of the particular proceeding."[12] The restrictions on *ex parte* communications in a Section 18 rulemaking proceeding are set forth in § 1.18(c) of the Commission's Rules of Practice, 16 CFR 1.18(c). In brief, they require that a communication on the merits to a Commissioner from a person outside the Commission be placed in the record of the proceeding if timely, and on the public record if untimely, and that a communication on the merits to a Commissioner from the rulemaking staff be disclosed on the record to the extent it contains any fact not already on the record.

By direction of the Commission.

Emily H. Rock,

Secretary.

[FR Doc. 85-11094 Filed 5-7-85; 8:45 am]

BILLING CODE 8750-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 271 and 276

[Release Nos. IC-14492, IAA-969]

Commission Policy and Guidelines for Filing of Applications for Exemption

AGENCY: Securities and Exchange Commission.

ACTION: Statement of Position of Commission's Division of Investment Management.

SUMMARY: The Securities and Exchange Commission has authorized this release to facilitate the review of exemptive applications by the Division of Investment Management and to streamline the process by which such applications are considered. The Commission's Division of Investment Management advises any prospective applicant contemplating filing an application for exemption from some or all of the provisions of the Investment Company Act of 1940 or the Investment Advisers Act of 1940 to follow certain procedures and guidelines. (Where applicable, the procedures and guidelines also should be followed by persons submitting request for no-action or interpretative advice or by persons filing disclosure documents under those Acts.)

EFFECTIVE DATE: May 8, 1985.

FOR FURTHER INFORMATION CONTACT: Glen A. Payne, Assistant Director (202) 272-3018, Mary A. Cole, Special Counsel (202) 272-3023, or Meryl Dewey, Staff Attorney (202) 272-3032, Division of Investment Management, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Division of Investment Management (the "Division") requires the cooperation of the mutual fund and investment advisory industries and the securities bar to assist it in the processing of exemptive applications and other filings under the Investment Company Act of 1940 (the "Act") and the Investment Advisers Act of 1940 (the "Advisors Act") (Collectively, the "Acts"). For the reasons stated below, the Division believes that improvements can be made in processing these filings.

Background

Recent years have seen an increase in both the number and complexity of applications requesting exemptions from some or all of the provisions of the Acts. During each of the last three years, the Division has received more than 300 exemptive applications, and this number continues to grow. While the Commission has codified routinely granted exemptions into rules of general applicability wherever possible, the time saved thereby has been more than offset by the time spent processing the increased number of novel applications involving new and sophisticated financial products. In addition, in many instances, the Division's staff must spend more time processing certain exemptive applications than should be necessary because applications have often been filed before the proposed transaction or arrangement has been finalized. Further, applicants have often decided not to effect the proposed transaction or arrangement and have simply withdrawn their applications, thereby wasting the staff time spent reviewing them. Multiple amendments have also been needed where the original application did not comply with the Commission's procedural rules and/or where the applicant misstated or omitted crucial facts or legal analyses needed to justify the request for relief. Consequently, too much staff time has been spent on clearly deficient or repetitive filings to attempt to bring them within the standards of the Acts. Inevitably, these situations have led to processing delays and to an increase in the Division's backlog of pending applications.

Discussion

The Division has taken various internal steps to ensure that all exemptive applications and other filings are processed as expeditiously as possible.[1] However, further measures are needed to reduce delays. While section 6(c) of the Act [15 U.S.C. 80a-6(c)] and section 206A of the Advisers Act [15 U.S.C. 80B-6a] give the Commission authority to grant exemptions where "necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions" of the Acts, those provisions are not blanket authority to waive any provision of the Acts. Potential applicants should be particularly mindful of this fact when considering filing applications requesting unprecedented exemptive relief seeking a waiver of express statutory prohibitions.

The Division's staff should not have to spend an inordinate amount of time processing clearly deficient or untimely applications at the expense of delaying action on comprehensive or routine applications. Accordingly, to ensure prompt and fair consideration of all exemptive applications, each applicant must adhere to the following procedures. Where applicable, they should be followed for all submissions to the Division, including requests for no-action or interpretative letters and disclosure documents.

Procedures and Guides

1. Persons contemplating filing exemptive applications should carefully review all relevant provisions of the Acts, the rules thereunder and applicable Commission releases before filing an exemptive application.[2] Applicants should recognize the differences between their proposal and prior applications requesting similar relief and, to the extent possible, bring their proposal within applicable precedent. Further, applicants should cite and discuss applicable precedent. Where the request is unprecedented, the applicant should so state in its transmittal letter.

2. The application should be filed in a timely and comprehensive manner.

[12] 16 CFR 1.26(b).

[1] Division guidelines require, *e.g.*, that (i) initial comments on an exemptive application be given at one time and within 45 days of receipt of the application (novel or complex applications may require a longer review period); (ii) notices of routine applications which require no amendment be published within 60 days; and (iii) orders under delegated authority be issued within two business days after the expiration of the notice period, if no hearing request is filed.

[2] Prospective applicants who are unfamiliar with the exemptive application process should also review prior applications on file with the Commission which concern similar matters. Copies of applications are available from the Public Reference Branch of the Commission's Office of Consumer Affairs.

Exemptive applications that require review of supporting documents (*e.g.*, a registration statement pursuant to the Securities Act of 1933 [15 U.S.C. 77a *et seq.*] or a partnership agreement in connection with a "two-tier real estate" transaction) should not be filed until all necessary supporting documents have been received by the Commission. Otherwise, the Division will ask that the application be withdrawn unless the applicant can justify, based on the facts of its situation, why they have not been submitted. If the application is not withdrawn, it will be placed on inactive status.

3. Each applicant should state an adequate basis for the relief requested, including detailed justification for removal of any statutory protections, and identify any positive benefits expected for investors and any conditions imposed to protect investors. The Division will not support an application that requests relief not adequately justified. In such instances, the Division will request that the application be either withdrawn or significantly amended.[3]

4. The application should meet the Acts' procedural requirements. Rules 0–2, 0–4 and 0–5 under the Act [17 CFR 270.0–2, 0–4 and 0–5] and Rules 0–4, 0–5 and 0–6 under the Advisers Act [17 CFR 275.0–4, 0–5 and 0–6] govern the execution and filing of exemptive applications. Applications and amendments often fail to include proper authorization and verification. Applicants will have to correct any procedural deficiency by amendment.[4]

5. Rule 0–2(g) under the Act [17 CFR 270.02(g)] and Rule 0–4(g) under the Advisers Act [17 CFR 275.04(g)] require that the application be accompanied by a proposed notice. The Commission is charged approximately $400 per page for publishing notices in the **Federal Register.** To reduce publication costs, the Division has had to devote substantial staff time to condense applications into notices that are brief as well as informative. Thus, proposed notices submitted by applicants should be brief, modeled on releases issued since 1983, and include only statements that are necessary to understand the essence of the requested relief. Generally, a proposed notice should identify the parties involved, briefly describe the relevant transactions and why the applicant believes it qualifies for an exemption, and summarize the critical representations and undertakings contained in the application. An applicant who submits a deficient or verbose proposed notice will be asked to file an amendment to resubmit a notice in usable form.

6. Applications will be reviewed in the order in which they are received.[5] The Division will not be receptive to requests for expedited review absent the most compelling demonstration that the application could not be filed in time to allow it to be processed in due course. Applicants may submit a courtesy copy of their application to the Assistant Director of the Division's Office of Investment Company Regulation or to the appropriate Division Special Counsel (if known), concurrently with the filing of the application. The courtesy copy should be clearly marked to indicate that it is *not* Applicant's official filing. One copy of each relevant supporting document (such as those referred to in Guide 2) should be included with with the courtesy copy.

7. Amendments to an application should be prepared and filed as described in Guides 3 and 4.[6] If desired, a courtesy copy of the amendment (marked to show changes) may also be submitted as described in Guide 6. For processing purposes, an amendment normally will date back to the filing of the original application and will be given priority over new applications. However, if an amendment is required because of a deficient filing as described in Guides 3 or 4, the application will be considered to have been received on the date the staff receives an acceptable amendment.

8. Amendments should be promptly filed.[7] The Division recognizes that amendments to complex or novel applications require more time to prepare than routine amendments.[8] However, in all cases applicants should either file their amendment within 60 days of receipt of comments or explain, in writing, to the reviewer why preparation of the amendment requires additional time. At the discretion of the Division, an applicant who does not do so will have its application placed on inactive status. An applicant who is notified that its application is being placed on inactive status may reactivate the application at any time by filing an appropriate request with the Division or by filing the required amendment, and need not pay any additional filing fee. Action on reactivated applications will commence from the date of receipt of the request or the amendment by the Division and will *not* date back to the filing of the original application.

9. Pre-filing conferences will be scheduled only upon a showing that a proposal involves issues that must be resolved before an application can be formally filed with the Commission.[9] Persons who believe that a pre-filing conference is necessary should contact the appropriate Branch Chief or Special Counsel (if known) or the Assistant Director or Chief of the relevant Division office. Where a pre-filing conference is scheduled, the Division requires submission of written summaries of the issues proposed to be discussed at least four business days prior to the conference.[10] The staff will not, except in the most extraordinary situations, review draft applications or

[3] If the Division cannot support an application, the Division will submit the application to the Commission with a recommendation that the application be set down for a hearing, unless it is withdrawn.

[4] The procedures for filing a request for no-action or interpretative advice are set forth in Investment Company Act Release Nos. 6220 and 6330, dated October 29, 1970, and January 25, 1971, respectively.

[5] All filings are made through the Commission's central filing office. Applicants seeking confidential treatment pursuant to Section 45(a) of the Act [15 U.S.C. 80a–44(a)] or section 210(a) of the Advisers Act [15 U.S.C. 80b–10(a)] with respect to a proposed transaction should not incorporate or attach to the exemptive application that portion for which confidential treatment is sought. Instead, the application should refer to a named exhibit, state that confidential treatment is being requested and explain the basis of the request. The application should then be filed as described herein. The confidential exhibit, and the request for confidentiality, should be submitted to the Division.

[6] An amendment may either take the form of a restated application or a modification of the original application, but must conform to the requirements of Rules 0–2 and 0–4 under the Act [17 CFR 270.0–2 and 0–4] and Rules 0–4 and 0–6 under the Advisers Act [17 CFR 275.0–4 an 0–6].

[7] The Division expects all amendments to respond fully to staff comments or be accompanied by a cover letter, directed to the attention of the reviewer, explaining why the applicant has elected not to meet certain staff comments.

[8] In the case of requests for no-action or interpretative advice, the Division's Office of Chief Counsel, as a matter of policy, will deny any such request if supplemental information is not received within 60 days after it is requested.

[9] This policy on pre-filing conferences specifically applies to all proposals submitted to the Division pursuant to the Acts: *e.g.*, exemptive applications, requests for no-action or interpretative advice and disclosure documents.

[10] While the staff will attempt to be as helpful as possible at pre-filing conferences, the staff must have the opportunity to review actual filings before taking definitive positions on the issues presented.

draft requests for no-action or interpretative advice. Of course, in all cases, the Division's staff is available to respond to telephone inquiries about any aspect of the Acts, including answering specific questions relating to preparation of filings.

The Division believes that adherence to these procedures and guidelines will make optimal use of its staff and result in better overall service to the financial industry and investing public.

List of Subjects in 17 CFR Parts 271 and 276

Investment companies, Investment advisers, Securities.

PARTS 271 AND 276—[AMENDED]

Accordingly, 17 CFR Parts 271 and 276 are hereby amended by adding a reference to this statement of Division position.

By the Commission.

John Wheeler,

Secretary.

April 30, 1985.

[FR Doc. 85-11091 Filed 5-7-85; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Drugs and Biologics Officials

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority regarding orphan products and distribution of biological products to update the list of delegates according to changes in organization titles.

EFFECTIVE DATE: May 8, 1985.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: In a recent reorganization, the Center for Drugs and Biologics (CDB) amended the titles of two divisions by dropping the word biological from the titles. This document amends § 5.58 *Orphan products* (21 CFR 5.58) by changing reference to the Division of Biological Product Certification to the Division of Product Certification in the list of delegates and § 5.69 *Notification of release for distribution of biological products* (21 CFR 5.69) by changing reference to Division of Biological Product Quality Control to Division of Product Quality Control.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

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

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for Part 5 continues to read as follows:

Authority: Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371), unless otherwise noted.

2. By revising § 5.58(c)(3)(ii) to read as follows:

§ 5.58 Orphan products.

* * * * *

(c) * * *

(3) * * *

(ii) The Directors and Deputy Directors of the Divisions of: Anti-Infective Drug Products, Metabolism and Endocrine Drug Products, Product Certification, and Biological Investigational New Drugs, Office of Biologics Research and Review, CDB.

3. By revising § 5.69(c) to read as follows:

§ 5.69 Notification of release for distribution of biological products.

* * * * *

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biologics Research and Review, CDB.

Effective date. This regulation shall become effective May 8, 1985.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: May 1, 1985.

Mervin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-11041 Filed 5-7-85; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 201, 203, and 234

[Docket No. N-85-1530; FR-2071]

Mortgage Insurance; Changes to the Maximum Mortgage Limits for Single Family Residences, Condominiums and Manufactured Homes and Lots

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, (HUD).

ACTION: Notice of revisions to FHA maximum mortgage limits for high-cost areas.

SUMMARY: This Notice amends the listing of areas eligible for "high-cost" mortgage limits under certain of HUD's insuring authorities under the National Housing Act by adding ten areas and further increasing the limits of two previously designated high-cost areas. Mortgage limits are adjusted in an area when the Secretary determines that middle- and moderate-income persons have limited housing opportunities because of high prevailing housing sales prices.

FOR FURTHER INFORMATION CONTACT: For single family: Brian Chappelle, Acting Director, Single Family Development Division, Room 9270, Telephone (202) 755-8720. For manufactured homes: Christopher Peterson, Director, Office of Title I Insured Loans, Room 9160, Telephone, (202) 755-6880; 451 Seventh Street SW., Washington, D.C. 20410. (Telephones are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Background

The National Housing Act (NHA) (12 U.S.C. 1710-1749) authorizes HUD to insure mortgages for single family residences (from one- to four-family structures), condominiums, manufactured home lots, and manufactured homes, combination manufactured homes and lots. The NHA, as amended by the Housing and Community Development Act of 1980 and the Housing and Community Development Amendments of 1981, permits HUD to increase the maximum mortgage limits under most of these programs to reflect regional differences in the cost of housing. In addition, section 2(b) and 214 of the NHA provide for special high-cost limits for insured