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02/13/2013

NO ACT



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

Received SEC

FEB 14 2013

Washington, DC 20549



13000328

February 14, 2013

Jon Filderman  
Merck & Co., Inc.  
jon\_filderman@merck.com

Re: Merck & Co., Inc.

Act: 1934  
Section: \_\_\_\_\_  
Rule: 14a-8  
Public  
Availability: 2/14/13

Dear Mr. Filderman:

This is in regard to your letter dated February 13, 2013 concerning the shareholder proposal submitted by People for the Ethical Treatment of Animals for inclusion in Merck's proxy materials for its upcoming annual meeting of security holders. Your letter indicates that the proponent has withdrawn the proposal, and that Merck therefore withdraws its January 18, 2013 request for a no-action letter from the Division. Because the matter is now moot, we will have no further comment.

Copies of all of the correspondence related to this matter will be made available on our website at <http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml>. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Matt S. McNair  
Special Counsel

cc: Jared S. Goodman  
People for the Ethical Treatment of Animals  
jaredg@petaf.org

Jon Filderman  
Managing Counsel  
Corporate Staff

Merck & Co., Inc.  
WS3AB-05  
One Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100  
Fax: 908-735-1224



Via e-mail - [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov)

February 13, 2013

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Chief Counsel  
100 F Street, NE  
Washington, DC 20549

Re: Shareholder Proposal of People for the Ethical Treatment of Animals

Ladies and Gentlemen:

On January 18, 2013, Merck & Co., Inc., a New Jersey corporation ("Merck"), submitted to the U.S. Securities and Exchange Commission notice under Rule 14a-8(j) regarding Merck's plans to exclude from the proxy materials for its 2013 Annual Meeting a shareholder proposal submitted by People for the Ethical Treatment of Animals ("PETA"). Thereafter, on January 31, 2013, Merck received notification (attached as Exhibit 1) from Mr. Jared Goodman, on behalf of PETA, that PETA was withdrawing its shareholder proposal from consideration for inclusion in the proxy materials for Merck's 2013 Annual Meeting.

Accordingly, Merck wishes to formally withdraw its request to exclude from the proxy materials for its 2013 Annual Meeting the shareholder proposal submitted by PETA.

If you have any questions or require any further information, please contact me at 908-423-3853.

Very truly yours,

A handwritten signature in black ink, appearing to read "Jared Goodman", written over a white background.

cc: Goodman, Jared S.  
PETA

**Filderman, Jon**

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**From:** Jared Goodman <JaredG@PetaF.org>  
**Sent:** Thursday, January 31, 2013 4:36 PM  
**To:** Filderman, Jon; shareholderproposals@sec.gov  
**Subject:** RE: Merck & Co., Inc. - Omission of Shareholder Proposal Submitted by PETA - 2013

Dear Mr. Filderman and Sirs and Madams of the Staff,

On behalf of PETA, I am writing to inform you that PETA hereby withdraws its shareholder proposal from consideration for inclusion in the proxy materials for Merck's 2013 Annual Meeting.

Please contact me using the details below if you have any questions. Thank you.

Very truly yours,

**Jared S. Goodman**  
Counsel  
PETA Foundation  
1536 16th St. NW  
Washington, DC 20036  
T: (202) 540-2204  
F: (202) 540-2208  
M: (516) 319-5906

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**From:** Filderman, Jon [[mailto:jon\\_filderman@merck.com](mailto:jon_filderman@merck.com)]  
**Sent:** Friday, January 18, 2013 10:51 AM  
**To:** [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov)  
**Cc:** Jared Goodman  
**Subject:** Merck & Co., Inc. - Omission of Shareholder Proposal Submitted by PETA - 2013

Dear Ladies and Gentlemen,

On behalf of Merck & Co., Inc. ("Merck"), attached please find a notice under Rule 14a-8(j) regarding Merck's plans to exclude from the proxy materials for its 2013 Annual Meeting a shareholder proposal submitted by People for the Ethical Treatment of Animals. A full copy of the attached notice is being sent to the Proponent simultaneously with this submission.

Please do not hesitate to contact me at 908-423-3853 if you have any questions or have any difficulties opening the attachment. In addition, if possible, please acknowledge receipt of the email and the related attachment.

Very truly yours,

Jon Filderman  
Managing Counsel  
Office of the General Counsel  
Merck & Co., Inc.  
One Merck Drive, P.O. Box 100  
Whitehouse Station, New Jersey 08889-0100  
Assistant: [Kim\\_Horvath@Merck.com](mailto:Kim_Horvath@Merck.com) (x7298)  
Phone: 908-423-3853  
Email: [Jon\\_Filderman@merck.com](mailto:Jon_Filderman@merck.com)

cc: Goodman, Jared S.  
PETA

Jon Filderman  
Managing Counsel  
Corporate Staff

Merck & Co., Inc.  
WS3AB-05  
One Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100  
Fax 908-735-1224



January 18, 2013

U.S. Securities and Exchange Commission  
Division of Corporation Finance  
Office of Chief Counsel  
100 F Street, NE Washington, DC 20549

Re: Shareholder Proposal of People for the Ethical Treatment of Animals

Ladies and Gentlemen:

Merck & Co., Inc., a New Jersey corporation ("Merck" or the "Company"), received a shareholder proposal (the "Proposal") from People for the Ethical Treatment of Animals ("PETA" or the "Proponent"), for inclusion in the proxy materials for the Company's 2013 Annual Meeting of Stockholders (the "Proxy Materials").

In accordance with Staff Legal Bulletin 14D (November 7, 2008), this letter is being transmitted via electronic mail to [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov). Also, in accordance with Rule 14a-8(j) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company is simultaneously sending a copy of this letter and its attachments to the Proponent as notice of its intention to exclude the Proposal and supporting statements from the Proxy Materials and the reasons for the omission. The Company intends to file its definitive Proxy Materials with the Commission on or after April 8, 2013. Accordingly, pursuant to Rule 14a-8(j), this letter is being timely submitted (not less than 80 days in advance of such filing).

#### SUMMARY

We believe that pursuant to Rule 14a-8(i)(10) the Proposal may properly be excluded from our Proxy Materials because the Company already has substantially implemented the Proposal.

#### BACKGROUND

On November 28, 2012, the Company received an email which contained a letter dated the same from the Proponent which included a shareholder proposal for inclusion in the Company's Proxy Materials. The Proponent requests the Company's Proxy Materials include the following proposal:

RESOLVED, despite the existence of an animal use policy intended to assure adherence with federal animal welfare laws, our Company's in-house laboratories and external research laboratories it has used have been cited repeatedly by the government for violations of these laws; to prevent further violations, the Board should issue a report detailing all new and additional measures implemented to oversee the welfare of animals used both in-house and at external laboratories.

A copy of the Proposal is attached hereto as Exhibit J.

## ANALYSIS

### The Proposal May Be Excluded Pursuant to Rule 14a-8(i)(10)

Rule 14a-8(i)(10) permits a company to exclude a proposal from its proxy materials if the company "has already substantially implemented the proposal." The Commission has stated that for a proposal to be omitted as moot under this rule it must be "substantially implemented" by a company, not implemented in full or precisely as presented. *See* Exchange Act Release No. 20091 (August 16, 1983). The general policy underlying the "substantially implemented" basis for exclusion is "to avoid the possibility of shareholders having to consider matters which have already been favorably acted upon by the management." *See* Exchange Act Release No. 12598 (July 7, 1976).

The Staff has consistently permitted exclusion of a shareholder proposal when a company has already substantially implemented the essential objective of the proposal even if by means other than those suggested by the shareholder proponent. *See, e.g., Wal-Mart Stores, Inc.* (March 30, 2010) (concurring that a company's adoption of various internal policies and adherence to particular principles substantially implemented a proposal seeking the adoption of principles for national and international action to stop global warming specified in the proposal); *PG&E Corporation* (March 10, 2010) (concurring that a company's practice of disclosing annual charitable contributions in various locations on its website substantially implemented a proposal seeking a semi-annual report on specific information regarding the company's charitable contributions); *Aetna Inc.* (March 27, 2009) (concurring that a report on gender considerations in setting insurance rates substantially implemented a proposal seeking a report on the company's policy responses to public concerns about gender and insurance, despite the proponent's arguments that the report did not fully address all issues addressed in the proposal).

Furthermore, the Staff consistently has concurred in the exclusion of proposals under Rule 14a-8(i)(10) where companies' compliance with legal or regulatory requirements, rather than specific management or board action, addressed the concerns underlying the proposals. *See Johnson & Johnson* (Feb. 17, 2006) (permitting the exclusion of a proposal that required the company to verify employment eligibility of current and future employees and to terminate any employee not authorized to work in the United States on the basis that the company already was required to take such actions under federal law); *AMR Corp.* (April 17, 2000) (permitting the exclusion of a proposal recommending that the company's audit, nominating and compensation committees consist entirely of independent directors on the basis that the company was subject to the independence standards set forth in New York Stock Exchange ("NYSE") listing standards, Section 162(m) of the Internal Revenue Code and Exchange Act Rule 16b-3 for directors serving on such committees); and *Eastman Kodak Co.* (Feb. 1, 1991) (permitting the exclusion of a proposal recommending that the company's board of directors adopt a policy of publishing in the company's annual report the costs of all fines paid by the company for violations of environmental laws based on a representation by the company that it complied with Item 103 of Regulation S-K, which requires similar (albeit not identical) disclosure).

Accordingly, Rule 14a-8(i)(10) permits the exclusion of a proposal when a company has implemented the essential objective of the proposal, even where there the company's actions do not exactly correspond to the actions sought by the proposal. The Proposal's essential objective is the "report detailing all new and additional measures [the Company is] implement[ing] to oversee the welfare of animals used" in the Company's laboratories. The Company's website has an entire page devoted to the essential objective of the proposal. The website can be found at:

<http://www.merckresponsibility.com/focus-areas/access-to-health/research-and-development/animal-research/home.html>

A printed copy of the content found on that page as of the date hereof is attached hereto as Exhibit 2. The page describes the various methods Merck employs to ensure proper animal care and measures to improve the living conditions of all animals used. The website points out that:

The care and use of laboratory animals in biomedical research is highly regulated. In general, the regulations govern housing, feeding, veterinary care, research project review and include both internal and external inspections. Our standards for animal care and use meet or exceed all applicable local, national and international laws and regulations.

The website is updated as necessary to reflect new or additional methods employed by Merck to ensure proper animal care.

One example of the regulatory framework that the Company is subject to with respect to animal welfare is the Animal Welfare Act of 1966 ("AWA"). The AWA regulates the treatment of animals in research, exhibition and transport. Those covered by the AWA must provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures. Of the many provisions contained in the AWA, the AWA requires facilities subject to the AWA establish specialized committees that include at least one veterinarian and one person not affiliated with the facility in any way.

The website noted above currently discusses Merck's Institutional Animal Care and Use Committees (IACUCs) and Ethical Review Committees and how they provide oversight of the Company's animal care and use programs. Specifically: "[t]hey review all proposed animal studies, review the animal care and use programs, inspect facilities, investigate any concerns and report all findings to the Institutional Official for Animal Welfare, which is globally accountable for compliance with all of our animal welfare policies and regulations."

Furthermore, as stated on the Company's website:

Merck holds similar expectations for standards of animal care and use at our contract laboratories. Merck performs due diligence and monitors external laboratories performing in vivo studies on our behalf, and holds them accountable to the same regulations and standards that govern our animal care and use. Additionally, in vivo research conducted at third-party laboratories is subject to protocol review by a Merck IACUC or equivalent committee. Non-compliance with regulations or standards can lead to termination of the relationship.

In addition to these efforts, it should be noted that contract laboratories are also subject to and required to comply with the provisions of the AWA that specify minimum welfare standards for animals used by such entities. Part of the statutory compliance framework includes disclosure regarding animal usage. The Company and each of the contract research laboratories engaged by the Company, as required under the AWA, submit, on an annual basis, information disclosing the numbers and types of certain animals used to the United States Department of Agriculture ("USDA"). This information is supplied annually to the USDA on the Animal and Plant Health Inspection Service ("APHIS") Form 7023 ("Form7023"). All animals that are required to be disclosed under the Animal Welfare Act are disclosed by the Company and each of the contract research laboratories engaged by the Company.

An examination of Form 7023 shows six columns of information labeled A, B, C, D, E and F. Columns A and F relate to the animals covered by the Animal Welfare Act and the total number of animals used, respectively. Columns B through E categorize the use of such animals. Column B lists the number of animals not yet used for research purposes; column C lists the number of animals whose use involved "no pain, distress, or use of pain-relieving drugs"; column D lists the number of animals whose use involved "pain or distress to the animals and for which appropriate anesthetic, analgesic or tranquilizing drugs were used" and column E lists the number of animals whose use "involved accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research experiments, surgery or tests." The forms, which are publicly available and filed every year, provides substantial amounts of useful information regarding animal usage at the Company.

In addition to compliance with the broad regulatory framework of the AWA, the Company's research division also has attained and maintained accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International ("AAALAC"). The following is from AAALAC's website:

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. For some, animal research is a controversial topic. But like others in the animal welfare arena, AAALAC endorses the use of animals to advance medicine and science when there are no non-animal alternatives, and when it is done in an ethical and humane way. When animals are used, AAALAC works with institutions and researchers to serve as a bridge between progress and animal well-being. This is done through AAALAC's voluntary accreditation process in which research programs demonstrate that they meet the minimum standards required by law, and are also going the extra step to achieve excellence in animal care and use.

Third party accreditation by an independent, nonprofit organization is another way the Company exemplifies its commitment to animal welfare. The names of Merck's accredited sites are publicly listed on AAALAC's website.

Furthermore, in addition to regulatory requirements and third party accreditation, the Company has publicly committed to various initiatives on a voluntary basis to further ensure proper animal care and improve living conditions of animals used. One example is the "3Rs" initiative which stands for "Replacement, Reduction and Refinement." As stated on the Company's website, the 3Rs are:

Replacement—using non-animal systems or less-sentient species (for example cell cultures, computer modeling, bacterial assays and fish models)

Reduction—using the minimum number of research animals necessary to obtain valid scientific data. (sophisticated animal models that yield precise data, like telemetric monitoring models that monitor ECG and blood pressure, reduce the number of animals needed)

Refinement—minimizing any distress or discomfort during a study (extensive literature searches contribute to the use of the best scientific models, and analgesics or tranquilizers are used whenever possible)

The Company provides extensive training in the 3Rs, provides funding to groups that help support 3R research initiatives and has invested in a state of the art imaging department for cancer and disease research. Merck also issues two awards annually, the Animal Alternative Award and the Dieter Lütticken Award, which honor the teams within the company that best exemplifies the Company's commitment to the 3Rs. The awards help the Company to communicate its commitment to animal welfare to all stakeholders.

The Company has taken great measures to ensure that the treatment of the animals used in its research efforts exceed statutory and regulatory minimum standards. The internal guidelines and initiatives as described above and on the Company's website, the existing regulatory framework of the AWA in addition to the third party accreditation that the Company obtains, are all designed to ensure that the Company has proper animal care procedures which include measures to improve living conditions of all animals used in-house and at contract laboratories. As such, the Proposal is again excludable pursuant to Rule 14a-8(a)(i)(10).

We note that last year the Proponent submitted a proposal requesting that "the Board should issue an annual report to shareholders disclosing procedures to ensure proper animal care, including measures to improve the living conditions of all animals used in-house and at contract laboratories." The Staff granted the Company's no-action request that this proposal was excludable pursuant to Rule 14a-8(a)(i)(10).

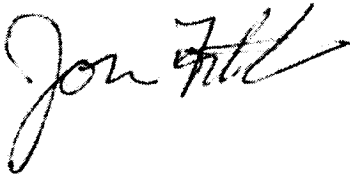
The Proposal submitted this year is changed from last year's proposal (only minimally) in that it seeks the issuance of a "report detailing all *new and additional measures* [the Company is] implement[ing] to oversee the welfare of animals used" in the Company's laboratories (emphasis added). As indicated above, the Company's website is updated as necessary to reflect new or additional methods employed by Merck to ensure proper animal care. Accordingly, the inclusion this year of the reference to all "new and additional measures" in the Proponent's Proposal should not change the conclusion the Staff reached last year as to the excludability of the Proposal under Rule 14a-8(a)(i)(10). The Proponent is essentially submitting again this year the same proposal as last year. This year's Proposal should similarly be excludable.

#### CONCLUSION

Accordingly, for the reasons explained above, and without addressing or waiving any other possible grounds for exclusion, the Company requests the Staff to concur in our opinion that the Proposal may be excluded from the Company's Proxy Materials for the reasons set forth herein.

If you have any questions or require any further information, please contact me at 908-423-3853. Should you disagree with the conclusions set forth in this letter, we respectfully request the opportunity to confer with you prior to the determination of the Staff's final position.

Very truly yours,

A handwritten signature in black ink, appearing to read "Jon Hill". The signature is written in a cursive, flowing style.



# EXHIBIT 1



PEOPLE FOR  
THE ETHICAL  
TREATMENT  
OF ANIMALS

November 28, 2012

Celia A. Colbert  
Senior Vice President, Secretary and Assistant General Counsel  
Merck & Co., Inc.  
WS3A-65 P.O. Box 100  
Whitehouse Station, NJ 08889-0100

**VIA UPS NEXT DAY AIR SAVER**

Dear Ms. Colbert:

Attached to this letter is a shareholder proposal submitted for inclusion in the proxy statement for the 2013 annual meeting. Also enclosed is a letter from People for the Ethical Treatment of Animals' (PETA) brokerage firm, Morgan Stanley Smith Barney, confirming ownership of 101 shares of Merck & Co., Inc. common stock, most of which were acquired at least one year ago. PETA has held at least \$2,000 worth of common stock continuously for more than one year and intends to hold at least this amount through and including the date of the 2013 shareholders meeting.

Please communicate with PETA's authorized representative Jared S. Goodman if you need any further information. Mr. Goodman can be reached at Jared S. Goodman, PETA Foundation, 1536 16<sup>th</sup> St. NW, Washington, DC 20036, by telephone at (202) 540-2204, or by e-mail at [JaredG@PetaF.org](mailto:JaredG@PetaF.org). If Merck & Co., Inc. will attempt to exclude any portion of this proposal under Rule 14a-8, please advise Mr. Goodman within 14 days of your receipt of this proposal.

Sincerely,

Sara Britt, Department Coordinator  
PETA Corporate Affairs

Enclosures: 2013 Shareholder Resolution  
Morgan Stanley Smith Barney letter

Washington, D.C.  
1536 16<sup>th</sup> St. N.W.  
Washington, DC 20036  
202-483-PETA

Los Angeles  
2154 W. Sunset Blvd.  
Los Angeles, CA 90026  
323-644-PETA

Norfolk  
501 Front St.  
Norfolk, VA 23510  
757-622-PETA

Oakland  
554 Grand Ave.  
Oakland, CA 94610  
510-763-PETA

[Info@peta.org](mailto:Info@peta.org)  
[PETA.org](http://PETA.org)

Affiliates

- PETA India
- PETA Australia
- PETA Germany
- PETA Asia-Pacific
- PETA Netherlands
- PETA Foundation (U.K.)

## Accountability for Animal Welfare

**RESOLVED**, despite the existence of an animal use policy intended to assure adherence with federal animal welfare laws, our Company's in-house laboratories and external research laboratories it has used have been cited repeatedly by the government for violations of these laws; to prevent further violations, the Board should issue a report detailing all new and additional measures implemented to oversee the welfare of animals used both in-house and at external laboratories.

### Supporting Statement

In spite of its animal use policy, our Company has been repeatedly cited by the government for failing to adhere to minimal federal regulations governing the treatment of animals in its laboratories. These violations involved:

- Inadequate housing of animals, including caging primates in isolation without the ability to see one another. Primates are known to be such social animals that the National Research Council reported that "social interactions are considered to be one of the most important factors influencing the psychological well-being of most nonhuman primates."<sup>1</sup>
- Failure to notify a veterinarian or provide treatment for a dog with cysts on his paws or for several dogs observed to be bleeding following routine nail trimming.
- Inaccurate record keeping, including under-representation of the number of animals used in painful experiments and lack of documentation showing whether Merck representatives researched alternatives to painful procedures.

In 2011, 12,242 animals were held or used in-house by our Company, including approximately 1,700 dogs and 2,100 primates. More than 6,500 animals were used in painful experiments.<sup>2</sup>

These figures do not include the vast numbers of mice and rats who are used or the large number of animals used in Merck experiments at external contract laboratories.

Our Company's animal use policy states that Merck "monitors external laboratories performing in vivo [animal] studies on our behalf."<sup>3</sup> However, our Company purchased animals from – or paid for services conducted at – a minimum of five external organizations with numerous violations noted by government inspectors, including Professional Laboratory and Research Services (PLRS)<sup>4</sup>, Covance<sup>5</sup>, New Iberia Research Center, Alpha Genesis, and Marshall Farms.<sup>6</sup>

In 2011, a grand jury indicted four PLRS employees with 14 counts of felony cruelty-to-animals charges following an investigation of the conditions there. Documented abuses included:

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<sup>1</sup> National Research Council. *Psychological Well-being of Nonhuman Primates*. (National Academy Press., 1998).

<sup>2</sup> [http://www.aphis.usda.gov/animal\\_welfare/efoia/index.shtml](http://www.aphis.usda.gov/animal_welfare/efoia/index.shtml)

<sup>3</sup> <http://www.merckresponsibility.com/focus-areas/access-to-health/research-and-development/animal-research/home.html>

<sup>4</sup> <http://www.peta.org/features/professional-laboratory-and-research-services.aspx>

<sup>5</sup> [www.CovanceCruelty.com](http://www.CovanceCruelty.com)

<sup>6</sup> [http://www.aphis.usda.gov/animal\\_welfare/efoia/index.shtml](http://www.aphis.usda.gov/animal_welfare/efoia/index.shtml)

- Sick and injured animals – including dogs with ear and eye infections, diseased gums, facial wounds, and inflamed feet – were routinely denied veterinary care;
- A worker used pliers to pull a tooth from a struggling, under-sedated dog;
- Dogs and cats were slammed into cages, thrown, kicked and dragged;
- Cages were pressure-hosed with a bleach solution while dogs and cats were still in them.

Our Company should report all measures it is taking to fulfill its claimed commitment to animal welfare and ensure that its violations of animal protection laws – and its use of external animal experimentation laboratories with histories of welfare violations – do not continue.

We urge shareholders to vote FOR this proposal.

1650 Tysons Boulevard  
Suite 1000  
McLean, VA 22102  
tel 703 556 8100  
fax 703 356 6492  
toll free 800 336 0156

Morgan Stanley  
Smith Barney

November 28, 2012

Colia A. Colbert  
Senior Vice President, Secretary and Assistant General Counsel  
Merck & Co., Inc.  
WS3A-65 P.O. Box 100  
Whitehouse Station, NJ 08889-0100

Re: Shareholder Proposal for Inclusion in the 2013 Proxy Material

Dear Secretary:

This letter verifies that People for the Ethical Treatment of Animals is the beneficial owner of 101 shares of Merck & Co., Inc. common stock and that PETA has continuously held at least \$2,000.00 in market value, or 1% of Merck & Co., Inc. for at least one year prior to and including the date of this letter.

Should you have any questions or require additional information, please contact me at 703-556-8156.

Sincerely,



Archana Sahay  
Registered Associate

Morgan Stanley Wealth Management  
1650 Tysons Boulevard | Suite 1000 | McLean, VA 22102  
P 703 556 8156 | F 703 356 6492  
archna.sahay@morganstanley.com

## EXHIBIT 2

# ANIMAL RESEARCH

To discover, develop, manufacture and market innovative medicines and vaccines that treat and prevent illness, laboratory animal research is indispensable for scientific and regulatory reasons.

Merck is dedicated to the ethical and responsible treatment of all animals used in the development of medicines and vaccines. Merck does not perform animal testing on cosmetic products. Decisions regarding animal care, use and welfare are made by balancing scientific knowledge and regulatory requirements with consideration of ethical and societal values.

The care and use of laboratory animals in biomedical research is highly regulated. In general, the regulations govern housing, feeding, veterinary care and research-project review, and include both internal and external inspections. Our standards for animal care and use meet or exceed all applicable local, national and international laws and regulations.

As further evidence of our commitment to the highest level of animal care, Merck Research Laboratories' (MRL's) research sites voluntarily seek and secure a third-party review and accreditation of our animal research programs and facilities by an independent organization—the **Association for Assessment and Accreditation of Laboratory Animal Care-International (AAALACi)**. Merck also advocates for the development of best practices and dissemination of information by supporting and participating with nongovernmental organizations such as the Scientist Center for Animal Welfare, the Institute for Laboratory Animal Research at the National Academy of Sciences, and the American College of Laboratory Animal Medicine Foundation.

Merck's standing Institutional Animal Care and Use Committees (IACUCs)/Ethical Review Committees, which include veterinarians and independent, non-Merck members, provide oversight of the company's animal care and use programs. They review all proposed animal studies, review the animal care and use programs, inspect facilities, investigate any concerns and report all findings to the Institutional Official for Animal Welfare, who is globally accountable for compliance with all of our animal welfare policies and regulations.

To assist in this responsibility, an Animal Welfare Compliance group provides support and monitoring. Appropriately qualified veterinarians oversee the healthcare of all the animals. All employees who are involved with research animals are given animal-welfare training, which includes review of regulations and policies, instruction on how to search for animal research alternatives, explanation of the role of the IACUC/Ethical Review Committees and training on how to raise concerns. Merck places high value on its animal-welfare-stewardship responsibility; violating these policies would be grounds for employee disciplinary action, up to and including dismissal.

Merck holds similar expectations for standards of animal care and use at our contract laboratories. Merck performs due diligence and monitors external laboratories performing in vivo studies on our behalf, and holds them accountable to the same regulations and standards that govern our animal care and use. Additionally, in vivo research conducted at third-party laboratories is subject to protocol review by a Merck

IACUC or equivalent committee. Noncompliance with regulations or standards can lead to termination of the relationship.

### **Replacement, Reduction and Refinement**

Merck is committed to the philosophy of using the best scientific methodologies and animal alternatives whenever possible or permissible by law. To promote this commitment, we subscribe to the "3Rs"—Replacement, Reduction and Refinement for laboratory animal-based research.

- Replacement—using non-animal systems or less-sentient species (for example cell cultures, computer modeling, bacterial assays and fish models)
- Reduction—using the minimum number of research animals necessary to obtain valid scientific data (sophisticated animal models that yield precise data, such as telemetric monitoring models that monitor ECG and blood pressure, reduce the number of animals needed)
- Refinement—minimizing any distress or discomfort during a study (extensive literature searches contribute to the use of the best scientific models, and analgesics or tranquilizers are used whenever possible)

In 2012, Merck created a 3Rs Committee that will collect, promote and disseminate information on the 3Rs practice. Training in the 3Rs is part of staff orientation for in vivo research. It is our responsibility to use the most appropriate methodology and to aggressively seek scientifically valid 3Rs approaches to animal research. Merck also has extensive in vitro expertise and investments, including an In Vitro department that develops and utilizes nonanimal research methods (cell cultures) in the discovery and development of new medicines and therapies. Merck also provides funding to support 3Rs research at external organizations such as the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) and the European Partnership for Alternative Approaches to Animal Testing (EPAA).

As an example of refinement and reduction in the number of animals used, Merck has created a world-class imaging department that allows scientists to view cancers and other pathologic diseases in animals and monitor the long-term effectiveness of new treatments in a noninvasive manner. In addition, the company employs internal and external information specialists in our research library, trained by the Animal Welfare Information Center of the U.S. National Agricultural Library, to assist our scientists in identifying potential animal alternatives.

### **Internal Merck Animal Alternative Award**

To support the 3Rs philosophy, since 1994, Merck has presented an Animal Alternative Award annually to the team or teams of Merck scientists who develop new techniques that support the alternative principle, and has published their work to share with the scientific community. The 2011 Animal Alternatives Award went to process refinement in bladder catheterization. The 2010 award was for validation of an electrocardiogram (ECG) parameters model in a guinea pig model that replaced a canine model.

### **Animal Alternative Award for Veterinary Research**

The Dieter Lütticken Award, sponsored by **Merck Animal Health**, is used to promote scientists or life science research institutions working in areas that serve the 3Rs concept, i.e., replacing, reducing or refining the use of animals in testing, in the development and production of veterinary medicines. The total funding for this award is 20,000 euros.

The 2011 Award went to a scientist whose trendsetting work on the development, optimization and standardization of polymerase chain reaction (PCR) assays of extraneous agent testing of inactivated poultry vaccines replaced the need for testing on live chicks.

<http://www.merckresponsibility.com/focus-areas/access-to-health/research-and-development/animal-research/home.html>



The 2010 Award went to a team in the United Kingdom that established a physiologically relevant, rapid and sensitive in vitro air interface respiratory tract organ culture model to analyze host-pathogen interactions following single and mixed infections with the respiratory pathogens *Mannheimia haemolytica* and bovine herpesvirus 1 (BHV-1).<sup>1</sup> This model has replaced the use of animals in some studies of respiratory disease and has the potential to be used in developing new vaccines.

<sup>1</sup>Niesalla HS, Dale A, Slater JD, Scholes SFE, Archer J, Maskell DJ, Tucker AW. Critical assessment of an in vitro bovine respiratory organ culture system: a model of bovine herpesvirus-1 infection. *Journal of Virological Methods* 2009;158:123-129.