reasons, determination of riskless principal status would be made on the same basis for Rule 15g–3, discussed earlier in this release. See section III.D of this release.

[172] Rule 10b–10 requires broker-dealers, other than market makers, that execute riskless principal trades in equity securities to disclose the amount of any mark-up, mark-down, or similar remuneration received in the transaction. See Rule 10b–10(a)(8)(i)(A) (market-maker exclusion from markup disclosure requirement in riskless principal trades). 17 CFR 240.10b–10(a)(8)(i)(A).

[173] Proposing Release, 56 FR 19197.

[174] See the definition in Section 3(a)(18) of the Exchange Act (15 U.S.C. 78c(a)(18)).

[175] 56 FR 19188.

[176] *E.g.*, American Bar Association, Committee on Federal Regulation of Securities, Subcommittee on Broker-Dealer Matters, and Subcommittee on Partnerships ("ABA").

[177] Commonwealth of Virginia, State Corporation Commission, Division of Securities and Retail Franchising ("Virginia").

[178] This modification is drawn from a suggestion by the ABA in its comment letter.

[179] The definition of "associated person of a broker or dealer" contained in section 3(a)(18) of the Exchange Act excludes clerical or ministerial employees solely for purposes of section 15(b) of the Exchange Act, other than paragraph (6) thereof.

[180] The rule does not contain a note that was contained in the proposed rule stating that compensation would not be considered to be adequately disclosed if sales agents entered into reciprocal arrangements pursuant to which commissions were directed to persons other than customer representatives who communicated with the customer in order to evade the rule's requirements. The Commission believes that any such arrangement necessarily would be misleading and has determined that it is not necessary to attempt to identify in the rule itself particular practices that would be prohibited under existing antifraud provisions. See also section 20(b) of the Exchange Act (15 U.S.C. 78t(b)), providing that any act by a person that is unlawful under the Exchange Act or the rules adopted thereunder is likewise unlawful if conducted, directly or indirectly, through any other person.

[181] *E.g.*, North American Securities Administrators Association ("NASAA").

[182] Rule 10b–10 (17 CFR 240.10b–10), the Commission's confirmation rule, generally requires disclosure of the "amount" of "remuneration" received by a broker-dealer in a transaction for a customer.

[183] 56 FR 19188.

[184] *E.g.*, Consumer Federation of America ("CFA").

believes that the receipt of compensation from sources other than the broker-dealer presents a special inducement to recommend the security that should be disclosed to the customer.

The proposed rule would have required that firms disclose, in addition to compensation received directly in connection with the transaction, the compensation received by the salesperson from transactions in penny stocks during the prior year, if such compensation exceeded 25% of the salesperson's total sales-related compensation. This provision was intended to reflect compensation that is not paid in cash or is not paid on a transactional or per share basis and therefore to provide more accurate information to customers and prevent evasion of the Rule's requirements.[185] For example, firms may compensate their salespersons according to a "grid" system, whereby they receive a base percentage of the firm's transaction compensation that is determined at the time of each trade and also contingent payments that are tied to other factors, such as the sales revenue generated by the salesperson during each month from all or certain specified securities.

The Commission has determined to eliminate this requirement in response to a variety of strong objections. Commenters, argued, for example, that the proposed disclosure would be of limited or no value to investors, would represent significant compliance problems, or could be easily misused by salespersons to create a misleading impression.[186] Another comment noted that if the salesperson transferred to another broker-dealer, that firm would not be in a position to verify the amount of compensation paid by the previous employer.[187] Although the Commission recognizes that, depending on the compensation policies of a particular broker-dealer, the disclosure of fixed percentage compensation that is determined at the time of a trade may not completely disclose the salesperson's financial interest in that transaction, the Commission has determined that these concerns are outweighed by the practical compliance costs and difficulties that would be entailed by requiring more extensive information and by the potential that customer confusion or misuse of the information could result.

However, the Commission recognizes that "grid" or other contingent compensation arrangements may strongly motivate a salesperson's sales activities and recommendations.[188] Where the salesperson's financial interest is partly attributable to contingent payments that will be determined after the transaction, customers should be alerted to this fact in order that the disclosure required by paragraph (a)(1) will not be misleading. Accordingly, paragraph (c) of the rule requires that in such circumstances the confirmation disclosure required by the rule must indicate that contingent compensation may be paid to the salesperson in connection with the transaction and describe the basis upon which such compensation will be determined. This disclosure will serve to inform customers who wish to obtain more precise information of the need to inquire of the broker-dealer for the information. In addition, the Commission wishes to emphasize that false or misleading statements concerning compensation arrangements may violate the general antifraud provisions of the federal securities laws and that the rule does not limit or affect any affirmative obligation arising under those provisions to disclose in appropriate circumstances compensation arrangements that are not specifically covered by Rule 15g–5.[189]

G. Disclosure Procedures for Rules 15g–3, 15g–4, and 15g–5

Section 15(g)(3)(A) of the Exchange Act requires a broker-dealer effecting penny stock transactions "to disclose to each customer, prior to effecting any transaction in, and at the time of confirming any transaction with respect to any penny stock" certain information with respect to quotations, broker-dealer compensation, and associated person compensation at two different points in time.[190]

1. Description of Procedures Under the Rules

Pursuant to this provision of the Penny Stock Act, Rules 15g–3, 15g–4, and 15g–5 require a broker-dealer effecting penny stock transactions that are not exempted under Rule 15g–1 to disclose to its customers the required information at two different points in time. The initial disclosure must be given to the customer by the broker-dealer orally or in writing, prior to effecting any transaction in a penny stock. The second point at which disclosure must be made is by written confirmation to the customer. Rules 15g–3, 15g–4, and 15g–5 require broker-dealers to provide written disclosure of the information required thereunder prior to or at the time of providing customers the confirmation disclosure required under Rule 10b–10 of the Exchange Act.[191] The inclusion of the information required under Rules 15g–3, 15g–4, and 15g–5 on the Rule 10b–10 confirmation, or together with such confirmation, would comply with this requirement.

In addition, Rules 15g–3, 15g–4, and 15g–5 require the broker-dealer, at the time of making the pre-trade disclosure required under those rules to make and preserve, as part of its records, a record of such disclosure for the period specified in Rule 17a–4(b) under the Exchange Act.

2. Changes From Proposed Procedures

The timing provisions in the rules as proposed contained an exemption from the pre-trade disclosure requirement of the Penny Stock Act, provided that the broker-dealer satisfied certain conditions set forth in the exemption. Under the exemption, the broker-dealer would have been required to provide the required disclosure promptly after effecting the securities transaction, if at the time the broker-dealer provided this information, it informed the customer that the customer had the unconditional right to cancel the transaction until the end of the following business day. The broker-dealer could not attach any fee or penalty to the customer's exercise of the right of cancellation, or discourage the customer from exercising the right. In addition, the proposed rules required broker-dealers using the exemption to inform the customer in the written disclosure at the time of the confirmation that the customer had the right to cancel the transaction, that the broker-dealer has previously informed the customer of this right orally or in writing, and that the customer had not exercised this right.

The Commission requested comment on whether the proposed exemption offered protection to customers equivalent to pre-trade disclosure, and whether it would assist broker-dealers in satisfying their requirements under the rules. The Commission also requested comment whether allowing broker-dealers to provide the required information orally in the pre-trade

[185] 56 FR 19188.

[186] *E.g.*, Paulson Investment Company, Inc.

[187] RAF Financial Corporation.

[188] *See Report of the Special Study of the Securities Markets of the SEC* (1963), *reprinted in* H.R. Doc. No. 96, 88th Cong. 1st Sess. Part I 260–1.

[189] *See* Proposing Release, 56 FR 19187, n. 176 and accompanying text.

[190] 15 U.S.C. 78*o*(g)(3)(A). See Sections III.D, III.E, and III.F of this release.

[191] 17 CFR 240.10b–10. The confirmation must be provided "at or before completion" of the transaction. See 17 CFR 240.10b–10(a).

disclosure or under the exemption would provide adequate protection to customers.

Comments from both consumer organizations and the securities industry heavily criticized the provision exempting broker-dealers from the pre-trade requirement. Consumer groups believed that the exemption would greatly diminish the value of the disclosures to investors in penny stock. Comments from the securities industry focused on the procedural difficulties that would arise in complying with the requirements of the exemption.[192] Comments also were critical of providing broker-dealers with the option of oral, as opposed to written, disclosure, in either the pre-trade statement or the post-trade statement that would begin the customer's cancellation period under the exemption.[193]

The Commission agrees that the exemptive provision, with the right of cancellation, could prove to be difficult in application, and therefore has eliminated it from Rules 15g–3 through 15g–5 as adopted. The Commission had proposed the exemption principally to reduce the burden that it believed pre-trade disclosure would have imposed on firms actively engaged in the penny stock market. In reviewing written comments submitted to the Commission, and on the basis of staff discussions with broker-dealers, the Commission has concluded that pre-trade disclosure is feasible for broker-dealers because the required information is known by the firm's trading department, and thus is generally ascertainable by salespersons before a trade occurs.

Moreover, the Commission believes that the customer cancellation provision either could be the subject of broker-dealer abuse, or would be only infrequently used. On the one hand, some firms might rely on the exemption in order to avoid providing customers the required information. For example, the complexity of the exemptive provision could provide an opportunity for confusing customers. On the other hand, most broker-dealers would probably not regularly use the exemption because of the risks from the customer cancellation option.[194]

In response to the comments' generally critical view of oral, as opposed to written, pre-trade disclosure, the Commission has decided that such disclosure still may be given orally, but that the broker-dealer must make and preserve, as part of its records, a record of the facts and contents of the disclosure for the period specified in Rule 17a–4(b).[195] This would create an evidentiary record on behalf of both the broker-dealer and its customer, and, in addition, would facilitate the Commission's efforts, by inspection, to monitor compliance with the pre-trade disclosure requirement of Rules 15g–3, 15g–4, and 15g–5.

H. Rule 15g–6: Monthly Account Statements

Section 15(g)(3)(B) of the Exchange Act requires the Commission to adopt a rule to

> Require brokers and dealers to provide, to each customer whose account with the broker or dealer contains penny stocks, a monthly statement indicating the market value of the penny stocks in that account or indicating that the market value of such stock cannot be determined because of the unavailability of firm quotes * * *.

Rule 15g–6 requires a broker or dealer holding in a customer's account a penny stock, which was sold by the broker-dealer to the customer in a nonexempt transaction, to provide a monthly account statement containing specified information with respect to each penny stock held in the customer's account. The statement must be given or sent within ten days following the end of the month. Because the rule applies also to successors, any firm that acquires the business of a broker-dealer that has sold a penny stock to a customer will remain obligated to provide the monthly statements, unless the successor is separately exempted under Rule 15g–1. Rule 15g–6 and the statutory provision quoted above are intended to deter fraud and expand the availability to investors of information concerning the current market value of penny stock holdings.[196]

The account statement requirement is triggered by purchase transactions for a customer by a broker-dealer acting in either an agency or a principal capacity, unless the transaction is exempt under Rule 15g–1. Because Rule 15g–1 exempts transactions between broker-dealers, for example, the account statement requirement would not arise from solely interdealer transactions.[197]

The rule applies to firms that sell penny stocks directly to their customers, rather than to broker-dealers that provide clearing services only in connection with penny stock transactions. Introducing firms may delegate their responsibility to provide the statements required by the rule to another broker-dealer with whom they have clearing arrangements, but in each case the introducing firm remains responsible for the fulfillment of the obligation.[198]

The determination of whether a security is a penny stock for purposes of the rule is made on the last trading day of each monthly period. Paragraph (a) of the rule as adopted has been reworded to clarify this point. Paragraph (c) of the rule provides that the price of a security on a particular trading day for purposes of the rule is made at the close of business and in accordance with Rule 3a51–1(d).[199] Accordingly, a monthly statement would not be required for a security if the price of the security, based on the pricing provisions of Rule 3a51–1(d)(1), at the close of business on the last trading day of the month, is at least five dollars.[200]

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[192] For example, one comment raised the issue whether the exemptive provision required the post-trade written confirmation to state that the customer had not in fact exercised its right of cancellation due to expiration of the cancellation period, or that the customer had waived such right. If the former, the broker-dealer would have to wait until the end of the cancellation period to send the disclosure, which, if included in the confirmation pursuant to Rule 10b–10, could run afoul of the requirements of Regulation T under the Exchange Act. See 17 CFR 220.18.

Another comment argued that the right of cancellation would make compliance with Rules 15c3–1 and 15c3–3 difficult. See 17 CFR 240.15c3–1, 240.15c3–3.

[193] Comments from both consumer groups and the securities industry said that permitting oral disclosure would raise difficult evidentiary problems and that customers should have a record of the disclosure. One counsel for a broker-dealer argued that, as a legal matter, written disclosure would be required, such as notice to a customer through expedited mail delivery, but that such a procedure would be costly.

[194] The SIA stated that customers should not be given a right of cancellation because a price decline in a penny stock would induce a high rate of cancellation.

[195] 17 CFR 240.17a–4(b).

[196] Proposing Release, 56 FR 19191.

[197] The effect of the exemptions provided by Rule 15g–1 on the account statement requirement has been clarified by excluding, in paragraph (a) of Rule 15g–6, transactions that are exempt under Rule 15g–1 from the customer sale transactions that give rise to the account statement requirement.

[198] Proposing Release, 56 FR 19190.

[199] Under Rule 3a51–1(d)(1)(ii), a security is priced, other than in connection with a particular transaction, based on inside bid quotations on specified automated quotation systems or bid quotations on other interdealer quotation systems. Accordingly, if there is an inside bid quotation for the security at the close of business on the last trading day of the month, the price of the security on that day would be based on that quotation. In the absence of an inside bid quotation, the price would be based on at least three published interdealer bid quotations on the last trading day. In the absence of either an inside bid quotation or at least three interdealer bid quotations, the security would be deemed not to have a price of at least five dollars per share on that day. See section III.A.3.b.

[200] These provisions determine whether a broker-dealer must provide the market value information required by Rule 15g–6 concerning a particular security, with respect to a particular month. Although market value information is not being

Continued

In response to a request for comment, the ABA suggested that ten days was an appropriate period within which to compile and deliver the statements. In addition, several broker-dealers that now provide account statements to some or all of their customers indicated informally to the staff that these statements are provided within this ten-day period.

Under paragraph (b) of the rule, broker-dealers are granted exemptions under two different circumstances. These exemptions exist in addition to the more comprehensive exemptions contained in Rule 15g–1.[201] First, under paragraph (b)(1), if a broker-dealer does not effect any transactions in penny stocks for or with the account of the customer for a period of six consecutive months, then following that period, the broker-dealer would not be required to provide monthly statements for each consecutive quarterly period [202] in which it effects no penny stock transactions for the customer. Instead, the broker-dealer would provide statements on a quarterly basis, within ten days following the quarter-end, for each quarterly period to which the statement relates. In other words, paragraph (b)(1) provides that if there has not been any penny stock activity in a customer's account for a period of six months, the broker-dealer thereafter may send statements on a quarterly rather than monthly basis for so long as no further penny stock transactions for the customer are effected.[203]

In addition, paragraph (b)(2) provides an exemption to account for temporary price fluctuations. It permits a broker-dealer to omit sending monthly statements with respect to a security that has a price of five dollars or more on all but five or fewer trading days of any quarterly period. In such circumstances, the broker-dealer is not required to send monthly statements with respect to that security for the following quarter and each subsequent quarter, for so long as the security continues to achieve the five dollar price threshold on the last trading day of each such quarter. Pursuant to paragraph (c), each price determination is made at the close of business on each relevant trading day in accordance with Rule 3a51–1(d), as discussed above.

This exemption may be illustrated by the following example relating to a broker-dealer holding in a customer's account a penny stock that the broker-dealer sold to the customer in a nonexempt transaction. If the security is priced at or above five dollars per share on all but five trading days of the quarter from January through March 1993, the broker-dealer is not required to send monthly statements during the April–June quarter. However, if the security is priced below five dollars per share on June 30, 1993, which is the last trading day of that quarter, the exemption will no longer be available, and the broker-dealer's obligation to provide monthly statements will resume, beginning with July 1993.

This last exemption was not contained in the proposed rule.[204] The exemption has been added largely in response to comments relating to compliance burdens associated with the movement of stocks in and out of the penny stock definition based on price within short periods of time. Where a penny stock consistently has traded above the five dollar floor over a three-month period, the Commission believes that there is less need for customers to be informed of price changes in the security on an ongoing basis and less justification for subjecting broker-dealers to the responsibility of providing monthly statements. In such circumstances, for purposes of tracking their responsibility to provide monthly statements, broker-dealers will need to monitor the price of the security on the final trading day of each succeeding quarter. Accordingly, subsequent price declines in the security may give rise to a renewed monthly statement obligation.

Under paragraph (d), each statement must disclose (i) the identity and number of shares of each penny stock for which the statement is required and (ii) the estimated market value of each of these securities, based on prescribed methods of calculation. As proposed, the rule would have required disclosure of the dates of purchase and purchase prices paid by the customer, inclusive of commissions or commission equivalents. In response to a specific request for comment, several comments supported requiring disclosure of both the amount paid, including mark-ups or commissions, as well as separate disclosure of such amounts. However, the ABA stated that this requirement would duplicate information already contained on customer confirmations [205] and that technical difficulties would arise when shares were purchased in a series of transactions or were transferred from other firms and commingled with shares purchased by the broker-dealer for the customer. As adopted, Rule 15g–6 does not require disclosure of historical purchase price information. This change will serve to simplify the information requirements without significantly compromising the information needs of customers, particularly in view of the fact that they can independently preserve this information. Moreover, the Commission understands that most firms that currently provide account statements do not provide this historical profile.

The calculation of estimated market value is predicated on the availability of one of two different types of price information. First, if there is an inside bid quotation for the security on a Qualifying Electronic Quotation System, such as the Bulletin Board, on the last trading day of the statement period, the estimated market value is equal to the highest inside bid quotation on such date, multiplied by the number of shares or units of the security in the account. Under paragraph (g)(2), in order for an "inside bid quotation" for a security to exist, at least two market makers in the security must be contemporaneously displaying, on a Qualifying Electronic Quotation System, bid and offer quotations for the security at specified prices. Where these conditions exist, the inside bid quotation is the highest bid quotation displayed on the system by a market maker. This use of inside bid quotations to calculate market value is consistent with the pricing provisions of Rule 3a51–1. [206]

Where the characterization of a security as a penny stock or the availability of an exemption from the rule's requirements depends on the pricing provisions of the rule and Rule 3a51–1, which require the existence of sufficient interdealer bid quotations, the Rules require that these quotations be *bona fide* and not made for purposes of evading compliance with the Rules.[207] Circumstances may indicate that this is not the case. For example, if a broker-dealer that otherwise would be required

required for other securities excluded or exempted from Rule 15g–6, the Commission believes that such securities should be included on the periodic statement, even absent market value disclosure. Indeed, when a firm provides periodic account statements, pursuant to the rule or otherwise, the Commission believes that it could be misleading for the firm to fail to list all of the securities that are held in the customer's account.

[201] See section III.B, *supra*.

[202] The term "quarterly period" is defined in paragraph (f)(1) of the rule as any period of three consecutive full calendar months.

[203] See the example in the Proposing Release, 56 FR at 19190.

[204] The exemption contained in paragraph (b)(1) was incorporated in the proposed rule as paragraph (a)(1). The proposed exemption from Rule 15g–6 for securities of issuers with specified net tangible assets is not necessary because these securities are now excluded from the penny stock definition.

[205] See 17 CFR 240.10b–10.

[206] See section III.A.3.

[207] See discussion at section III.A.3.b.

to send account statements relating to a security, or an affiliate, entered or published bid quotations for the security only at the end of monthly or quarterly periods, or if, on a recurring basis, its end-of-period quotations were substantially higher than the quotations of other dealers or its own quotations made at other times, the Commission believes that such circumstances would create a strong inference that the quotations were not *bona fide*.

If there is no inside bid quotation for the security on the last day of the statement period, under paragraph (d)(2)(ii), the estimated value is equal to the weighted average price per share paid by the broker-dealer furnishing the statement in all Qualifying Purchases made during the last five trading days of the statement period, if the broker-dealer has made at least ten Qualifying Purchases during that five day period. The term Qualifying Purchases is defined by paragraph (g)(4) to mean *bona fide* purchases, each of which involves at least 100 shares, by the broker-dealer for its own account.

Block purchases involving more than 1% of the outstanding shares or units are excluded from the definition of Qualifying Purchases. The proposed rule would have excluded only those block purchases exceeding 5% of the outstanding shares. The Commission has determined that the 1% exclusion will more appropriately realize the purpose of avoiding, in calculating market value, the distorting effect of transactions of inordinate size on price. [208]

If an estimated market value cannot be provided for a statement period because of the absence of an inside bid quotation or Qualifying Purchases, the statement must show that there is "no estimated market value" for the security. The absence of an estimated market value would be explained in the prescribed legend required by paragraph (e).

The proposed rule would have required the calculation of market value based on Qualifying Purchases, or if this information were not available, based on at least three Qualifying Bids during the last five days of the statement period. Qualifying Bids were defined as *bona fide*, interdealer bid quotations entered in an interdealer quotation system by market makers acting independently of each other and the broker-dealer furnishing the statement.

[208] Compare paragraph (a)(14) of Rule 10b–18 under the Exchange Act, defining the term "block" for purposes of that rule's restrictions on issuer repurchases.

The Commission solicited comment on the costs that would be entailed in calculating market value and providing the account statements generally. Some comments criticized the cost of presenting a market value according to the proposed formulation, particularly in light of the fact that it would require calculations based on information that would not be available electronically and so would hinder the use of computer-generated statements. These comments suggested that this factor would cause broker-dealers to depart from current practice in providing account statements, which usually are generated by "computer feed" pursuant to an arrangement with a proprietary pricing service.

As described above, paragraph (d) permits firms to provide account statement information based on automated quotation information to the extent that it is available. [209] The Commission believes that this provision will simplify the burden and lessen the costs of complying with Rule 15g-6 and will further encourage the use of automated quotation systems for penny stocks, which may permit more effective surveillance of market activities by broker-dealers. In addition, the Penny Stock Act and section 17B of the Exchange Act [210] reflect a clear policy in favor of the development of such systems. [211]

Where these quotations are not available, the calculation of market value based on the firm's own Qualifying Purchases will permit the pricing of these securities based on information that is readily available to the broker-dealer. Further, in the absence of reliable current quotations, the prices of recent purchases by the broker-dealer furnishing the statement may provide a more reliable indicator of value to the investor than published quotation sheets, which are not binding and may reflect only indications of interest. [212]

Paragraph (e) requires that each account statement contain a legend containing prescribed language. In general, the legend states that: (i) Any estimated values contained in the statement are based on limited trades or quotes and that the customer may not be able to dispose of the securities at a price equal or near to the value indicated; (ii) the broker-dealer furnishing the statement may not refuse to accept the customer's order to sell the securities; (iii) the amount received by a customer pursuant to a sale generally will be reduced by the amount of commissions or similar charges; and (iv) if an estimated value is not provided for a particular security, such value could not be determined because of a lack of information. The legend is intended to provide perspective to investors who receive these statements and to explain the information contained in the statements.

Commenters generally supported the inclusion of a legend, although several suggested modifications. The prescribed legend has been modified in response to suggestions that it be more concise and readily understandable to unsophisticated investors. The ABA and Shearson Lehman Brothers also suggested that the legend should be permitted to be contained on the back of account statements. The Commission notes that the rule does not prescribe the placement of the legend within the account statement but does require that it be "conspicuous." In order to be considered conspicuous, the legend should contain large or otherwise distinguishable type that serves to set it apart from the other information contained in the statement. [213]

Paragraph (f) of the Rule 15g–6 requires broker-dealers furnishing account statements to maintain copies of the account statements required by paragraph (a) of the rule and to keep such records for the periods specified in 17 CFR 240.17a–4(b).

I. Proposed Rule 15g–7: Sole Market Maker Status

Proposed Rule 15g–7 would have required that, where a broker-dealer, or an affiliate, is a sole market maker with respect to a penny stock, the broker-dealer must disclose this fact to its customer and the broker-dealer or its affiliate's influence over the market for the security, prior to effecting any transaction in the security for the customer's account and in writing at or prior to the sending of the trade confirmation. In addition, proposed Rule 15g–7 also would have expressly prohibited certain representations by a market maker of a penny stock or an affiliate that effects a transaction in the security with a customer that the transaction is being effected "at the market" or a price related to the market price, unless the broker-dealer had reasonable grounds to believe that an

[209] The NASD suggested that estimated market value be based on the inside bid quotation on the Bulletin Board or in the absence thereof, the highest of three bid quotations obtained from other dealers at the end of each month.

[210] 15 U.S.C. 78q–2.

[211] House Report 31–33.

[212] See Proposing Release, 56 FR 19191.

[213] See Proposing Release, 56 FR 19192, n. 194 and accompanying text.

independent market for the security existed. These provisions were not mandated by the Penny Stock Act but were proposed under the general rulemaking authority granted by section 15(g)(5) [214] of the Exchange Act.

Rule 15g–7 was proposed as a means of addressing the special problems associated with the control of the market for a penny stock by a single firm. In proposing the rule, the Commission recognized the nexus between the existence of a sole market maker and many of the worst abuses identified by Congress in its consideration of the Penny Stock Act.[215]

A majority of the comments that specifically addressed proposed Rule 15g–7 were generally supportive.[216] Other comments expressed concern that compliance would be difficult because firms may move in or out of market maker status with respect to particular issues on an intermittent basis and that the rule would discourage firms from becoming sole market makers for thinly-traded issues.[217]

Although the Commission continues to believe that the requirements of the proposed rule may be useful, in light of the substantial other requirements imposed by the Rules that are mandated by the Penny Stock Act, the Commission has determined to defer action on proposed Rule 15g–7 until experience has been gained with those Rules. However, the Commission wishes to emphasize that manipulative trading by sole market makers or others is violative of existing general antifraud provisions, that representations by broker-dealers to their customers relating to market price may run afoul of these provisions where no independent market exists, and that these provisions may require that a dealer acting as a sole market maker disclose its status to customers in particular circumstances.[218]

J. Rule 15c2–6

As discussed previously, Rule 15c2–6 was designed to address high pressure sales of low-priced securities to new customers. The rule requires that broker-dealers selling "designated securities" to new customers obtain financial information from the customer, make a written suitability determination concerning the customer's purchase of designated securities, obtain the customer's signature on this statement, and obtain the customer's written agreement to the trade, before the trade is effected.

Although the definition of designated security is similar in scope to the definition of penny stock in the Rules, there are certain differences in these definitions. To avoid any unnecessary burden on those broker-dealers that must comply with both sets of rules in the low-priced securities market, the Commission intends to propose amendments, as needed, to conform the definition of designated security in Rule 15c2–6 to the definition of penny stock in Rule 3a51–1.

IV. Conclusion

The Commission is adopting the Rules in order to implement provisions of the Penny Stock Act and to limit fraud in the penny stock market. The Commission solicits comment on the effectiveness of the Rules, taken together, and the effectiveness of particular Rules in preventing fraudulent sales practices, the appropriateness of the various exemptions and exclusions from the penny stock definition contained in the Rules, and the effect of the Rules on the capital-raising ability of viable small issuers. The Commission is particularly interested in the views of commenters with respect to these matters based on practical experience following the effective date.

In particular, with respect to Rule 15g–2, the Commission requests comment on whether the risk disclosure document should be required to be executed and returned by the customer, prior to the customer's first transaction in a penny stock with the broker-dealer, in order to evidence compliance with the rule. The Commission requests comment on whether this provision would further the purposes of the rule without imposing an additional unnecessary compliance burden.

Pursuant to section 4(c) of the Administrative Procedure Act ("APA"),[219] publication of Rules 3a51–1 and 15g–1 may not be made less than thirty days before their effective date, absent good cause. Certain provisions of the Penny Stock Reform Act become effective on April 15, 1992. In order to provide exemptive relief with respect to these provisions and in order to effectively implement the Commission's new barring authority under section 15(b)(6) of the Exchange Act, Rules 3a51–1 and 15g–1 shall become effective upon publication in the **Federal Register**, based on the Commission's finding of good cause.

The effective date of Rule 15g–2 is July 15, 1992. This three-month period will allow sufficient time to enable broker-dealers to prepare and distribute the risk disclosure document to branch offices. The effective date of Rules 15g–3 through 15g–6 is January 1, 1993. During discussions on the proposed rules, broker-dealers generally indicated that they would need a minimum of six months to make the necessary adjustments.

V. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a) of the Exchange Act [220] requires that the Commission, in adopting rules under the Exchange Act, consider the anticompetitive effects of such rules, if any, and balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission is of the view that the Rules will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[221] regarding the Rules. A copy of the FRFA may be obtained from Alexander Dill, Attorney, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5–1, Washington, DC 20549, (202) 504–2418.

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

VI. Statutory Basis and Text of Amendments

In accordance with the foregoing, the Commission is amending title 17,

[214] 15 U.S.C. 78*o*(g)(5).

[215] See Proposing Release, 56 FR 19193–19194.

[216] The NASD suggested requiring disclosure, in addition to the matters covered by the proposed rule, of the risks that would result if the market maker terminated its market making activities and the general invalidity of "at the market representations" by firms that control the market.

[217] In addition, IDS Financial Services, which is a member of a large corporate family of affiliated companies, indicated that the proposed rule would pose compliance difficulties for large financial services companies with many affiliations and that procedures would need to be developed to determine if any affiliate was a sole market maker for any penny stock. Smith New Court, a market maker for securities of certain foreign issuers and American Depositary Receipts, indicated that it frequently is unaware if there are other market makers for a particular security and that, in any event, it does not exercise substantial control over the market for these securities.

[218] It is well established that broker-dealers may be liable under the antifraud provisions for failure to disclose to customers their status as market makers. *See Chasins* v. *Smith Barney & Co., Inc.*, 438 F.2d 1167 (2d Cir. 1970) and Proposing Release, 56 FR 19194, n. 202 and accompanying text.

[219] 5 U.S.C. 551 *et seq.*

[220] 15 U.S.C. 78w(a).

[221] 5 U.S.C. 604.

chapter II of the Code of Federal Regulations as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a–29, 80a–37, unless otherwise noted.

2. By adding § 240.3a51–1 to read as follows:

§ 240.3a51–1 Definition of penny stock.

For purposes of section 3(a)(51) of the Act, the term "penny stock" shall mean any equity security other than a security:

(a) That is a reported security, as defined in 17 CFR 240.11Aa3–1(a) of this chapter;

except that a security that is registered on the American Stock Exchange, Inc. pursuant to the listing criteria of the Emerging Company Marketplace, but that does not otherwise satisfy the requirements of paragraphs (b), (c), or (d) of this section, shall be a penny stock for purposes of section 15(b)(6) of the Act;

(b) That is issued by an investment company registered under the Investment Company Act of 1940;

(c) That is a put or call option issued by the Options Clearing Corporation;

(d) That has a price of five dollars or more;

(1) For purposes of paragraph (d) of this section:

(i) A security has a price of five dollars or more for a particular transaction if the security is purchased or sold in that transaction at a price of five dollars or more, excluding any broker or dealer commission, commission equivalent, mark-up, or mark-down; and

(ii) Other than in connection with a particular transaction, a security has a price of five dollars or more at a given time if the inside bid quotation is five dollars or more; *provided, however,* that if there is no such inside bid quotation, a security has a price of five dollars or more at a given time if the average of three or more interdealer bid quotations at specified prices displayed at that time in an interdealer quotation system, as defined in 17 CFR 240.15c2–7(c)(1), by three or more market makers in the security, is five dollars or more.

(iii) The term "inside bid quotation" shall mean the highest bid quotation for the security displayed by a market maker in the security on an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(2) If a security is a unit composed of one or more securities, the unit price divided by the number of shares of the unit that are not warrants, options, rights, or similar securities must be five dollars or more, as determined in accordance with paragraph (d)(1) of this section, and any share of the unit that is a warrant, option, right, or similar security, or a convertible security, must have an exercise price or conversion price of five dollars or more;

(e) That is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available pursuant to 17 CFR 240.11Aa3–1 of this chapter, provided that:

(1) Price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the national securities exchange; and

(2) The security is purchased or sold in a transaction that is effected on or through the facilities of the national securities exchange, or that is part of a distribution of the security;

except that a security that satisfies the requirements of this paragraph, but that does not otherwise satisfy the requirements of paragraphs (a), (b), (c), or (d) of this section, shall be a penny stock for purposes of Section 15(b)(6) of the Act;

(f) That is authorized, or approved for authorization upon notice of issuance, for quotation in the National Association of Securities Dealers' Automated Quotation system (NASDAQ), provided that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the National Association of Securities Dealers, Inc.;

except that a security that satisfies the requirements of this paragraph, but that does not otherwise satisfy the requirements of paragraphs (a), (b), (c), or (d) of this section, shall be a penny stock for purposes of section 15(b)(6) of the Act; or

(g) Whose issuer has:

(1) Net tangible assets (*i.e.*, total assets less intangible assets and liabilities) in excess of $2,000,000, if the issuer has been in continuous operation for at least three years, or $5,000,000, if the issuer has been in continuous operation for less than three years; or

(2) Average revenue of at least $6,000,000 for the last three years.

(3) For purposes of paragraph (g) of this section, net tangible assets or average revenues must be demonstrated by financial statements dated less than fifteen months prior to the date of the transaction that the broker or dealer has reviewed and has a reasonable basis for believing are accurate in relation to the date of the transaction, and:

(i) If the issuer is other than a foreign private issuer, are the most recent financial statements for the issuer that have been audited and reported on by an independent public accountant in accordance with the provisions of 17 CFR 210.2–02; or

(ii) If the issuer is a foreign private issuer, are the most recent financial statements for the issuer that have been filed with the Commission or furnished to the Commission pursuant to 17 CFR 240.12g3–2(b); *provided, however,* that if financial statements for the issuer dated less than fifteen months prior to the date of the transaction have not been filed with or furnished to the Commission, financial statements dated within fifteen months prior to the transaction shall be prepared in accordance with generally accepted accounting principles in the country of incorporation, audited in compliance with the requirements of that jurisdiction, and reported on by an accountant duly registered and in good standing in accordance with the regulations of that jurisdiction.

(4) The broker or dealer shall preserve, as part of its records, copies of the financial statements required by paragraph (g)(3) of this section for the period specified in 17 CFR 240.17a–4(b).

3. By adding § 240.15g–1 to read as follows:

§ 240.15g–1 Exemptions for certain transactions.

The following transactions shall be exempt from 17 CFR 240.15g–2, 17 CFR 240.15g–3, 17 CFR 240.15g–4, 17 CFR 240.15g–5, and 17 CFR 240.15g–6:

(a) Transactions by a broker or dealer:

(1) Whose commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, or during the immediately preceding six months, did not exceed five percent of its total

commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months; and

(2) Who has not been a market maker in the penny stock that is the subject of the transaction in the immediately preceding twelve months.

Note: Prior to April 28, 1993, commissions, commission equivalents, mark-ups, and mark-downs from transactions in designated securities, as defined in 17 CFR 240.15c2-6(d)(2) as of April 15, 1992, may be considered to be commissions, commission equivalents, mark-ups, and mark-downs from transactions in penny stocks for purposes of paragraph (a)(1) of this section.

(b) Transactions in which the customer is an institutional accredited investor, as defined in 17 CFR 230.501(a)(1), (2), (3), (7), or (8).

(c) Transactions that meet the requirements of Regulation D (17 CFR 230.501-230.508), or transactions with an issuer not involving any public offering pursuant to section 4(2) of the Securities Act of 1933.

(d) Transactions in which the customer is the issuer, or a director, officer, general partner, or direct or indirect beneficial owner of more than five percent of any class of equity security of the issuer, of the penny stock that is the subject of the transaction.

(e) Transactions that are not recommended by the broker or dealer.

(f) Any other transaction or class of transactions or persons or class of persons that, upon prior written request or upon its own motion, the Commission conditionally or unconditionally exempts by order as consistent with the public interest and the protection of investors.

4. By adding § 240.15g-2 to read as follows:

§ 240.15g-2 Risk disclosure document relating to the penny stock market.

It shall be unlawful for a broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless, prior to effecting such transaction, the broker or dealer has furnished to the customer a document containing the information set forth in Schedule 15G, 17 CFR 240.15g-100.

5. By adding section 240.15g-3 to read as follows:

§ 240.15g-3 Broker or dealer disclosure of quotations and other information relating to the penny stock market.

(a) *Requirement.* It shall be unlawful for a broker or dealer to effect a transaction in any penny stock with or for the account of a customer unless such broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the following information:

(1) The inside bid quotation and the inside offer quotation for the penny stock.

(2) If paragraph (a)(1) of this section does not apply because of the absence of an inside bid quotation and an inside offer quotation:

(i) With respect to a transaction effected with or for a customer on a principal basis (other than as provided in paragraph (a)(2)(ii) of this section):

(A) The dealer shall disclose its offer price for the security:

(1) If during the previous five days the dealer has effected no fewer than three *bona fide* sales to other dealers consistently at its offer price for the security current at the time of those sales, and

(2) If the dealer reasonably believes in good faith at the time of the transaction with the customer that its offer price accurately reflects the price at which it is willing to sell one or more round lots to another dealer. For purposes of paragraph (a)(2)(i)(A) of this section, "consistently" shall constitute, at a minimum, seventy-five percent of the dealer's *bona fide* interdealer sales during the previous five-day period, and, if the dealer has effected only three *bona fide* inter-dealer sales during such period, all three of such sales.

(B) The dealer shall disclose its bid price for the security:

(1) If during the previous five days the dealer has effected no fewer than three *bona fide* purchases from other dealers consistently at its bid price for the security current at the time of those purchases, and

(2) If the dealer reasonably believes in good faith at the time of the transaction with the customer that its bid price accurately reflects the price at which it is willing to buy one or more round lots from another dealer. For purposes of paragraph (a)(2)(i)(B) of this section, "consistently" shall constitute, at a minimum, seventy-five percent of the dealer's *bona fide* interdealer purchases during the previous five-day period, and, if the dealer has effected only three *bona fide* inter-dealer purchases during such period, all three of such purchases.

(C) If the dealer's bid or offer prices to the customer do not satisfy the criteria of paragraphs (a)(2)(i)(A) or (a)(2)(i)(B) of this section, the dealer shall disclose to the customer:

(1) That it has not effected inter-dealer purchases or sales of the penny stock consistently at its bid or offer price, and

(2) The price at which it last purchased the penny stock from, or sold the penny stock to, respectively, another dealer in a *bona fide* transaction.

(ii) With respect to transactions effected by a broker or dealer with or for the account of the customer:

(A) On an agency basis or

(B) On a basis other than as a market maker in the security, where, after having received an order from the customer to purchase a penny stock, the dealer effects the purchase from another person to offset a contemporaneous sale of the penny stock to such customer, or, after having received an order from the customer to sell the penny stock, the dealer effects the sale to another person to offset a contemporaneous purchase from such customer, the broker or dealer shall disclose the best independent interdealer bid and offer prices for the penny stock that the broker or dealer obtains through reasonable diligence. A broker-dealer shall be deemed to have exercised reasonable diligence if it obtains quotations from three market makers in the security (or all known market makers if there are fewer than three).

(3) With respect to bid or offer prices and transaction prices disclosed pursuant to paragraph (a) of this section, the broker or dealer shall disclose the number of shares to which the bid and offer prices apply.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b-10 of this chapter.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a-4(b).

(c) *Definitions.* For purposes of this section:

(1) The term *bid price* shall mean the price most recently communicated by the dealer to another broker or dealer at which the dealer is willing to purchase one or more round lots of the penny stock, and shall not include indications of interest.

(2) The term *offer price* shall mean the price most recently communicated by the dealer to another broker or dealer at which the dealer is willing to sell one or

more round lots of the penny stock, and shall not include indications of interest.

(3) The term *inside bid quotation* for a security shall mean the highest bid quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(4) The term *inside offer quotation* for a security shall mean the lowest offer quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(5) The term *Qualifying Electronic Quotation System* shall mean an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section.

6. By adding § 240.15g–4 to read as follows:

§ 240.15g–4 Disclosure of compensation to brokers or dealers.

Preliminary Note: Brokers and dealers may wish to refer to Securities Exchange Act Release No. 30608 (April 20, 1992) for a discussion of the procedures for computing compensation in active and competitive markets, inactive and competitive markets, and dominated and controlled markets.

(a) *Disclosure requirement.* It shall be unlawful for any broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless such broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the aggregate amount of any compensation received by such broker or dealer in connection with such transaction.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b–10.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a–4(b).

(c) *Definition of Compensation.* For purposes of this section, *compensation* means, with respect to a transaction in a penny stock:

(1) If a broker is acting as agent for a customer, the amount of any remuneration received or to be received by it from such customer in connection with such transaction;

(2) If, after having received a buy order from a customer, a dealer other than a market maker purchased the penny stock as principal from another person to offset a contemporaneous sale to such customer or, after having received a sell order from a customer, sold the penny stock as principal to another person to offset a contemporaneous purchase from such customer, the difference between the price to the customer and such contemporaneous purchase or sale price; or

(3) If the dealer otherwise is acting as principal for its own account, the difference between the price to the customer and the prevailing market price.

(d) *"Active and competitive"* market. For purposes of this section only, a market may be deemed to be "active and competitive" in determining the prevailing market price with respect to a transaction by a market maker in a penny stock if the aggregate number of transactions effected by such market maker in the penny stock in the five business days preceding such transaction is less than twenty percent of the aggregate number of all transactions in the penny stock reported on a Qualifying Electronic Quotation System (as defined in 17 CFR 240.15g–3(c)(5)) during such five-day period. No presumption shall arise that a market is not "active and competitive" solely by reason of a market maker not meeting the conditions specified in this paragraph.

7. By adding § 240.15g–5 to read as follows:

§ 240.15g–5 Disclosure of compensation of associated persons in connection with penny stock transactions.

(a) *General.* It shall be unlawful for a broker or dealer to effect a transaction in any penny stock for or with the account of a customer unless the broker or dealer discloses to such customer, within the time periods and in the manner required by paragraph (b) of this section, the aggregate amount of cash compensation that any associated person of the broker or dealer who is a natural person and has communicated with the customer concerning the transaction at or prior to receipt of the customer's transaction order, other than any person whose function is solely clerical or ministerial, has received or will receive from any source in connection with the transaction and that is determined at or prior to the time of the transaction, including separate disclosure, if applicable, of the source and amount of such compensation that is not paid by the broker or dealer.

(b) *Timing.* (1) The information described in paragraph (a) of this section:

(i) Shall be provided to the customer orally or in writing prior to effecting any transaction with or for the customer for the purchase or sale of such penny stock; and

(ii) Shall be given or sent to the customer in writing, at or prior to the time that any written confirmation of the transaction is given or sent to the customer pursuant to 17 CFR 240.10b–10.

(2) A broker or dealer, at the time of making the disclosure pursuant to paragraph (b)(1)(i) of this section, shall make and preserve as part of its records, a record of such disclosure for the period specified in 17 CFR 240.17a–4(b).

(c) *Contingent compensation arrangements.* Where a portion or all of the cash or other compensation that the associated person may receive in connection with the transaction may be determined and paid following the transaction based on aggregate sales volume levels or other contingencies, the written disclosure required by paragraph (b)(1)(ii) of this section shall state that fact and describe the basis upon which such compensation is determined.

8. By adding § 240.15g–6 to read as follows:

§ 240.15g–6 Account statements for penny stock customers.

(a) *Requirement.* It shall be unlawful for any broker or dealer that has effected the sale to any customer, other than in a transaction that is exempt pursuant to 17 CFR 240.15g–1, of any security that is a penny stock on the last trading day of any calendar month, or any successor of such broker or dealer, to fail to give or send to such customer a written statement containing the information described in paragraphs (c) and (d) of this section with respect to each such month in which such security is held for the customer's account with the broker or dealer, within ten days following the end of such month.

(b) *Exemptions.* A broker or dealer shall be exempted from the requirement

of paragraph (a) of this section under either of the following circumstances:

(1) If the broker or dealer does not effect any transactions in penny stocks for or with the account of the customer during a period of six consecutive calendar months, then the broker or dealer shall not be required to provide monthly statements for each quarterly period that is immediately subsequent to such six-month period and in which the broker or dealer does not effect any transaction in penny stocks for or with the account of the customer, *provided* that the broker or dealer gives or sends to the customer written statements containing the information described in paragraphs (d) and (e) of this section on a quarterly basis, within ten days following the end of each such quarterly period.

(2) If, on all but five or fewer trading days of any quarterly period, a security has a price of five dollars or more, the broker or dealer shall not be required to provide a monthly statement covering the security for subsequent quarterly periods, until the end of any such subsequent quarterly period on the last trading day of which the price of the security is less than five dollars.

(c) *Price Determinations.* For purposes of paragraphs (a) and (b) of this section, the price of a security on any trading day shall be determined at the close of business in accordance with the provisions of 17 CFR 240.3a51–1(d)(1).

(d) *Market and price information.* The statement required by paragraph (a) of this section shall contain at least the following information with respect to each penny stock covered by paragraph (a) of this section, as of the last trading day of the period to which the statement relates:

(1) The identity and number of shares or units of each such security held for the customer's account; and

(2) The estimated market value of the security, to the extent that such estimated market value can be determined in accordance with the following provisions:

(i) The highest inside bid quotation for the security on the last trading day of the period to which the statement relates, multiplied by the number of shares or units of the security held for the customer's account; or

(ii) If paragraph (d)(2)(i) of this section is not applicable because of the absence of an inside bid quotation, and if the broker or dealer furnishing the statement has effected at least ten separate Qualifying Purchases in the security during the last five trading days of the period to which the statement relates, the weighted average price per share paid by the broker or dealer in all Qualifying Purchases effected during such five-day period, multiplied by the number of shares or units of the security held for the customer's account; or

(iii) If neither of paragraphs (d)(2)(i) nor (d)(2)(ii) of this section is applicable, a statement that there is "no estimated market value" with respect to the security.

(e) *Legend.* In addition to the information required by paragraph (d) of this section, the written statement required by paragraph (a) of this section shall include a conspicuous legend that is identified with the penny stocks described in the statement and that contains the following language:

If this statement contains an estimated value, you should be aware that this value may be based on a limited number of trades or quotes. Therefore, you may not be able to sell these securities at a price equal or near to the value shown. However, the broker-dealer furnishing this statement may not refuse to accept your order to sell these securities. Also, the amount you receive from a sale generally will be reduced by the amount of any commissions or similar charges. If an estimated value is not shown for a security, a value could not be determined because of a lack of information.

(f) *Preservation of records.* Any broker or dealer subject to this section shall preserve, as part of its records, copies of the written statements required by paragraph (a) of this section and keep such records for the periods specified in 17 CFR 240.17a–4(b).

(g) *Definitions.* For purposes of this section:

(1) The term *Quarterly period* shall mean any period of three consecutive full calendar months.

(2) The *inside bid quotation* for a security shall mean the highest bid quotation for the security displayed by a market maker in the security on a Qualifying Electronic Quotation System, at any time in which at least two market makers are contemporaneously displaying on such system bid and offer quotations for the security at specified prices.

(3) The term *Qualifying Electronic Quotation System* shall mean an automated interdealer quotation system that has the characteristics set forth in section 17B(b)(2) of the Act, or such other automated interdealer quotation system designated by the Commission for purposes of this section.

(4) The term *Qualifying Purchases* shall mean *bona fide* purchases by a broker or dealer of a penny stock for its own account, each of which involves at least 100 shares, but excluding any block purchase involving more than one percent of the outstanding shares or units of the security.

9. By adding § 240.15g–100 to read as follows:

§ 240.15g–100 Schedule 15G—Information to be included in the document distributed pursuant to 17 CFR 240.15g–2.

Securities and Exchange Commission

Washington, DC 20549

Schedule 15G

Under the Securities Exchange Act of 1934

Instructions to Schedule 15G

A. The information contained in Schedule 15G ("Schedule") must be reproduced in its entirety. No language of the document may be omitted, added to, or altered in any way. No material may be given to a customer that is intended in any way to detract from, rebut, or contradict the Schedule.

B. The document entitled "Important Information on Penny Stocks" must be distributed as the first page of Schedule 15G, and on one page only. The remainder of Schedule 15G, entitled "Further Information," explains the items discussed in the first page in greater detail.

C. The disclosures made through the Schedule are in addition to any other disclosure(s) that are required to be made under the federal securities laws, including without limitation the disclosures required pursuant to the rules adopted under Sections 15(c)(1), 15(c)(2), and 15(g) of the Securities Exchange Act of 1934, 15 U.S.C. 78o(c) (1) and (2), and 15 U.S.C. 78o(g), respectively.

D. The format and typeface of the document must be reproduced as presented in the Schedule. The document may be reproduced from the Schedule by photographic copying that is clear, complete, and at least satisfies the type-size requirements set forth below for printing. In the alternative, the document may be printed and must meet the following criteria regarding typeface:

1. Words appearing in capital letters in the Schedule must be reproduced in capital letters and printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded.

2. Words appearing in lower-case letters must be reproduced in lower-case roman type at least as large as ten point modern type and at least two points leaded.

3. Words that are underlined in the document must be underlined in reproduction and appear in bold-faced roman type at least as large as ten point modern type and at least two points leaded, and meet the criteria for lower-case or capital letters in paragraphs (1) and (2) above, whichever is applicable.

E. Recipients of the document must not be charged any fee for the document.

F. The content of the Schedule is as follows:

[next page]

Important Information on Penny Stocks

This statement is required by the U.S. Securities and Exchange Commission (SEC) and contains important information on penny stocks. You are urged to read it before making a purchase or sale.

Penny stocks can be very risky.

• Penny stocks are low-priced shares of small companies not traded on an exchange or quoted on NASDAQ. Prices often are not available. Investors in penny stocks often are unable to sell stock back to the dealer that sold them the stock. Thus, you may lose your investment. Be cautious of newly issued penny stock.

• Your salesperson is not an impartial advisor but is paid to sell you the stock. Do not rely only on the salesperson, but seek outside advice before you buy any stock. If you have problems with a salesperson, contact the firm's compliance officer or the regulators listed below.

Information you should get.

• *Before you buy penny stock,* federal law requires your salesperson to tell you the "*offer*" and the "*bid*" on the stock, and the "*compensation*" the salesperson and the firm receive for the trade. The firm also must mail a confirmation of these prices to you after the trade.

• You will need this price information to determine what profit, if any, you will have when you sell your stock. The offer price is the wholesale price at which the dealer is willing to sell stock to other dealers. The bid price is the wholesale price at which the dealer is willing to buy the stock from other dealers. In its trade with you, the dealer may add a retail charge to these wholesale prices as compensation (called a "markup" or "markdown").

• The difference between the bid and the offer price is the dealer's "*spread.*" A spread that is large compared with the purchase price can make a resale of a stock very costly. To be profitable when you sell, the bid price of your stock must rise above the amount of this spread *and* the compensation charged by both your selling and purchasing dealers. If the dealer has no bid price, you may not be able to sell the stock after you buy it, and may lose your whole investment.

Brokers' duties and customer's rights and remedies.

• If you are a victim of fraud, you may have rights and remedies under state and federal law. You can get the disciplinary history of a salesperson or firm from the NASD at 1–800–289–9999, and additional information from your state securities official, at the North American Securities Administrators Association's central number: (202) 737–0900. You also may contact the SEC with complaints at (202) 272–7440.

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Further Information

The securities being sold to you have not been approved or disapproved by the Securities and Exchange Commission. Moreover, the Securities and Exchange Commission has not passed upon the fairness or the merits of this transaction nor upon the accuracy or adequacy of the information contained in any prospectus or any other information provided by an issuer or a broker or dealer.

Generally, penny stock is a security that:

• Is priced under five dollars;

• Is *not* traded on a national stock exchange or on NASDAQ (the NASD's automated quotation system for actively traded stocks);

• May be listed in the "pink sheets" or the NASD OTC Bulletin Board;

• Is issued by a company that has less than $5 million in net tangible assets and has been in business less than three years, by a company that has under $2 million in net tangible assets and has been in business for at least three years, or by a company that has revenues of $6 million for 3 years.

Use Caution When Investing in Penny Stocks

1. *Do not make a hurried investment decision.* High-pressure sales techniques can be a warning sign of fraud. The salesperson is not an impartial advisor, but is paid for selling stock to you. The salesperson also does not have to watch your investment for you. Thus, you should think over the offer and seek outside advice. Check to see if the information given by the salesperson differs from other information you may have. Also, it is illegal for salespersons to promise that a stock will increase in value or is risk-free, or to guarantee against loss. If you think there is a problem, ask to speak with a compliance official at the firm, and, if necessary, any of the regulators referred to in this statement.

2. *Study the company issuing the stock.* Be wary of companies that have no operating history, few assets, or no defined business purpose. These may be sham or "shell" corporations. Read the prospectus for the company carefully before you invest. Some dealers fraudulently solicit investors' money to buy stock in sham companies, artificially inflate the stock prices, then cash in their profits before public investors can sell their stock.

3. *Understand the risky nature of these stocks.* You should be aware that you may lose part or all of your investment. Because of large dealer spreads, you will not be able to sell the stock immediately back to the dealer at the same price it sold the stock to you. In some cases, the stock may fall quickly in value. New companies, whose stock is sold in an "initial public offering," often are riskier investments. Try to find out if the shares the salesperson wants to sell you are part of such an offering. Your salesperson must give you a "prospectus" in an initial public offering, but the financial condition shown in the prospectus of new companies can change very quickly.

4. *Know the brokerage firm and the salespeople with whom you are dealing.* Because of the nature of the market for penny stock, you may have to rely solely on the original brokerage firm that sold you the stock for prices and to buy the stock back from you. Ask the National Association of Securities Dealers, Inc. (NASD) or your state securities regulator, which is a member of the North American Securities Administrators Association, Inc. (NASAA), about the licensing and disciplinary record of the brokerage firm and the salesperson contacting you. The telephone numbers of the NASD and NASAA are listed on the first page of this document.

5. *Be cautious if your salesperson leaves the firm.* If the salesperson who sold you the stock leaves his or her firm, the firm may reassign your account to a new salesperson. If you have problems, ask to speak to the firm's branch office manager or a compliance officer. Although the departing salesperson may ask you to transfer your stock to his or her new firm, you do not have to do so. Get information on the new firm. Be wary of requests to sell your securities when the salesperson transfers to a new firm. Also, you have the right to get your stock certificate from your selling firm. You do not have to leave the certificate with that firm or any other firm.

Your Rights

Disclosures to you. Under penalty of federal law, your brokerage firm must tell you the following information at two different times—*before* you agree to buy or sell a penny stock, and after the trade, by *written confirmation:*

• *The bid and offer price quotes for penny stock, and the number of shares to which the quoted prices apply.* The *bid* and *offer* quotes are the wholesale prices at which dealers trade among themselves. These prices give you an idea of the market value of the stock. The dealer must tell you these price quotes if they appear on an automated quotation system approved by the SEC. If not, the dealer must use its own quotes or trade prices. You should calculate the *spread,* the difference between the bid and offer quotes, to help decide if buying the stock is a good investment.

A lack of quotes may mean that the market among dealers is not active. It thus may be difficult to resell the stock. You also should be aware that the actual price charged to you for the stock may differ from the price quoted to you for 100 shares. You should therefore determine, before you agree to a purchase, what the actual sales price (before the *markup*) will be for the exact number of shares you want to buy.

• *The brokerage firm's compensation for the trade.* A *markup* is the amount a dealer adds to the wholesale offer price of the stock and a *markdown* is the amount it subtracts from the wholesale bid price of the stock as *compensation.* A markup/markdown usually serves the same role as a broker's commission on a trade. Most of the firms in the penny stock market will be dealers, not brokers.

• *The compensation received by the brokerage firm's salesperson for the trade.* The brokerage firm must disclose to you, as a total sum, the cash compensation of your salesperson for the trade that is known at the time of the trade. The firm must describe in the written confirmation the nature of any other compensation of your salesperson that is unknown at the time of the trade.

In addition to the items listed above, your brokerage firm must send to you:

• *Monthly account statements. In general, your brokerage firm must send you a monthly statement* that gives an estimate of the value of each penny stock in your account, if there is enough information to make an estimate. If the firm has not bought or sold any penny stocks for your account for six months, it can provide these statements every three months.

Legal remedies. If penny stocks are sold to you in violation of your rights listed above, or other federal or state securities laws, you may be able to cancel your purchase and get

your money back. If the stocks are sold in a fraudulent manner, you may be able to sue the persons and firms that caused the fraud for damages. If you have signed an arbitration agreement, however, you may have to pursue your claim through arbitration. You may wish to contact an attorney. The SEC is not authorized to represent individuals in private litigation.

However, to protect yourself and other investors, you should report any violations of your brokerage firm's duties listed above and other securities laws to the SEC, the NASD, or your state securities administrator at the telephone numbers on the first page of this document. These bodies have the power to stop fraudulent and abusive activity of salespersons and firms engaged in the securities business. Or you can write to the SEC at 450 Fifth St., NW., Washington, DC 20549; the NASD at 1735 K Street, NW., Washington, DC 20006; or NASAA at 555 New Jersey Avenue, NW., Suite 750, Washington, DC 20001. NASAA will give you the telephone number of your state's securities agency. If there is any disciplinary record of a person or a firm, the NASD, NASAA, or your state securities regulator will send you this information if you ask for it.

Market Information

The market for penny stocks. Penny stocks usually are not listed on an exchange or quoted on the NASDAQ system. Instead, they are traded between dealers on the telephone in the "over-the-counter" market. The NASD's OTC Bulletin Board also will contain information on some penny stocks. At times, however, price information for these stocks is not publicly available.

Market domination. In some cases, only one or two dealers, acting as "market makers," may be buying and selling a given stock. You should first ask if a firm is acting as a *broker* (your agent) or as a dealer. A *dealer* buys stock itself to fill your order or already owns the stock. A *market maker* is a dealer who holds itself out as ready to buy and sell stock on a regular basis. If the firm is a market maker, ask how many other market makers are dealing in the stock to see if the firm (or group of firms) dominates the market. When there are only one or two market makers, there is a risk that the dealer or group of dealers may control the market in that stock and set prices that are not based on competitive forces. In recent years, some market makers have created fraudulent markets in certain penny stocks, so that stock prices rose suddenly, but collapsed just as quickly, at a loss to investors.

Mark-ups and mark-downs. The actual price that the customer pays usually includes the mark-up or mark-down. Markups and markdowns are direct profits for the firm and its salespeople, so you should be aware of such amounts to assess the overall value of the trade.

The "spread." The difference between the bid and offer price is the spread. Like a mark-up or mark-down, the spread is another source of profit for the brokerage firm and compensates the firm for the risk of owning the stock. A large spread can make a trade very expensive to an investor. For some penny stocks, the spread between the bid and offer may be a large part of the purchase price of the stock. Where the bid price is much lower than the offer price, the market value of the stock must rise substantially before the stock can be sold at a profit. Moreover, an investor may experience substantial losses if the stock must be sold immediately.

Example: If the bid is $0.04 per share and the offer is $0.10 per share, the spread (difference) is $0.06, which appears to be a small amount. But you would lose $0.06 on every share that you bought for $0.10 if you had to sell that stock immediately to the same firm. If you had invested $5,000 at the $0.10 offer price, the market maker's repurchase price, at $0.04 bid, would be only $2,000; thus you would lose $3,000, or more than half of your investment, if you decided to sell the stock. In addition, you would have to pay compensation (a "mark-up," "mark-down," or commission) to buy and sell the stock.

In addition to the amount of the spread, the price of your stock must rise enough to make up for the compensation that the dealer charged you when it first sold you the stock. Then, when you want to resell the stock, a dealer again will charge compensation, in the form of a markdown. The dealer subtracts the markdown from the price of the stock when it buys the stock from you. Thus, to make a profit, the bid price of your stock must rise above the amount of the original spread, the markup, and the markdown.

Primary offerings. Most penny stocks are sold to the public on an ongoing basis. However, dealers sometimes sell these stocks in initial public offerings. You should pay special attention to stocks of companies that have never been offered to the public before, because the market for these stocks is untested. Because the offering is on a first-time basis, there is generally no market information about the stock to help determine its value. The federal securities laws generally require broker-dealers to give investors a "prospectus," which contains information about the objectives, management, and financial condition of the issuer. In the absence of market information, investors should read the company's prospectus with special care to find out if the stocks are a good investment. However, the prospectus is only a description of the current condition of the company. The outlook of the start-up companies described in a prospectus often is very uncertain.

For more information about penny stocks, contact the Office of Filings, Information, and Consumer Services of the U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, (202) 272–7440.

Dated: April 20, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92–9602 Filed 4–27–92; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 240

[Release Nos. 33–6932; 34–30577; IC–18651]

RIN 3235–AD54

Blank Check Offerings

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: To implement provisions of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Reform Act"), the Commission today is adopting rules relating to registration statements filed by blank check companies offering penny stock. The rules include requirements to deposit in a special account securities issued and funds received in the offering, prohibit trading in deposited securities, disclose information regarding acquisitions by the blank check company, provide purchasers with the right to obtain a refund of deposited funds upon receipt of the information, and return deposited funds to investors if an acquisition meeting specified criteria has not been consummated within 18 months after the initial offering date.

EFFECTIVE DATES: April 28, 1992. The rules will apply to registration statements filed by blank check companies on or after April 28, 1992, as well as registration statements pending on that date.

FOR FURTHER INFORMATION CONTACT: Richard P. Konrath, Office of Disclosure Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth St., NW., Washington, DC 20549, (202) 272–2589.

SUPPLEMENTARY INFORMATION: The Commission today is adopting new Rule 419 under the Securities Act of 1933 ("Securities Act"),[1] new Rule 15g–8 under the Securities Exchange Act of 1934 ("Exchange Act"),[2] and an amendment to Securities Act Rule 174.[3]

I. Executive Summary and Background

In adopting the Penny Stock Reform Act,[4] Congress recognized that fraud

[1] 15 U.S.C. 77a *et seq.* (1988).

[2] 15 U.S.C. 78a *et seq.* (1988).

[3] 17 CFR 230.174.

[4] S.647, Pub. L. 101–429.

undermines investor confidence and thereby inhibits capital formation.[5] Finding blank check offerings to be a common vehicle for fraud and manipulation in the penny stock market, Congress expressly directed the Commission to adopt rules governing registration statements filed by blank check companies offering penny stock.[6] The statute states that the special rules may include additional disclosure requirements, limitations on the use of proceeds and the distribution of securities by the issuer until the required disclosure has been made, and a right of rescission to shareholders who invested in the offering.

Pursuant to that mandate, the Commission published for comment proposed Rule 419 under the Securities Act, new Rule 15g–8 under the Exchange Act, and an amendment to Securities Act Rule 174.[7] Those proposals prescribed registration procedures for offerings by blank check companies designed to assure adequate disclosure and restrict the potential for market manipulation.[8]

The Commission today is adopting Rule 419 substantially as proposed, with changes discussed below.[9] The rule requires funds received and securities issued in an offering of penny stock by a blank check company to be placed in an escrow or trust account ("Rule 419 Account") until consummation of an acquisition(s) in which the fair value of the business(es) or the net assets that constitute a business ("net assets") acquired represents at least 80 percent of the maximum offering proceeds, including amounts received or to be received upon exercise or conversion of securities offered but excluding underwriter compensation payable to non-affiliates. The conditions include the filing of a post-effective amendment upon execution of an agreement for the acquisition of a business or assets meeting the above criteria. Upon receipt of the prospectus describing the acquisition(s), purchasers will have the opportunity to have their deposited funds (less certain withdrawals) returned. Funds will not be released from the Rule 419 Account to the registrant until the acquisition(s) meeting the specified criteria is consummated. If such an acquisition does not occur within 18 months after the effective date of the initial registration statement, funds must be returned to purchasers.

The Commission also is adopting, as proposed, new Exchange Act Rule 15g–8 and an amendment to Securities Act Rule 174. Rule 15g–8 prevents trading of securities held in the Rule 419 Account. Securities Act Rule 174 has been amended to provide that the statutory prospectus delivery period would not terminate until 90 days following the release of the blank check company's securities from the Rule 419 Account.

The principal changes from the proposed rules are as follows. First, as adopted, funds to pay certain expenses to underwriters or dealers unaffiliated with the registrant need not be deposited in the Rule 419 Account, regardless of whether the offering is on a firm commitment or contingent basis.[10] Second, the registrant may use up to 10 percent of the offering proceeds after payment of unaffiliated underwriter and dealer compensation, regardless of whether the offering is on a firm commitment or contingent basis.[11] Third, execution of an agreement for the acquisition(s) of a business(es) or assets meeting specified criteria, rather than consummation of the acquisition(s), will trigger the requirement to file a post-effective amendment under Rule 419(e). However, the release of funds from the Rule 419 Account to the registrant will not be permitted until the acquisition(s) is consummated. Fourth, the criteria that the acquisition(s) must meet have been modified to provide that the fair value of the business(es) or net assets to be acquired must represent 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered. Finally, the rule has been reorganized for clarity.

II. Discussion of the Rules

A. Scope of Rule 419

Rule 419 applies to every registration statement filed under the Securities Act relating to an offering by a blank check company.[12] The term "blank check company," restructured from the proposal,[13] means a development stage company [14] that either has no specific business plan or purpose, or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies; and is issuing "penny stock" as defined in Exchange Act Rule 3a51–1.[15] Rule 419 does not apply to offerings by small businesses other than blank check companies, such as investments in limited partnerships or other direct participation programs (sometimes called "blind pools") where a detailed plan of business is developed, but specific investment properties are unidentified (*e.g.*, a real estate limited partnership formed to invest in apartment buildings that have not yet been selected).[16] Likewise, start-up companies with specific business plans are not subject to Rule 419, even if operations have not commenced at the time of the offering.

In the Proposing Release, comment was solicited as to whether the definition of "blank check company" should include companies that do not have a specific percentage of offering proceeds committed to a specific business plan or purpose or an identified acquisition. While the Commission has determined not to adopt a specific percentage test as this time, it will scrutinize registered offerings for attempts to create the appearance that the registrant is not a development stage company or has a

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[5] See H.R. Rep. No. 101–617; 101 Cong., 2d. Sess. at 23 (1990).

[6] See H.R. Rep. No. 101–617; 101 Cong., 2d. Sess. 10–11, 15 (1990). Of the 179 registration statement filings received and reviewed by the Commission's regional offices in calendar year 1991, approximately 36 percent involved blank check offerings (48 percent by dollar amount of the offering).

[7] Release No. 33–6891 (April 17, 1991) (56 FR 19201) ("Proposing Release").

[8] Twelve letters of comment were received in response to the proposals. The comment letters and a staff summary of the letters may be inspected and copied at the Commission's Public Reference Room (File No. S7–10–91).

[9] The Penny Stock Reform Act also mandated adoption of rules regarding secondary market trading in penny stocks. Pursuant to that mandate, the Commission is adopting today, *inter alia*, a definition of the term "penny stock," which is referred to in Rule 419, as discussed in II.A. *infra*. *See* Release No. 34–30608 (April 20, 1992).

[10] Note, however, the discussion of Exchange Act Rule 15c2–4 (17 CFR 240.15c2–4) in II.B.1, *infra*.

[11] *Id.*

[12] Rule 419(a)(1). Offerings pursuant to Regulation A [17 CFR 230.251 *et seq.* (1991)] and Regulation D [17 CFR 230.501 *et seq.* (1991)] under the Securities Act are not subject to Rule 419. *But see* Securities Act Release No. 6924 [57 FR 9768] (March 23, 1992), proposing to exclude blank check offerings from Regulation A.

[13] Rule 419(a)(2) corresponds to the definition of "blank check company" in section 7(b)(3) of the Securities Act (15 U.S.C. 77g(b)(3)).

[14] A development stage company is defined in Rule 1–02(h) of Regulation S–X (17 CFR 210.1–02(h)) as a company that is devoting substantially all of its efforts to establishing a new business in which planned principal operations have not commenced, or have commenced but there has been no significant revenue therefrom.

[15] 17 CFR 240.3a51–1, adopted in Release No. 34–30608 (April 20, 1992); *see* n.9, *supra*.

[16] The Commission has recently issued an interpretative release designed to enhance the quality of information provided to investors in connection with limited partnership transactions. See Release No. 33–6900 (56 FR 28979) (June 17, 1991).

specific business plan, in an effort to avoid the application of Rule 419.

B. Rule 419 Account

1. Deposit of Funds Into an Escrow or Trust Account

Rule 419 requires the proceeds received pursuant to a blank check offering to be deposited into (i) an escrow account maintained by an insured depository institution [17] or (ii) a separate bank account established by a broker or dealer acting as trustee for persons having beneficial interests in the account.[18] If funds and securities are deposited into an escrow account maintained by an insured depository institution, that institution's deposit account records must specify that funds are held for the named purchasers of the securities in accordance with specified regulations of the Federal Deposit Insurance Corporation.[19] If funds are deposited in a separate bank account by a broker or dealer acting as a trustee, the books and records of the broker or dealer must indicate the name, address, and interest of each person for whom the account is held.[20]

As proposed, Rule 419 would have required all proceeds received in a contingent offering (*i.e.*, offering on an all-or-none or part-or-none basis) to remain in the Rule 419 Account until termination of that account. By contrast, in a firm commitment offering under the proposed rule, underwriting commissions, underwriting expenses, and dealer allowances of entities unaffiliated with the registrant were excluded from amounts required to be deposited, and up to ten percent of the proceeds to be deposited could be used by the registrant. In response to commenter concerns regarding this disparate treatment, Rule 419, as adopted, permits excluding underwriting commissions, underwriting expenses, and dealer allowances of entities unaffiliated with the registrant from amounts required to be deposited, regardless of whether the offering is on a firm commitment or contingent basis.[21] Moreover, ten percent of the net proceeds, after payment of underwriter and dealer compensation, may be released to the registrant as the proceeds are deposited in both contingent and firm commitment offerings.[22]

Unlike Rule 419, Exchange Act Rule 15c2–4 [23] does not permit the payment of underwriting commissions, underwriting expenses, and dealer allowances from proceeds required to be deposited, and prohibits the disbursal of deposited funds to the registrant in a contingent offering until the specified contingency is satisfied. With respect to a blank check offering subject to both Rule 419 and Rule 15c2–4, the requirements of Rule 15c2–4 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a part-or-none offering). Upon satisfaction of those conditions, Rule 419 continues to govern the use of offering proceeds.[24] This interplay between Rule 15c2–4 and Rule 419 is required to be disclosed in the initial registration statement filed by the blank check company.[25]

For example, a registrant makes a blank check offering on a best efforts, part-or-none basis, through an unaffiliated underwriter, the terms of which provide that the minimum offering is $500,000, which must be received on or before October 1, 1992, and the maximum offering is $1 million. If $500,000 is raised by the specified date, securities can continue to be sold until the stated maximum of $1 million is raised. Until the earlier of the satisfaction of the contingency or October 1, 1992, Rules 419, 15c2–4 and 10b–9 apply and no offering proceeds may be released from deposit. If on October 1, 1992, $500,000 has not been raised proceeds must be returned promptly to investors pursuant to Rules 15c2–4 and 10b–9.

If on October 1, 1992, at least $500,000 has been raised and the other obligations under Rules 15c2–4 and 10b–9 have been satisfied, such obligations cease but funds would continue to be held pursuant to Rule 419. A $50,000 underwriter commission (assuming a 10 percent commission to non-affiliates) may be paid on October 2, 1992. Ten percent of the remaining proceeds of $450,000 or $45,000, may be paid to the registrant, leaving $405,000 of offering proceeds, as well as the securities issued, in the Rule 419 Account. As further offering proceeds are received, for example, $1,000 on October 2, 1992, underwriters may be paid commissions ($100) and the registrant may receive 10 percent of the remainder ($90), leaving $810 of proceeds to be deposited in the Rule 419 Account. Thus, $405,810 of the offering proceeds is held in Rule 419 Account.

Contemplating the use of escrowed funds and bank borrowings, on December 1, 1992, the registrant files a post-effective amendment reflecting the execution of an acquisition agreement accounting for $850,000, which represents in excess of 80 percent of the maximum offering proceeds of $900,000.[26] Once the post-effective amendment is effective, the registrant must distribute the prospectus to investors. Assume that investors request refunds of $20,000 so that proceeds now in the Rule 419 Account total $385,810. The registrant would not be required pursuant to Rule 10b–9 to refund offering proceeds for failure to maintain the stated $500,000 minimum offering amount. A broker would not be deemed

[17] Rule 419(b)(1)(i)(A). Section 3(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1813(c)(2) (1991)) defines "insured depository institution" to mean any bank or savings and loan association with deposits insured by the Federal Deposit Insurance Corporation. See also 12 U.S.C. 1813(1) (1991); and 12 U.S.C. 1821 (1991), as well as FDIC 88-47, 1988 FDIC Interp. Ltr. Lexis 47 (July 15, 1988) as to federal deposit insurance governing such accounts. If there is a material risk of non-insurance of purchasers' funds resulting from deposits in excess of the insured amounts, appropriate disclosure should be included in the prospectus. See Rule 419(c)(1).

[18] Rule 419(b)(1)(i)(B). A broker-dealer acting as trustee under Rule 419 must have net capital equal to or greater than $25,000. See Rule 15c3–1 under the Exchange Act (17 CFR 240.15c3–1).

[19] Rule 419(b)(1)(ii). Under § 330.1 of the regulations of the Federal Deposit Insurance Corporation ("FDIC") (12 CFR 330.1), the deposit account records of the insured bank are conclusive as to the existence of insurance coverage for a deposit. The relationship under which funds are deposited (*e.g.*, trustee, agent custodian or executor) must be clearly established by the deposit agreement and clearly indicated in the deposit account records to permit a claim for deposit insurance. The details of the relationship and interests of other parties in the account must be ascertainable either from the records of the bank or records of the depositor.

[20] Rule 419(b)(1)(ii).

[21] Rule 419(b)(2)(i).

[22] Rule 419(b)(2)(vi). For example, if a registrant making a $5 million blank check offering receives $100,000, amounts needed to pay the portion allocated to underwriter compensation (*e.g.*, $10,000) and ten percent of the remainder ($9,000) may be paid to the underwriter and the issuer, respectively. The remaining $81,000 would be invested in the Rule 419 Account.

[23] Under Rule 15c2–4, in a best efforts distribution of securities conducted on an "all or none" basis, or on any other basis in which payment will not be made to the issuer until some further event or contingency occurs, a broker-dealer participant is obligated either to segregate funds received in a separate bank account, as agent or trustee, or to deposit promptly such funds with a bank pursuant to a written escrow agreement, pending the occurrence of the contingency. Under Rule 15c3–1(b) (17 CFR 240.15c3–1(b)), broker-dealers that do not carry customer accounts or that are affiliated with the issuer must deposit offering funds in an escrow account established at a bank.

[24] An explanatory note has been added to Rule 419(b).

[25] Rule 419(c). See also the discussion of Rule 10b–9 [17 CFR 240.10b–] in II.C *infra*.

[26] Although the maximum was $1 million, for purposes of the 80 percent calculation, Rule 419(e)(1) permits the exclusion of underwriter and dealer compensation payable to non-affiliates, which would amount to $100,000 in this example.

to be in violation of Rule 15c2–4 for having received commissions after October 1, since the minimum offering terms were met as initially specified.

Funds deposited in a Rule 419 Account and interest or dividends thereon must be held for the sole benefit of the purchasers [27] in one of the following accounts: (1) An obligation that constitutes a "deposit" as that term is defined in section 3(1) of the Federal Deposit Insurance Act; [28] (2) securities of any open-end investment company registered under the Investment Company Act of 1940 that holds itself out as a money market fund [29]; or (3) securities that are direct obligations of, or obligations guaranteed as to principal or interest by, the United States.[30] Commenters expressed concern regarding the potential fluctuation in value of government securities and the ability to liquidate those securities within time periods specified in Rule 419. Although the Rule continues to permit investments in government securities, registrants are cautioned that such an investment would be inappropriate unless the instrument could be readily sold or otherwise disposed of for cash within the constraints of Rule 419 without any dissipation of offering proceeds invested.[31]

The proposing release solicited comment regarding the registration of the Rule 419 Account as an investment company under the Investment Company Act. Although a Rule 419 Account may be an investment company under the Investment Company Act of 1940,[32] in light of the purposes served by the regulatory requirement to establish such an account, the limited nature of the investments, and the limited duration of the account, such an account will neither be required to register as an investment company nor regulated as an investment company as long as it meets the requirements of Rule 419.

2. Deposit of Securities Into and Escrow or Trust Account

Requirements regarding the deposit of securities into the Rule 419 Account are adopted as proposed. Accordingly, all securities sold in an offering by a blank check company, as well as securities issued in connection with the offering to underwriters, promoters or others as compensation or otherwise, must be placed in the Rule 419 Account and subject to the following conditions.[33] The securities must be issued in the name of the purchaser, remain in that form, and held for the sole benefit of purchasers, who will have the voting rights, if any, provided by applicable state law.[34] In addition, deposited securities may not be transferred or disposed of, except by will or the laws of descent and distribution, pursuant to a qualified domestic relations order as defined, or to permit the exercise or conversion of derivative securities held in the escrow or trust account.[35]

Frequently, securities sold by blank check companies are issued in units consisting of common stock and warrants or convertible securities relating to the common stock (*e.g.*, a unit consisting of one share of common stock and two common stock warrants or other derivative securities relating to the common stock). While permitting the exercise or conversion of securities held in a Rule 419 Account, Rule 419 requires the deposit of securities received upon exercise or conversion, as well as any cash or other consideration paid in connection with exercise or conversion.[36]

3. Prohibition on Trading in Deposited Securities

Exchange Act Rule 15g–8 is adopted as proposed. Following the initial sale of the blank check company's securities, new Exchange Act Rule 15g–8 prohibits any sale of deposited securities or interests in these securities until the securities are released from the Rule 419 Account. Therefore, contracts of sale to be satisfied by delivery of the deposited security, such as contracts for sale on a when, as, and if-issued basis, and sale of derivative securities settled by delivery of the security, such as a physically-settled option on the security, are prohibited by Rule 15g–8 while the securities are in the Rule 419 Account. In addition, Rule 15g–8 prohibits the sale of other interests based on the deposited security, whether or not physical delivery is required.

C. Release of Funds and Securities From the Rule 419 Account

To effect release of funds and securities from the Rule 419 Account, the following conditions must be met. First, the registrant must execute an agreement for the acquisition(s) of a business(es) or assets for which the fair value of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered, but excluding underwriting commissions, underwriting expenses and dealer allowances payable to non-affiliates.[37] Second, upon execution of that agreement, the registrant must file a post-effective amendment with the Commission providing the disclosure required by Rule 419(e).[38] Third, no later than five business days after the effective date of that post-effective amendment, the registrant must send each purchaser a copy of the prospectus contained in the post-effective amendment and any amendment or supplement thereto.[39]

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[27] Rule 419(b)(2)(iii). Rule 419(a)(3) defines "purchaser" as any person acquiring securities in the offering, for cash or otherwise, including promoters or others receiving securities as compensation in connection with the offering.

[28] 12 U.S.C. 1813(1) (1991).

[29] Money market funds are open-end management investment companies registered under the Investment Company Act of 1940 ("Investment Company Act") 15 U.S.C. 80a-1 *et seq.*) that invest in short-term debt instruments. There are currently 710 money market funds with over $538 billion in assets. See IBC/Donoghue's Money Fund Report (Feb. 8, 1991). Most money market funds maintain a stable price of $1.00 per share. The stable $1.00 per share prices has encouraged investors to view money market funds as an alternative to bank deposit and checking accounts, even though money market funds lack federal deposit insurance. See Investment Company Act Release No. 18005 (February 20, 1991) (56 FR 8113), at n. 2 and 3.

[30] Rule 419 (b)(2)(iv).

[31] A cautionary note has been set forth in the Rule. The staff of the Division of Market Regulation has articulated this approach with respect to investments in government securities in the context of Exchange Act Rule 15c2–4. See NASD Notice to Members 84–7 (January 30, 1984)

[32] *See Prudential Insurance Co.* v. *S.E.C.*, 326 F.2d 383 (3d Cir. 1964), *cert. denied*, 377 U.S. 953 (1964) (a "fund" need not be a recognizable business entity in order to be an issuer for purposes of the investment Company Act).

[33] Rule 419(b)(3)(i). Securities issued for consideration other than cash (*e.g.*, as a dividend) also must be deposited, as well as securities issued in respect of already deposited securities (*e.g.*, securities issued as a result of a stock split or dividend or upon exercise or conversion).

[34] Rule 419(b)(3)(ii). Upon request by the Commission or the staff, the registrant would be required to furnish as supplemental information the names and addresses of purchasers of securities in the Rule 419 Account. Rule 419(b)(5).

[35] Rule 419(b)(3) (ii) and (iii).

[36] Rule 419(b)(3)(iii).

[37] Rule 419(e)(1). The acquisition must constitute the business or a line of business of the registrant. Two or more acquisitions that together meet the criteria specified in Rule 419(e) will be treated in the same manner as a single such acquisition.

[38] *Id.* If at any time during the offering a significant acquisition between the registrant and another company is probable, a post-effective amendment to the registration statement would be required pursuant to Rule 419(d), adopted as proposed (proposed Rule 419(c)). See also Item 512(a)(1)(ii) of Regulation S–K (17 CFR 229.512(a)(1)(ii)); and Securities Act Release No. 6383 (March 16, 1982)(47 FR 11380), text accompanying n. 80, 47 FR at 11396.

[39] Rule 419(e)(2)(i).

Fourth, the registrant must give each purchaser no fewer than 20 business days and no more than 45 business days from the effective date of the post-effective amendment to notify the registrant that he or she elects to remain an investor.[40] If purchaser notification is not received by the registrant within the prescribed time, the purchaser's deposit must be refunded. Fifth, the registrant must consummate the acquisition(s) meeting the criteria set forth above.[41] Funds may not be released until the consummation of the acquisition and the receipt by the escrow agent or trustee of a signed representation from the registrant that the above conditions have been met.[42]

There are two circumstances under which funds will be returned to the purchaser and securities returned to the registrant. First, as noted above, if upon receipt of the prospectus purchasers do not confirm an intent to invest within the prescribed time, their funds must be returned to them.[43] Second, if the conditions noted above are not met within 18 months after the effective date of the registrant's initial registration statement, deposited funds must be returned to purchasers.[44]

The following requirements have been changed from the proposals. Execution of an agreement for the acquisition(s) of a business(es) or assets meeting specified criteria, rather than consummation of the acquisition as proposed, will trigger filing of the post-effective amendment required in Rule 419(e). Difficulties noted by commenters in consummating an acquisition without knowledge of the amount of confirmed investments prompted this change. However, the acquisition(s) must be consummated before funds may be released from the Rule 419 Account to the registrant. The criteria for the acquisition(s), as adopted, are that the fair value of the business(es) or net assets to be acquired must represent at least 80 percent of the maximum offering proceeds, including funds received or to be received upon exercise or conversion of securities offered, but excluding underwriter and dealer compensation payable to non-affiliates.[45]

In the Proposing Release, the Commission inquired as to the conditions which would be most appropriate for the release of funds and securities from a Rule 419 Account. Following a review of the public comments and its experience with blank check offerings, the Commission has determined that the protection of investors is best served through a test that is measured against the maximum proceeds sought to be acquired in the offering. Thus under the Rule as adopted, funds in a Rule 419 Account may be disbursed to the registrant only when an amount equivalent to at least 80 percent of the maximum offering proceeds sought, including those obtainable, currently or in the future, through the exercise or conversion of any security offered, has been applied to an acquisition(s) of a business or assets that constitute the business or a line of business of the registrant.[46]

Further, with respect to stock acquisitions, the proposing release provided that the resulting entity must have net tangible assets equal to the greater of 80 percent of proceeds or $100,000. Since there is not a sufficient basis to distinguish a cash acquisition and a stock acquisition in a blank check offering, the Rule adopted today provides for one acquisition standard applicable to both. The net tangible asset standard proposed is, accordingly, unnecessary. An acquisition for either cash or securities will be able to meet the standard if the fair value [47] of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds.

In certain contingent offerings, Rule 419 provisions relating to the release of funds and Exchange Act Rule 10b–9 obligations will apply. Rule 10b–9 prohibits as a "manipulative or deceptive device or contrivance" under section 10(b) of the Exchange Act [48] any representation that a security is being offered on an "all or none" or "part or none" basis, unless prompt refunds are made to purchasers if the represented number of securities is not sold at the specified price within the specified time and the total amount due the seller is not received by the seller by the specified date.

Just as with Rule 15c2–4, for blank check offerings subject to both Rule 419 and Rule 10b–9, the requirements of Rule 10b–9 apply until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a part-or-none offering). Upon satisfaction of Rule 10b–9, the provisions of Rule 419 will continue to govern.[49] Proposed Rule 419(b)(2)(i)(B) would have required a refund of proceeds if as a result of purchaser refund the terms of the offering governed by Rule 10b–9 were no longer met, but that requirement has not been adopted. The initial registration statement filed by the blank check company making a contingent offering subject to Rule 10b–9 must disclose that the provisions of that Rule apply only until the conditions subject to that Rule are met, but after satisfaction of such conditions an investor is not guaranteed a return of proceeds even if, as a result of investor refund requests under Rule 419, the Rule 10b–9 conditions would no longer be met.[50] The risks to the investor resulting from the issuer receiving less than the minimum specified proceeds as a result of later refunds under Rule 419 must be clearly disclosed.

D. Disclosure Obligations Under Rule 419

Disclosure obligations under Rule 419 are adopted substantially as proposed.

1. Disclosure in Initial Prospectus

The initial prospectus for a Rule 419 offering must describe the obligation of the registrant to deposit funds and securities in the Rule 419 Account, the restrictions on trading in securities held in the Account, and the conditions for release of deposited funds and securities.[51] The effect of these requirements on purchasers and the registrant's right to receive funds also must be described.[52] In addition, a copy of the executed escrow or trust agreement must be filed as an exhibit to the initial registration statement and

[40] Rule 419(e)(2)(ii).

[41] Rule 419(e)(2)(iii).

[42] Rule 419(e)(3)(i).

[43] Rule 419(e)(2)(ii).

[44] Rule 419(e)(2)(iv).

[45] As proposed, the criteria would have been that the post-effective amendment be filed upon consummation of an acquisition that would account for at least 80 percent of the deposited proceeds or, where securities were issued in the acquisition, the resulting entity would have net tangible assets equivalent to the greater of 80 percent of the deposited proceeds or $100,000.

[46] Rule 419(e)(1).

[47] A note has been added to the Rule providing that in a cash acquisition, fair value is presumed to be equal to the cash paid. When non-cash consideration, such as securities, is used, fair value is to be determined by an accepted standard, such as bona fide sales, forecasts of expected cash flows, independent appraisals, etc. The valuation must be reasonable at the time made.

[48] 15 U.S.C. 78j(b).

[49] An explanatory note has been added to Rule 419(e). *See* the example of the interaction of Rules 419, 15c2–4 and 10b–9 in II.B.1. *supra*.

[50] Rule 419(c). Of course, the registrant may choose to provide that funds be returned to investors if a minimum is not met because of Rule 419 refunds.

[51] Rule 419(c).

[52] If purchasers receive interest or dividends on deposited funds, the prospectus must set forth the tax effect on the purchaser, including the possibility of having to pay taxes on such income and being required to file an amended tax return to receive a tax refund if ultimately the interest or dividend income is released to the blank check company.

contain provisions specified in Rule 419.[53]

2. Disclosure in Post-Effective Amendment Describing an Acquisition Agreement

A post-effective amendment filed pursuant to Rule 419(e) describing an acquisition agreement must contain the following information. First, all information specified by the applicable registration statement form and Industry Guides would be included.[54] That information would include financial statements of the issuer and company to be acquired, as well as pro forma financial information reflecting the acquisition, as specified by the form and applicable rules and regulations. Second, the gross amount of offering proceeds received pursuant to the offering would be required to be disclosed, specifying the amounts paid for underwriter commissions, underwriting expenses and dealer allowances, amounts disbursed to the registrant, and amounts remaining in the escrow or trust account.[55] Third, the registrant would be required to detail the use of funds received, if any, under the terms of the escrow or trust agreement.[56] This disclosure would delineate amounts paid to officers, directors, promoters and others and the reasons for such payments, *e.g.*, compensation, reimbursement of expenses, purchase of assets from such individuals, etc. Finally, the post-effective amendment prospectus, like the initial prospectus, must describe the terms of the offering, including the conditions imposed on the offering by Rule 419.[57] If funds and securities are released from the Rule 419 Account, this prospectus would be supplemented by sticker to indicate the amount of funds and securities released and the date of release.[58]

3. Financial Statements

Rule 419(f), adopted substantially as proposed, requires the blank check company to furnish security holders with audited financial statements for the first full fiscal year of operations following the date an acquisition is consummated pursuant to the Rule,[59] accompanied by a management's discussion and analysis of such information,[60] no later than 90 days after the end of the fiscal year.[61] That information also would be filed with the Commission under cover of Form 8–K.[62] Pursuant to this provision, investors in the blank check company would have the financial statements and related information for at least a full accounting period following commencement of operations of the company. If at the end of its first full fiscal year of operations the blank check company was filing reports pursuant to Section 13(a) or 15(d) of the Exchange Act,[63] this requirement would not be applicable, since it would duplicate those reporting requirements.

E. Amendment to Rule 174

The amendment to Rule 174 is adopted as proposed. Rule 174 under the Securities Act prescribes prospectus delivery requirements with respect to transactions subject to section 4(3) of the Securities Act.[64] Under section 4(3), transactions by dealers are exempt from the prospectus delivery and other requirements of section 5 of the Securities Act unless those transactions are within 40 days of the date securities were first offered to the public, or 90 days if the securities have not been sold previously pursuant to an earlier effective registration statement. New paragraph (g) of Rule 174 provides that with respect to offerings subject to Rule 419, the prospectus delivery period would not terminate until 90 days after the release of funds and securities from the Rule 419 Account.

III. Cost-Benefit Analysis

No specific empirical data was submitted in response to the Commission's invitation to provide information on the costs and benefits of the proposed rules. A review of the information provided by blank check issuers in their registration statements reveals that their cost of initial registration are typically the lowest of any issuers. The purpose for the legislative directive to develop these rules was to counteract many abusive practices which were found in markets for blank check securities. While additional costs to registrants and broker-dealers may result from the new rules, such costs are expected to be outweighed by the increased protection of investors in blank check offerings.

IV. Availability of Final Regulatory Flexibility Analysis

The Commission has prepared a Final Regulatory Flexibility Analysis, pursuant to the requirements of the Regulatory Flexibility Act,[65] regarding the new rules. The Final Regulatory Flexibility Analysis indicates that the rules could impose some additional costs on small broker-dealers and small issuers. The rules are designed to minimize these costs to the greatest extent possible consistent with the provisions of the Penny Stock Reform Act. A copy of the Final Regulatory Flexibility Analysis may be obtained from Richard P. Konrath, Attorney-Advisor, Office of Disclosure Policy, Division of Corporation Finance, Securities and Exchange Commission, 450 Fifth Street, NW., Mail Stop 3–12, Washington, D.C. 20549, (202) 272–2589.

V. Effective Date

The rules relating to blank check offerings are effective upon publication in the **Federal Register**. The Commission finds that there is good cause to dispense with the 30 day delay between publication and effectiveness normally required by the Administrative Procedure Act.[66] Focusing on demonstrated abuses in connection with blank check offerings that cause harm to investors, Congress in the Penny Stock Reform Act directed the Commission to enact a special regulatory scheme that goes beyond disclosure to provide substantive protections to investors. Congressional concern was focused on the recent history of blank check offerings as an area rife with fraud and manipulation, particularly in view of the lack of information at the commencement of a blank check offering about the manner in which proceeds will be used, and the potential for dissipation of those proceeds. These abuses were found to be inadequately addressed by the current regulatory

[53] Rule 419(b)(4). Those provisions include Rule 419(b)(2) (deposit and investment of proceeds), Rule 419(b)(3) (deposit of securities), and Rule 419(e)(3) (conditions for the release of deposited securities and funds).

[54] Rule 419(e)(1)(i). This information also would be included in a post-effective amendment filed pursuant to Rule 419(d) reflecting a probable significant acquisition.

[55] Rule 419(e)(1)(ii).

[56] *Id.* In addition, Form SR under the Securities Act (17 CFR 239.61) requires first-time registrants to file with the Commission at specified intervals reports describing its use of offering proceeds. See Securities Act Rule 463 (17 CFR 230.463).

[57] Rule 419(e)(1)(iii).

[58] Rule 419(e)(4).

[59] The registrant, as currently required, would be subject to section 15(d) of the Exchange Act for at least the first fiscal year following the effective date of the initial registration statement.

[60] Item 303(a) of Regulation S–K (17 CFR 229.303(a)).

[61] Rule 419(f). Proposed Rule 419(d)(6) required financial statements for the first full fiscal year of operations following the effective date of the post-effective amendment; a specific reference to the date of a consummated acquisition was not contained because under the proposals, unlike the adopted rules, consummation was a condition to filing the post-effective amendment.

[62] 17 CFR 249.308, Item 7.

[63] 15 U.S.C. 78m(a) (1988); 15 U.S.C. 78*o*(d) (1988).

[64] 15 U.S.C. 77d(3) (1988).

[65] 5 U.S.C. 603 (1988).

[66] 5 U.S.C. 553(d)(3).

scheme, and in need of immediate attention in order to prevent investors from further harm. These abuses and the protections that would be imposed by the new rules have been publicized in the Proposing Release and elsewhere.

None of the Commission's current provisions provide for the escrowing of proceeds and securities, the restriction on trading in escrowed securities or the right of investors to obtain the return of invested funds upon receipt of complete information about an acquisition. Congress believed that such protections were needed for the protection of investors in blank check offerings. Delay in the effectiveness of these rules very likely could frustrate the legislative intent behind the provisions by permitting anticipatory filings in order to avoid compliance. Similarly, a substantial number of registration statements by blank check issuers are currently on file with the Commission. Very few provide restrictions on the use of proceeds or other protections similar to those required by the new rules, which are needed in order to prevent the abuse that was the subject of Congressional concern. The Commission finds that it is in the interest of investors that these rules apply to both pending as well as future filings by blank check issuers.

VI. Statutory Basis

New Rule 419 and the amendment to Rule 174 are being adopted by the Commission pursuant to sections 3,[67] 4,[68] 5,[69] 7,[70] and 19 [71] of the Securities Act. New Rule 15g–8 is being adopted pursuant to sections 3,[72] 9,[73] 10,[74] 15,[75] and 23 [76] of the Exchange Act.

List of Subjects in 17 CFR Parts 230 and 240

Advertising, Brokers, Confidential business information, fraud, Investment companies, Reporting and recordkeeping requirements, and Securities.

VII. Text of New Rules

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

[67] 15 U.S.C. 77c (1988).
[68] 15 U.S.C. 77d (1988).
[69] 15 U.S.C. 77e (1988).
[70] 15 U.S.C. 77g (1988).
[71] 15 U.S.C. 77s (1988).
[72] 15 U.S.C. 78c (1988).
[73] 15 U.S.C. 78i (1988).
[74] 15 U.S.C. 78j (1988).
[75] 15 U.S.C. 78o (1988).
[76] 15 U.S.C. 78w (1988).

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. The authority citation for part 230 is revised to read as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77e, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m 78n, 78o, 78w, 79t, and 80a–37, as amended, unless otherwise noted.

2. By amending § 230.174 by adding paragraph (g) to read as follows:

§ 230.174 Delivery of prospectus by dealers; exemptions under section 4(3) of the Act.

* * * * *

(g) If the registration statement relates to an offering of securities of a "blank check company," as defined in Rule 419 under the Act (17 CFR 230.419), the statutory period for prospectus delivery specified in section 4(3) of the Act shall not terminate until 90 days after the date funds and securities are released from the escrow or trust account pursuant to Rule 419 under the Act.

3. By adding § 230.419 under the undesignated center heading "General Requirements" to read as follows:

§ 230.419 Offerings by blank check companies.

(a) *Scope of the rule and definitions.* (1) The provisions of this section shall apply to every registration statement filed under the Act relating to an offering by a blank check company.

(2) For purposes of this section, the term "blank check company" shall mean a company that:

(i) Is a development stage company that has no specific business plan or purpose or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies, or other entity or person; and

(ii) Is issuing "penny stock," as defined in Rule 3a51–1 (17 CFR 240.3a51–1) under the Securities Exchange Act of 1934 ("Exchange Act").

(3) For purposes of this section, the term "purchaser" shall mean any person acquiring securities directly or indirectly in the offering, for cash or otherwise, including promoters or others receiving securities as compensation in connection with the offering.

(b) *Deposit of securities and proceeds in escrow or trust account*—(1) General. (i) Except as otherwise provided in this section or prohibited by other applicable law, all securities issued in connection with an offering by a blank check company and the gross proceeds from the offering shall be deposited promptly into:

(A) An escrow account maintained by an "insured depository institution," as that term is defined in section 3(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1813(C)(2)); or

(B) A separate bank account established by a broker or dealer registered under the Exchange Act maintaining net capital equal to or exceeding $25,000 (as calculated pursuant to Exchange Act Rule 15c3–1 (17 CFR 240.15c3–1), in which the broker or dealer acts as trustee for persons having the beneficial interests in the account.

(ii) If funds and securities are deposited into an escrow account maintained by an insured depository institution, the deposit account records of the insured depository institution must provide that funds in the escrow account are held for the benefit of the purchasers named and identified in accordance with 12 CFR 330.1 of the regulations of the Federal Deposit Insurance Corporation, and the records of the escrow agent, maintained in good faith and in the regular course of business, must show the name and interest of each party to the account. If funds and securities are deposited in a separate bank account established by a broker or dealer acting as a trustee, the books and records of the broker-dealer must indicate the name, address, and interest of each person for whom the account is held.

(2) Deposit and investment of proceeds. (i) All offering proceeds, after deduction of cash paid for underwriting commissions, underwriting expenses and dealer allowances, and amounts permitted to be released to the registrant pursuant to paragraph (b)(2)(vi) of this section, shall be deposited promptly into the escrow or trust account; *provided, however,* that no deduction may be made for underwriting commissions, underwriting expenses or dealer allowances payable to an affiliate of the registrant.

(ii) Deposited proceeds shall be in the form of checks, drafts, or money orders payable to the order of the escrow agent or trustee.

(iii) Deposited proceeds and interest or dividends thereon, if any, shall be held for the sole benefit of the purchasers of the securities.

(iv) Deposited proceeds shall be invested in one of the following:

(A) An obligation that constitutes a "deposit," as that term is defined in section 3(*l*) of the Federal Deposit Insurance Act (12 U.S.C. 1813 (*l*));

(B) Securities of any open-end investment company registered under the Investment Company Act of 1940 (15

U.S.C. 80a–1 et seq.) that holds itself out as a money market fund meeting the conditions of paragraphs (c)(2), (c)(3), and (c)(4) of 17 CFR 270.2a–7 (Rule 2a–7) under the Investment Company Act; or

(C) Securities that are direct obligations of, or obligations guaranteed as to principal or interest by, the United States.

Note to § 230.419(b)(2)(iv): Issuers are cautioned that investments in government securities are inappropriate unless such securities can be readily sold or otherwise disposed of for cash at the time required without any dissipation of offering proceeds invested.

(v) Interest or dividends earned on the funds, if any, shall be held in the escrow or trust account until the funds are released in accordance with the provisions of this section. If funds held in the escrow or trust account are released to a purchaser of the securities, the purchasers shall receive interest or dividends earned, if any, on such funds up to the date of release. If funds held in the escrow or trust account are released to the registrant, interest or dividends earned on such funds up to the date of release may be released to the registrant.

(vi) The registrant may receive up to 10 percent of the proceeds remaining after payment of underwriting commissions, underwriting expenses and dealer allowances permitted by paragraph (b)(2)(i) of this section, exclusive of interest or dividends, as those proceeds are deposited into the escrow or trust account.

(3) Deposit of securities. (i) All securities issued in connection with the offering, whether or not for cash consideration, and any other securities issued with respect to such securities, including securities issued with respect to stock splits, stock dividends, or similar rights, shall be deposited directly into the escrow or trust account promptly upon issuance. The identity of the purchaser of the securities shall be included on the stock certificates or other documents evidencing such securities. See also 17 CFR 240.15g–8 regarding restrictions on sales of, or offers to sell, securities deposited in the escrow or trust account.

(ii) Securities held in the escrow or trust account are to remain as issued and deposited and shall be held for the sole benefit of the purchasers, who shall have voting rights, if any, with respect to securities held in their names, as provided by applicable state law. No transfer or other disposition of securities held in the escrow or trust account or any interest related to such securities shall be permitted other than by will or the laws of descent and distribution, or pursuant to a qualified domestic relations order as defined by the Internal Revenue Code of 1986 as amended (26 U.S.C. 1 *et seq.*), or Title 1 of the Employee Retirement Income Security Act (29 U.S.C. 1001 *et seq.*), or the rules thereunder.

(iii) Warrants, convertible securities or other derivative securities relating to securities held in the escrow or trust account may be exercised or converted in accordance with their terms; *provided, however*, that securities received upon exercise or conversion, together with any cash or other consideration paid in connection with the exercise or conversion, are promptly deposited into the escrow or trust account.

(4) Escrow or trust agreement. A copy of the executed escrow or trust agreement shall be filed as an exhibit to the registration statement and shall contain the provisions of paragraphs (b)(2), (b)(3), and (e)(3) of this section.

(5) Request for supplemental information. Upon request by the Commission or the staff, the registrant shall furnish as supplemental information the names and addresses of persons for whom securities are held in the escrow or trust account.

Note to § 230.419(b): With respect to a blank check offering subject to both Rule 419 and Exchange Act Rule 15c2–4 (17 CFR 240.15c2–4, the requirements of Rule 15c2–4 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a "part-or-none" offering). When those conditions are satisfied, Rule 419 continues to govern the use of offering proceeds.

(c) *Disclosure of offering terms.* The initial registration statement shall disclose the specific terms of the offering, including, but not limited to:

(1) The terms and provisions of the escrow or trust agreement and the effect thereof upon the registrant's right to receive funds and the effect of the escrow or trust agreement upon the purchaser's funds and securities required to be deposited into the escrow or trust account, including, if applicable, any material risk of non-insurance of purchasers' funds resulting from deposits in excess of the insured amounts; and

(2) The obligation of the registrant to provide, and the right of the purchaser to receive, information regarding an acquisition, including the requirement that pursuant to this section, purchasers confirm in writing their investment in the registrant's securities as specified in paragraph (e) of this section.

(d) *Probable acquisition post-effective amendment requirement.* If, during any period in which offers or sales are being made, a significant acquisition becomes probable, the registrant shall file promptly a post-effective amendment disclosing the information specified by the applicable registration statement form and Industry Guides, including financial statements of the registrant and the company to be acquired as well as pro forma financial information required by the form and applicable rules and regulations. Where warrants, rights or other derivative securities issued in the initial offering are exercisable, there is a continuous offering of the underlying security.

(e) *Release of deposited and funds securities*— (1) Post-effective amendment for acquisition agreement. Upon execution of an agreement(s) for the acquisition(s) of a business(es) or assets that will constitute the business (or a line of business) of the registrant and for which the fair value of the business(es) or net assets to be acquired represents at least 80 percent of the maximum offering proceeds, including proceeds received or to be received upon the exercise or conversion of any securities offered, but excluding amounts payable to non-affiliates for underwriting commissions, underwriting expenses, and dealer allowances, the registrant shall file a post-effective amendment that:

(i) Discloses the information specified by the applicable registration statement form and Industry Guides, including financial statements of the registrant and the company acquired or to be acquired and pro forma financial information required by the form and applicable rules and regulations;

(ii) Discloses the results of the initial offering, including but not limited to:

(A) The gross offering proceeds received to date, specifying the amounts paid for underwriter commissions, underwriting expenses and dealer allowances, amounts disbursed to the registrant, and amounts remaining in the escrow or trust account; and

(B) The specific amount, use and application of funds disbursed to the registrant to date, including, but not limited to, the amounts paid to officers, directors, promoters, controlling shareholders or affiliates, either directly or indirectly, specifying the amounts and purposes of such payments; and

(iii) Discloses the terms of the offering as described pursuant to paragraph (e)(2) of this section.

(2) Terms of the offering. The terms of the offering must provide, and the registrant must satisfy, the following conditions.

(i) Within five business days after the effective date of the post-effective

amendment(s), the registrant shall send by first class mail or other equally prompt means, to each purchaser of securities held in escrow or trust, a copy of the prospectus contained in the post-effective amendment and any amendment or supplement thereto;

(ii) Each purchaser shall have no fewer than 20 business days and no more than 45 business days from the effective date of the post-effective amendment to notify the registrant in writing that the purchaser elects to remain an investor. If the registrant has not received such written notification by the 45th business day following the effective date of the post-effective amendment, funds and interest or dividends, if any, held in the escrow or trust account shall be sent by first class mail or other equally prompt means to the purchaser within five business days;

(iii) The acquisition(s) meeting the criteria set forth in paragraph (e)(1) of this section will be consummated if a sufficient number of purchasers confirm their investments; and

(iv) If a consummated acquisition(s) meeting the requirements of this section has not occurred by a date 18 months after the effective date of the initial registration statement, funds held in the escrow or trust account shall be returned by first class mail or equally prompt means to the purchaser within five business days following that date.

(3) Conditions for release of deposited securities and funds. Funds held in the escrow or trust account may be released to the registrant and securities may be delivered to the purchaser or other registered holder identified on the deposited securities only at the same time as or after:

(i) The escrow agent or trustee has received a signed representation from the registrant, together with other evidence acceptable to the escrow agent or trustee, that the requirements of paragraphs (e)(1) and (e)(2) of this section have been met; and

(ii) Consummation of an acquisition(s) meeting the requirements of paragraph (e)(2)(iii) of this section.

(4) Prospectus supplement. If funds and securities are released from the escrow or trust account to the registrant pursuant to this paragraph, the prospectus shall be supplemented to indicate the amount of funds and securities released and the date of release.

Notes to § 230.419(e)

Note 1. With respect to a blank check offering subject to both Rule 419 and Exchange Act Rule 10b–9 (17 CFR 240.10b–9), the requirements of Rule 10b–9 are applicable only until the conditions of the offering governed by that Rule are met (*e.g.*, reaching the minimum in a "part-or-none" offering). When those conditions are satisfied, Rule 419 continues to govern the use of offering proceeds.

Note 2. If the business(es) or assets are acquired for cash, the fair value shall be presumed to be equal to the cash paid. If all or part of the consideration paid consists of securities or other non-cash consideration, the fair value shall be determined by an accepted standard, such as bona fide sales of the assets or similar assets made within a reasonable time, forecasts of expected cash flows, independent appraisals, etc. Such valuation must be reasonable at the time made.

(f) *Financial statements.* The registrant shall:

(1) Furnish to security holders audited financial statements for the first full fiscal year of operations following consummation of an acquisition pursuant to paragraph (e) of this section, together with the information required by Item 303(a) of Regulation S–K (17 CFR 229.303(a)), no later than 90 days after the end of such fiscal year; and

(2) File the financial statements and additional information with the Commission under cover of Form 8–K (17 CFR 249.308); *provided, however,* that such financial statements and related information need not be filed separately if the registrant is filing reports pursuant to Section 13(a) or 15(d) of the Exchange Act.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

4. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a–29, 80a–37, unless otherwise noted:

5. By adding § 240.15g–8 to read as follows:

§ 240.15g–8 Sales of Escrowed Securities of Blank Check Companies

As a means reasonably designed to prevent fraudulent, deceptive, or manipulative acts or practices, it shall be unlawful for any person to sell or offer to sell any security that is deposited and held in an escrow or trust account pursuant to Rule 419 under the Securities Act of 1933 (17 CFR 230.419), or any interest in or related to such security, other than pursuant to a qualified domestic relations order as defined by the Internal Revenue Code of 1986, as amended (26 U.S.C. 1 *et seq.*), or Title I of the Employee Retirement Income Security Act (29 U.S.C. 1001 *et seq.*), or the rules thereunder.

Dated: April 13, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92–9605 Filed 4–27–92; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34-30610; File No. S7-10-92]

RIN 3235-AF46

Sales Practice Requirements for Certain Low-Priced Securities

AGENCY: Securities and Exchange Commission.

ACTION: Proposed amendments.

SUMMARY: The Securities and Exchange Commission ("Commission") is publishing for comment amendments to Rule 15c2-6 under the Securities Exchange Act of 1934 ("Exchange Act"). In general, unless a transactional exemption is available, Rule 15c2-6 makes it unlawful for a broker or dealer to sell or effect the purchase of a "designated security" unless the broker or dealer has specifically approved the purchaser's account for transactions in designated securities and has received the purchaser's written agreement to the transaction. The proposed amendments would conform the definition of "designated security" in Rule 15c2-6 with the definition of "penny stock" in Rule 3a51-1 and, except for the established customer exemption, would replace the transactional exemptions under the rule with the transactional exemptions under Rule 15g-1. With a few exceptions, the changes to Rule 15c2-6 would be primarily structural and would not significantly alter the scope of the rule. In addition, the Commission is proposing to amend Schedule 15G under the Exchange Act to include a brief description of a broker-dealer's obligations to its customers under Rule 15c2-6.

DATES: Comments should be received on or before May 28, 1992.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. All comment letters should refer to File No. S7-10-92. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, 450 5th Street, NW., Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: Robert L. D. Colby, Chief Counsel, John M. Ramsay, Branch Chief, Belinda Blaine, Attorney, or Alexander Dill, Attorney, at (202) 504-2418, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street NW., Mail Stop 5-1, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Introduction

In August, 1989, the Commission adopted Rule 15c2-6 to address sales practice abuses involving speculative low-priced securities that are traded in the over-the-counter ("OTC") market.[1] Rule 15c2-6, which became effective on January 1, 1990, generally prohibits a broker-dealer from selling to or effecting the purchase of a "designated security" by any person, unless the broker-dealer has approved the purchaser's account for transactions in designated securities and received the purchaser's written agreement to the transaction. In approving an account for transactions in designated securities, a broker-dealer must obtain sufficient information from the purchaser to make an appropriate suitability determination, provide the purchaser with a written statement setting forth the basis of the determination, and obtain a signed copy of the suitability statement from the purchaser.

Subsequent to the adoption of Rule 15c2-6, Congress passed the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Penny Stock Act").[2] Section 503 of the Penny Stock Act added a new Section 3(a)(51) to the Exchange Act, which generally defines the term "penny stock" to include equity securities other than securities that are traded on a national exchange or automated quotation system meeting criteria established by the Commission, issued by a registered investment company, or otherwise excluded or exempted by the Commission based on price, net tangible assets, or other relevant criteria. Section 3(a)(51) also gives the Commission broad discretion to exclude or exempt other securities from the definition of penny stock. The Penny Stock Act also added section 15(g) to the Exchange Act, which, in addition to mandating specific disclosures by broker-dealers in penny stock transactions, gives the Commission the authority to exempt persons or transactions from the disclosure requirements of section 15(g).

Pursuant to this authority, on April 10, 1992, the Commission adopted Rule 3a51-1, which defines the term "penny stock" to exclude certain additional categories of equity securities, and Rule 15g-1, which exempts certain transactions from the disclosure requirements of Rules 15g-2 through 15g-6 under the Exchange Act ("Penny Stock Rules").[3] In proposing the Penny Stock Rules, the Commission had particularly solicited comment on whether Rule 15c2-6 should be amended to be consistent with those rules.[4] In response, several comments urged the Commission to adopt conforming changes to Rule 15c2-6.[5] These comments argued that making the scope of Rule 15c2-6 consistent with the Penny Stock Rules would eliminate costs and facilitate compliance with all of the rules.

In light of these comments, the Commission is proposing to amend Rule 15c2-6 to replace the definition of designated security with Rule 3a51-1's definition of penny stock and, except for the established customer exemption, to substitute the list of exempt transactions in paragraph (c) of Rule 15c2-6 with the exempt transactions under Rule 15g-1. With certain exceptions, discussed below, the changes to Rule 15c2-6 would be primarily structural, and would not alter the scope or the substantive requirements of the rule. The Commission believes that Rule 15c2-6 and the Penny Stock Rules should be consistent because these rules are aimed at curbing abuses in essentially the same market—namely, the market for low-priced securities that principally are quoted in the "pink sheets" published by the National Daily Quotation Service and in the NASD's OTC Bulletin Board. Moreover, making the scope of Rule 15c2-6 consistent with the Penny Stock Rules will simplify compliance with all of the rules. Broker-dealers will be able to avoid having to implement separate but overlapping compliance procedures to monitor

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[1] Securities Exchange Act Release No. 27160 (August 22, 1989), 54 FR 35468.

[2] Public Law 101-429, 104 Stat. 931 (1990). The Penny Stock Act was designed to address the lack of public information about penny stocks, as well as problems of recidivism among promoters and other persons involved in penny stock offerings.

[3] Securities Exchange Act Release No. 30608 (April 20, 1992) ("Adopting Release"). The Penny Stock Rules require broker-dealers, prior to effecting a transaction in a penny stock, to disclose to their customers certain information concerning the transaction and the penny stock market in general. Specifically, Rule 15g-2 requires broker-dealers to provide a risk disclosure document, as set forth in Schedule 15G; Rule 15g-3 requires disclosure of bid and ask quotations; Rules 15g-4 and 15g-5 require disclosure of any broker-dealer and associated person compensation in connection with the transaction; and Rule 15g-6 requires the provision of monthly account statements.

[4] The Penny Stock Rules were proposed for public comment in Securities Exchange Act Release No. 29093 (April 17, 1991), 56 FR 19165 ("Proposing Release").

[5] American Bar Association; Dean Witter Reynolds, Inc.; Merrill Lynch, Pierce, Fenner & Smith Inc.; National Association of Securities Dealers, Inc. ("NASD"); Shearson Lehman Brothers, Inc.; and the Security Traders Association.

trades in both designated securities and penny stocks. Finally, to make the risk disclosure document required by Rule 15g–2 more comprehensive, the Commission is proposing amendments to Schedule 15G under the Exchange Act to add to the existing discussion of broker-dealer obligations under the Penny Stock Rules a brief description of broker-dealer responsibilities under Rule 15c2–6.

II. Description of the Proposed Amendments

A. Amendments to Rule 15c2–6

1. Definition

Rule 15c2–6's requirement that broker-dealers document their suitability determination and obtain written customer consent to the transaction only applies to non-exempt transactions in "designated securities." The proposed amendments would replace the definition of "designated security" and this term, which is used solely for purposes of Rule 15c2–6, with Rule 3a51–1's definition of "penny stock."

Although the definition of penny stock is substantially the same as the current definition of designated security, it differs in a few respects.[6] The proposed amendments would eliminate these differences. Specifically, Rule 3a51–1(g) also contains an exclusion for securities whose issuer has demonstrated net tangible assets of $2 million, but limits the exclusion to issuers that have been in operation for at least three years. Issuers that have been in operation for less than three years must have at least $5 million in net tangible assets to be excluded from the definition of penny stock. In the Adopting Release, the Commission stated that the rule imposes a separate higher standard for start-up companies in order to prevent the types of abusive activities that have occurred both prior to and since the adoption of Rule 15c2–6 in August of 1989.[7] In addition to the exclusion based on issuer net tangible assets, however, Rule 3a51–1 includes an alternative exclusion for any penny stock that is issued by an issuer with average revenues of $6 million for the past three years.[8] This new alternative exclusion was added to mitigate the impact of the Penny Stock Rules on small operating issuers that are unable to meet the net tangible assets level, but that nevertheless have significant revenues.

Like Rule 15c2–6, Rule 3a51–1 contains an exclusion for any security that is authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ. The exclusion in Rule 3a51–1, however, is subject to the condition that price and volume information with respect to transactions in that security is required to be reported on a current and continuing basis and is made available to vendors of market information pursuant to the rules of the NASD. The Commission recently approved an NASD proposal to require members to report to the NASD the execution price and the number of shares of each trade in NASDAQ securities within 90 seconds after execution.[9] Once the NASD implements real-time last sale trade reporting pursuant to the terms of this proposal, all NASDAQ securities will be excluded from the definition of penny stock under paragraph (f) of Rule 3a51–1.

Similarly, Rule 3a51–1 provides an exclusion in paragraph (e) for any security that is registered, or approved for registration upon notice of issuance, on a national securities exchange,[10] provided that current price and volume information with respect to transactions in that security is required to be reported and is made available to vendors pursuant to the rules of the national securities exchange. Unlike the analogous exclusion in 15c2–6, this exclusion is only available for regional exchange-listed securities that actually are purchased or sold through the facilities of the exchange or in a distribution.[11] As the Commission noted in the Adopting Release, the exclusion is limited in order to address Congress' concern that securities that would otherwise be considered penny stocks because they are primarily traded in the non-NASDAQ OTC market nevertheless may be able to avoid Commission rules designed to protect investors by becoming listed on an exchange.[12]

Finally, several technical changes would be made to Rule 15c2–6 to make the rule consistent with the Penny Stock Rules. For example, the exemption for transactions in securities priced at five dollars or more, described below, would instead become an exclusion from the definition. Thus, securities with a price of five dollars or more would continue to be outside of the coverage of Rule 15c2–6,[13] as would securities issued by a registered investment company and put and call options issued by the OCC.

2. Exemptions

Paragraph (c) of Rule 15c2–6 provides an exemption for any transaction: (1) In which the price of the security is five dollars or more (including any share of any unit that has an independent exercise or conversion price); (2) in which the purchaser is an accredited investor, as defined in Regulation D under the Securities Act of 1933 ("Securities Act"); (3) that is not recommended by the broker-dealer; and (4) by a broker-dealer who is not acting as a market maker in the designated security and whose commissions, commission equivalents, and mark-ups from transactions in designated securities during a specified period, did not exceed five percent of its total commissions, commission equivalents, and mark-ups from transactions in securities during that period. The rule also contains an exemption for transactions with established customers, as defined in paragraph (d)(3) of the rule.

Except for the established customer exemption, the Commission is proposing to substitute the exemptions described above with the exemptions under Rule 15g–1.[14] Thus, Rule 15c2–6 would exempt transactions with institutional accredited investors,[15] the issuer of the penny stock, and any director, officer, general partner, or beneficial owner of more than five percent of any class of equity security of the issuer, but would not exempt transactions with other individual accredited investors.[16]

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[6] For a detailed discussion of Rule 3a51–1 and the rationale for the specific exclusions from the definition of penny stock, see Adopting Release.

[7] See also Proposing Release, 56 FR 19176.

[8] *I.e.*, revenues of at least $18 million by the end of the three-year period.

[9] Securities Exchange Act Release No. 30569 (April 10, 1992).

[10] This exclusion is conditioned on the national securities exchange making transaction reports available for at least some securities pursuant to Rule 11Aa3–1 (17 CFR 240.11Aa3–1).

[11] "Reported securities," as defined in 17 CFR 240.11Aa3–1(a)(4), are separately excluded from the definition of penny stock pursuant to paragraph (a) of Rule 3a51–1, and therefore are not required to meet the conditions set forth in paragraph (e) of the rule. *See* Adopting Release.

[12] See House Comm. on Energy and Commerce, Report to accompany the Penny Stock Reform Act of 1990, H.R. Rep. No. 617, 101st Cong. 2d Sess. (July 23, 1990), at 27; and Proposing Release, 56 FR at 19167.

[13] The only difference would be that, in calculating the price of a security for purposes of Rule 15c2–6, broker-dealers would be required to exclude the amount of any commission, commission equivalent, or mark-up charged in both agency and principal transactions.

[14] Moreover, as discussed above, the transactional exemption in Rule 15c2–6 for securities priced at five dollars or more would become a definitional exclusion.

[15] The term "institutional accredited investor" is defined in 17 CFR 230.501(a) (1), (2), (3), (7), and (8).

[16] The term "individual accredited investor" is defined in 17 CFR 230.501(a)(4), (5), and (6).

Continued

Instead, Rule 15c2–6 would provide an exemption for private offerings; that is, the rule would exempt transactions that meet the requirements of Regulation D under the Securities Act, [17] as well as transactions with an issuer not involving any public offering pursuant to Section 4(2) of the Securities Act.[18]

Under the proposed amendments, Rule 15c2–6 would continue to provide an exemption for broker-dealers receiving less than five percent of their total sales-related revenue from transactions in low-priced non-NASDAQ OTC securities. The *de minimis* revenue exemption, however, would be based on transactions in penny stocks, as defined in Rule 3a51–1, rather than transactions in "designated securities," as defined in current Rule 15c2–6(d)(2). As a result, the exemption would be somewhat broader than the current exemption in that it would allow broker-dealers to exclude from their five percent revenue calculation transactions in securities that are priced at five dollars or more.[19] In addition, broker-dealers would have the option of calculating their revenue over a six month period, rather than on a monthly basis.[20]

As the Commission stated in the Adopting Release, in the absence of price and trading information about particular penny stocks and the penny stock market in general, many affluent individual investors have been convinced through abusive sales practices to purchase penny stocks without sufficiently understanding the risks or the nature of their investment. If amended as proposed, Rule 15c2–6 would require broker-dealers to determine that the investor, regardless of his or her affluence, is capable of evaluating the risks of investing in speculative low-priced securities. The rule also would protect these investors from high pressure sales tactics by requiring broker-dealers to obtain the investor's written consent to the transaction.

[17] 17 CFR 230.501 through 230.508.

[18] 15 U.S.C. 77d(2). Assuming that the requirements of either of those provisions have been met, this exemption would apply even if the particular customer involved is not an accredited investor.

[19] Broker-dealers also could exclude transactions based on the average revenues of the issuer. As discussed above, however, broker-dealers would only be able to exclude from their five percent revenue calculation securities that are issued by an issuer with $2 million in net tangible assets if the issuer has been in business for at least three years.

[20] Specifically, amended Rule 15c2–6 would exempt transactions by a broker-dealer whose commissions, commission-equivalents, mark-ups, and mark-downs from transactions in penny stocks during each of the immediately preceding three months and during eleven or more of the preceding twelve months, or during the immediately preceding six months, did not exceed five percent of its total commissions, commission equivalents, mark-ups, and mark-downs from transactions in securities during those months.

Finally, the proposed amendments would not affect Rule 15c2–6's exemption for transactions that are not recommended by a broker-dealer or for transactions in which the purchaser is an established customer of the broker-dealer. Although Rule 15g–1 does not contain an established customer exemption, the Commission is proposing to retain the exemption solely for purposes of Rule 15c2–6. The Commission believes that persons that have previous investment experience in penny stocks or that are familiar with their broker-dealer are less susceptible to high pressure sales tactics and therefore are less in need of the particular protections provided by Rule 15c2–6.

B. Amendments to Schedule 15G

The Commission recently adopted Rule 15g–2 to implement the provisions of section 15(g)(2) of the Exchange Act.[21] The rule makes it unlawful for a broker-dealer to effect a transaction in a penny stock with or for the account of a customer unless the broker-dealer distributes to the customer, prior to effecting a transaction in a penny stock, a document describing the risks of investing in the penny stock market and other relevant information. The risk disclosure document, as set forth in Schedule 15G, contains a brief description of a broker-dealer's obligations under the Penny Stock Rules. To make the document more comprehensive, the Commission is proposing to amend Schedule 15G to include a paragraph describing the duties of a broker-dealer under Rule 15c2–6. Specifically, the following paragraph would be added to the section entitled "Your Rights:"

In addition to the items listed above, your brokerage firm must send to you:

● A Written Statement of Your Financial Situation and Investment Goals. In general, unless you have had an account with your brokerage firm for more than one year, or you have previously bought three different penny stocks from that firm, your brokerage firm must send you a written statement for you to sign that accurately describes your financial situation, your investment experience, and your investment goals, and that contains a statement of why your firm decided that penny stocks are a suitable investment for you. The firm also must get your written consent to buy the penny stock.

III. Conclusion and Request for Comments

The Commission believes that the proposed amendments to Rule 15c2–6 would simplify compliance with the rule and the Penny Stock Rules. The Commission requests comment on whether the amendments as proposed would accomplish this objective. The Commission particularly requests comment on whether the exemption for transactions with established customers should be retained, or whether the definition of "established customer" under the rule should be revised in any respect. The Commission also solicits comment on whether the language proposed to be added to the risk disclosure document clearly communicates the obligations of a broker-dealer under Rule 15c2–6.

[21] *See* Adopting Release.

IV. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a) of the Exchange Act [22] requires that the Commission, in adopting rules under the Exchange Act, consider the anticompetitive effects of such rules, if any, and balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission is preliminarily of the view that the conforming amendments to Rule 15c2–6 would not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared an Initial Regulatory Flexibility Analysis ("IRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[23] regarding the proposed amendments. The IRFA indicates that the proposed amendments would eliminate some of the existing costs imposed on small broker-dealers and small issuers. A copy of the IRFA may be obtained from Belinda Blaine, Attorney, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW., Mail Stop 5–1, Washington, DC 20549, (202) 504–2418.

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

V. Statutory Basis and Text of Amendments

In accordance with the foregoing, part 240 of chapter II of title 17 of the Code of Federal Regulations is proposed to be amended as follows:

[22] 15 U.S.C. 78w(a)(2).

[23] 5 U.S.C. 603.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77s, 77ttt, 78c, 78d, 78i, 78j, 78l, 78m, 78n, 78o, 78p, 78s, 78w, 78x, 79q, 79t, 80a-29, 80a-37, unless otherwise noted.

2. In § 240.15c2-6, by amending paragraphs (a) introductory text (two places), (a)(2)(ii), and (b)(3)(ii) by removing the words "designated security" and in their place adding the words "penny stock," and by removing the words "designated securities" and in their place adding the words "penny stocks" in paragraphs (a)(2)(i), (b) introductory text, and (b)(2) two places, and by revising paragraphs (c) and (d) to read as follows:

§ 240.15c2-6 Sales practice requirements for certain low-priced securities.

* * * * *

(c) For purposes of this section, the following transactions shall be exempt—

(1) Transactions that are exempt under 17 CFR 240.15g-1.

(2) Transactions in which the purchaser is an established customer of the broker or dealer.

(d) For purposes of this section—

(1) The term "penny stock" shall have the same meaning as in 17 CFR 240.3a51-1.

(2) The term "established customer" shall mean any person for whom the broker or dealer, or a clearing broker on behalf of such broker or dealer, carries an account, and who in such account:

(i) Has effected a securities transaction, or made a deposit of funds or securities, more than one year previously; or

(ii) Has made three purchases of penny stocks that occurred on separate days and involved different issuers.

3. By amending § 240.15g-100 to add to the section entitled "Your Rights," before the paragraph entitled "*Legal remedies*," the following paragraph:

§ 240.15g-100 Schedule 15G—Information to be included in the document distributed pursuant to 17 CFR 240.15g-2.

• A Written Statement of Your Financial Situation and Investment Goals. In general, unless you have had an account with your brokerage firm for more than one year, or you have previously bought three different penny stocks from that firm, your brokerage firm must send you a written statement for you to sign that accurately describes your financial situation, your investment experience, and your investment goals, and that contains a statement of why your firm decided that penny stocks are a suitable investment for you. The firm also must get your written consent to buy the penny stock.

Dated: April 20, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-9604 Filed 4-27-92; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 30609]

Order Temporarily Exempting Broker-Dealers from Section 15(g)(2) of the Securities Exchange Act of 1934

April 20, 1992.

I

Section 15(g)(2) of the Securities Exchange Act of 1934 (the "Exchange Act") requires a broker-dealer, prior to effecting any transaction in a penny stock, to give the customer a risk disclosure document that contains certain information specified therein. Schedule 15G of Rule 15g–2 specifies the contents and format of the risk disclosure document that broker-dealers are required to distribute. Rule 15g–2 and Schedule 15G become effective on July 15, 1992.

However, pursuant to section 1(c)(3)(B) of the Securities Enforcement Remedies and Penny Stock Reform Act of 1990, section 15(g)(2) became effective prior to the effective date of Rule 15g–2 and Schedule 15G, on April 15, 1992. Section 15(g)(2) therefore has the effect, independent of Rule 15g–2, of requiring broker-dealers to provide a risk disclosure document to customers, without the information and format required in Schedule 15G.

II. Findings

Based on the above, the Commission finds it consistent with the public interest and the protection of investors to exempt retroactively all broker-dealers from the application of section 15(g)(2) of the Exchange Act until the effective date of Rule 15g–2 and Schedule 15G.

III. Order

Accordingly, *It Is Hereby Ordered*, pursuant to section 15(g)(4) of the Exchange Act, that all broker-dealers are exempt from section 15(g)(2) of the Exchange Act until July 15, 1992. This order shall be effective retroactively to the effective date of section 15(g)(2).

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

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