



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549-4561

DIVISION OF  
CORPORATION FINANCE

March 14, 2012

Jimmy Yang  
Merck & Co., Inc.  
jimmy.yang5@merck.com

Re: Merck & Co., Inc.  
Incoming letter dated January 20, 2012

Dear Mr. Yang:

This is in response to your letter dated January 20, 2012 concerning the shareholder proposal submitted to Merck by People for the Ethical Treatment of Animals. We also have received a letter from the proponent dated January 31, 2012. Copies of all of the correspondence on which this response is based 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,

Ted Yu  
Senior Special Counsel

Enclosure

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

March 14, 2012

**Response of the Office of Chief Counsel**  
**Division of Corporation Finance**

Re: Merck & Co., Inc.  
Incoming letter dated January 20, 2012

The proposal requests that the board 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.

There appears to be some basis for your view that Merck may exclude the proposal under rule 14a-8(i)(10). Based on the information you have presented, it appears that Merck's public disclosures compare favorably with the guidelines of the proposal and that Merck has, therefore, substantially implemented the proposal. Accordingly, we will not recommend enforcement action to the Commission if Merck omits the proposal from its proxy materials in reliance on rule 14a-8(i)(10). In reaching this position, we have not found it necessary to address the alternative basis for omission upon which Merck relies.

Sincerely,

Joseph McCann  
Attorney-Adviser

**DIVISION OF CORPORATION FINANCE  
INFORMAL PROCEDURES REGARDING SHAREHOLDER PROPOSALS**

The Division of Corporation Finance believes that its responsibility with respect to matters arising under Rule 14a-8 [17 CFR 240.14a-8], as with other matters under the proxy rules, is to aid those who must comply with the rule by offering informal advice and suggestions and to determine, initially, whether or not it may be appropriate in a particular matter to recommend enforcement action to the Commission. In connection with a shareholder proposal under Rule 14a-8, the Division's staff considers the information furnished to it by the Company in support of its intention to exclude the proposals from the Company's proxy materials, as well as any information furnished by the proponent or the proponent's representative.

Although Rule 14a-8(k) does not require any communications from shareholders to the Commission's staff, the staff will always consider information concerning alleged violations of the statutes administered by the Commission, including argument as to whether or not activities proposed to be taken would be violative of the statute or rule involved. The receipt by the staff of such information, however, should not be construed as changing the staff's informal procedures and proxy review into a formal or adversary procedure.

It is important to note that the staff's and Commission's no-action responses to Rule 14a-8(j) submissions reflect only informal views. The determinations reached in these no-action letters do not and cannot adjudicate the merits of a company's position with respect to the proposal. Only a court such as a U.S. District Court can decide whether a company is obligated to include shareholder proposals in its proxy materials. Accordingly a discretionary determination not to recommend or take Commission enforcement action, does not preclude a proponent, or any shareholder of a company, from pursuing any rights he or she may have against the company in court, should the management omit the proposal from the company's proxy material.

**Jared S. Goodman**  
Counsel  
(202) 540-2204  
JaredG@petaf.org

January 31, 2012

**VIA E-MAIL: [shareholderproposals@sec.gov](mailto:shareholderproposals@sec.gov)**

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

Re: Merck & Co., Inc., 2012 Annual Meeting Shareholder Proposal  
Submitted by People for the Ethical Treatment of Animals

Dear Sir or Madam:

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) and pursuant to Rule 14a-8(k) in response to Merck & Co., Inc.'s ("Merck" or the "Company") request that the Staff of the Division of Corporation Finance ("Staff") of the Securities and Exchange Commission ("Commission") concur with its view that it may properly exclude PETA's shareholder resolution and supporting statement ("Proposal") from the proxy materials to be distributed by Merck in connection with its 2012 annual meeting of shareholders (the "proxy materials"). As the Proposal has not been substantially implemented and does not contain any false or misleading statements, PETA respectfully requests that Merck's request for a no-action letter on the basis of Rules 14a-8(i)(10) and 14a-8(i)(3) be denied.

### **I. The Proposal**

PETA's resolution, titled "Transparency in Animal Research," provides:

RESOLVED, to prevent repeated government citations and promote transparency in animal use, 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 supporting statement then discusses, *inter alia*, that the Company was cited by the U.S. Department of Agriculture (USDA) for a number of violations of the Animal Welfare Act and that appalling conditions at a contract laboratory used by the Company resulted in a USDA investigation of

**PETA**  
FOUNDATION

PEOPLE FOR THE ETHICAL  
TREATMENT OF ANIMALS  
FOUNDATION

1112 14TH STREET NW  
WASH DC 20006  
TEL: 202-462-PETA  
FAX: 202-462-0208  
EMAIL: [info@peta.org](mailto:info@peta.org)

FOR MORE INFORMATION, PLEASE  
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that facility and fourteen felony cruelty to animals charges against its employees. A copy of the Proposal is attached hereto as Exhibit A.

## **II. The Proposal Has Not Been Substantially Implemented And Therefore May Not Be Excluded Pursuant to Rule 14a-8(i)(10).**

Rule 14a-8(i)(10) permits a company to omit a shareholder proposal from its proxy materials if “the company has already substantially implemented the proposal.” This Rule was “designed to avoid the possibility of shareholders having to consider matters which already have been favorably acted upon by management.” *Exchange Act Release No. 34-12598* (July 7, 1976). According to the Staff, “[a] determination that the company has substantially implemented the proposal depends upon whether [the company’s] particular policies, *practices and procedures* compare favorably with the guidelines of the proposal.” *Texaco, Inc.* (March 28, 1991) (emphasis added). When a company can demonstrate that it has already taken actions to address each element of a shareholder proposal, the Staff has concurred that the proposal has been “substantially implemented.” See, e.g., *Exxon Mobil Corp.* (Mar. 23, 2009); *The Gap, Inc.* (Mar. 8, 1996). It is therefore frequently acknowledged by companies seeking no-action letters that substantial implementation under Rule 14a-8(i)(10) *requires a company’s actions to have satisfactorily addressed both the proposal’s underlying concerns and its essential objective.* See, e.g., *Starbucks Corporation* (Dec. 1, 2011); *Exelon Corp.* (Feb. 26, 2010).

### *A. Merck Has Not Complied With Legal and Regulatory Requirements*

As Merck correctly states, “[t]he 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.” No-Action Request at 2 (emphasis added). The cases Merck imprudently cites in support of its argument actually confirm that this ground for exclusion is based on a company’s *compliance* with applicable laws and regulations, not their mere existence. As the Proposal demonstrates, Merck has not consistently complied with applicable laws and regulations.

In *Johnson & Johnson*, 2006 WL 407782 (Feb. 17, 2006), the Staff permitted the exclusion of a proposal that required the company “to verify the employment legitimacy of all current and future U.S. workers and to immediately terminate any workers not in compliance” on the basis that the company was already required to take these precise actions under federal law *and that it had consistently complied with the law in both respects.* The proposal did not request that specific procedures be followed to ensure compliance with the laws, but rather that the Board direct the company to take the exact measures that were already required of them. In other words, the company had already implemented the *identical objective* sought by the proponent through the requirements of federal law.

Similarly, the Company has cited *AMR Corp.*, 2000 WL 502310 (April 17, 2000), for the proposition that the Staff “permit[ ] 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.” No-Action Request at 2. This selective synopsis is misleading and deceptive, as not only did the company’s by-laws also require independent directors, but *the Staff also explicitly relied in its response on the company’s “representation that the members of the board committees identified in the proposal currently meet the specified criteria.”*

Finally, in *Eastman Kodak Co.*, 1991 WL 176616 (Feb. 1, 1991), the Staff permitted the exclusion of a proposal recommending that the company disclose “all fines paid for violations of environmental laws and regulations” for the past five years *explicitly based on the company’s representation that it complied fully with Item 103 of Regulation S-K*, which required the same disclosure but with a minimum sanctions threshold. *See Eastman Kodak Co., supra* (“You represent that the Company complies fully with Item 103 of Regulation S-K. . . . We further note your position . . . [that] the Company discloses all fines in accordance with Item 103.”).

It is indisputable that the critical facts to *Johnson & Johnson*, *ARM Corp.*, and *Eastman Kodak Co.*, as explicitly acknowledged and relied upon by the Staff in its responses, were that the companies represented that they were in compliance with the legal or regulatory requirements at issue and there was no evidence to the contrary. In those cases, the proponents’ resolutions were moot because they were not intended to ensure that the existing requirements were met, but merely duplicated those to which the companies already adhered.

Here, Merck argues in its Animal Research policy (“Policy”) and no-action request that the “care and use of laboratory animals in biomedical research is highly regulated” in light of the Animal Welfare Act’s (AWA) regulations and its requirement of an Institutional Animal Care and Use Committee (IACUC).<sup>1</sup> *See Merck, Animal Research*, <http://merckresponsibility.com/priorities-and-performance/access-to-health/research-and-development/animal-research/home.html>. However, the Company’s failure to comply with those regulations and the fact that it has been repeatedly cited—*notwithstanding systemic under-enforcement of the law*—clearly illustrates that that the Proposal’s request for procedures to ensure proper animal care has not been substantially implemented.

The first paragraph of the Proposal’s supporting statement provides:

Our Company has been repeatedly cited by the government for improper care of animals used in its laboratory experiments, including caging primates in isolation, issues relating to expired drugs and inadequate anesthesia, untrained personnel, inadequate housing of animals, and lack of proper veterinary care.

While the Company argues that this paragraph “gives shareholders a false and misleading impression that the Company is repeatedly not in compliance with its regulatory obligations,” on the contrary, *these violations of the AWA have been documented by the U.S. Department of*

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<sup>1</sup> The Animal Welfare Act requires research facilities to establish IACUCs to review research protocols, inspect facilities, review complaints, oversee ongoing animal experiments, and conduct regular evaluations of the institution’s animal care programs, focusing on practices involving pain to animals and the condition of the animals and their environments.

*Agriculture (USDA) just since 2008.* Last year, the Company was cited for individually housing primates in a manner such that they were isolated from others and for the failure to maintain housing in good repair to protect the animals from injury. *See* USDA, Merck Inspection Report (Apr. 6, 2011) (Exhibit B). In 2010, Merck was cited for violating the AWA's requirement to ensure that alternatives to painful animal experiments were considered before approving experimental protocols. *See* USDA, Merck Inspection Report (Feb. 22, 2010) (Exhibit C). Only a few months later, it was again cited for the failure to notify a veterinarian about a dog's cysts that required treatment, to remove expired drugs, and to make or keep necessary documentation related to administering anesthesia. *See* USDA, Merck Inspection Report (June 30, 2010) (Exhibit D). In 2009, it was cited for inadequate training and instruction of personnel on pre-procedural and post-procedural care of animals. *See* USDA, Merck Inspection Report (Sept. 9, 2009) (Exhibit E). In 2008, the Company was cited for failing to adequately clean and sanitize animal enclosures. *See* USDA, Merck Inspection Report (Aug. 11, 2008) (Exhibit F).

It is particularly noteworthy that Merck relies on the AWA and IACUC requirements in an attempt to demonstrate that its facilities are "highly regulated" and that it ensures proper animal care, as not only has it been cited for violations of the AWA's minimal standards every year since at least 2008, but the USDA's Office of the Inspector General (OIG) has reported systemic non-compliance and under-enforcement of the AWA.

A recent internal audit by the OIG discussed at length problems with the reliability of IACUC oversight and the failure of IACUCs to adequately review protocols and ensure compliance with federal animal welfare laws:

Some IACUCs are not effectively monitoring animal care activities or reviewing protocols. Most [USDA inspectors] believe there are still problems with the search for alternative research, veterinary care, review of painful procedures, and the researchers' use of animals. . . . This situation exists because (1) the IACUCs are only required to conduct facility reviews on a semiannual basis, (2) IACUCs experience a high turnover rate, and (3) some members are not properly trained. In very few cases, the facilities are resistant to change, showing a general disregard for APHIS regulations. As a result, the facilities are not conducting research in compliance with the [Animal Welfare Act] or, in some cases, not providing humane conditions for research animals.

USDA, OIG Audit Report: APHIS Animal Care Program, Inspection and Enforcement Activities 19 (Sept. 2005) (Executive Summary attached as Exhibit G). In the year before the report was issued, more than half of facilities were cited for violations of the AWA. *Id.* Despite the USDA and National Institutes of Health having previously issued detailed guidelines on laboratory animal care to assist the IACUCs in successfully accomplishing their mandate, the OIG found that "IACUCs are still having problems in such areas as adequately monitoring researchers for compliance with their protocols (e.g., the search for alternatives, review of painful procedures, and unnecessary duplication of research) and following up on the correction of deficiencies." *Id.* Another common violation was the failure of facilities to maintain adequate veterinary care. *Id.*

The OIG also criticized the USDA's Animal and Plant Health Inspection Service (APHIS) Animal Care division for under-enforcement of the AWA. The OIG found that APHIS' Eastern Region (the region in which Merck sits) "is not aggressively pursuing enforcement actions against violators of the AWA." *Id.* at i. In addition, OIG auditors expressed serious concerns relating to the APHIS policy of offering violators a 75% discount on stipulated fines, and for offering further concessions and discounts such that penalties for violating the AWA amount to nothing more than a "*a normal cost of conducting business rather than a deterrent for violating the law.*" *Id.* at ii (emphasis added).

In May 2010, the OIG conducted another internal audit and again reported serious concerns relating to under-enforcement of the AWA and unjustified reduction of penalties for violators. *See* USDA, OIG Audit Report: APHIS Animal Care Program, Inspections of Problematic Dealers (2010) (Executive Summary attached as Exhibit H). The OIG found that inspectors failed to correctly report all repeat and direct violations of the AWA and that the lack of appropriate enforcement "weakened the agency's ability to protect . . . animals." *Id.* at 1. The OIG further found that APHIS's enforcement process was "ineffective in achieving [violation] compliance with AWA and regulations" because the agency took "little or no enforcement action against most violators." *Id.* at 1, 2. The audit also revealed that APHIS misused guidelines to lower penalties for AWA violators by inconsistently counting violations, applying meritless "good faith" reductions, inappropriately applying "no history of violations" reductions for violators who had previous enforcement histories, and arbitrarily reducing the gravity of violations. *Id.* at 2.

While the Company alleges that its Policy constitutes "great measures to ensure that the treatment of the animals used in its research efforts exceed statutory and regulatory minimum standards," and that its "standards for animal care and use meet or exceed all applicable local, national and international laws and regulations," the plain facts necessitate the opposite conclusion. Merck's annual citations for violations of the AWA unequivocally demonstrate the failure to attain even the most basic standards of care. This is precisely the point of the Proposal—that the current Policy is inadequate, ineffective, and specific procedures must be employed to ensure proper animal care.

#### *B. Merck Has Not Substantially Implemented the Proposal By Any Other Means*

In addition to Merck's outright false claims of compliance with the AWA, the Company points to its accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and general policies on the "3Rs"<sup>2</sup> and contract testing laboratories. Yet the Company's inability to consistently adhere to the minimal standards required by federal law, as well as the use of a contract testing laboratory that was closed as a

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<sup>2</sup> The "3Rs" stands for "Replacement, Reduction and Refinement." While we would fully support the Company's adoption of non-animal testing methods, reduction of the number of animals used in experiments, and refinement of the way in which those animals are used, this policy simply does not relate to the essential objectives of the Proposal—which the Company seemingly acknowledges in including it as the final point in its discussion of Rule 14a-8(i)(10). As made explicit by the resolution, its concern is to ensure proper animal care and proper living conditions to prevent violations of federal law.

result of egregious violations of the AWA and state cruelty to animals law, clearly illustrate that these broad policies do not ensure proper animal care.

As the Company states, “[t]he Staff has consistently permitted exclusion of a 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.” No-Action Request at 2. However, the Company has not substantially implemented the essential objective of the Proposal by any means at all.

Where a proponent requests that the company issue a report on a particular subject matter, the mere existence of a company policy concerning that subject matter does not render the proposal “substantially implemented.” Rather, the policy must specifically address the proposal’s concerns and objectives and the company must be in compliance with it.

Earlier this month, in *Hanesbrands Inc.*, 2011 WL 6425339 (Jan. 13, 2012), the Staff informed the company that it could not exclude, under Rule 14a-8(i)(10), a proposal that requested “a report describing the company’s vendor standards pertaining to reducing supply chain environmental impacts—particularly water use and related pollution.” The company alleged that it had made public disclosures that covered the topics that the proposal sought to address, as it set forth on its website “extensive disclosures regarding its efforts to reduce the environmental impacts of its supply chain through its own manufacturing and distribution activities” and information and goals on its “overall environmental policies and practices, most of which focus specifically on water use and related pollution.” The website also included the following policies for vendors with respect to water use, pollution, and other environmental matters:

- HBI believes in doing business with suppliers who share the company’s commitment to protecting the quality of the environment around the world through sound environmental management.
- Suppliers will comply with all applicable environmental laws and regulations, and will promptly develop and implement plans or programs to correct any noncompliant practices.
- HBI will favor suppliers who seek to reduce waste and minimize the environmental impact of their operations.

The company argued that “[b]ecause of this robust disclosure, implementation of the Proposal would not result in any additional disclosure to be provided to shareholders” and that the proposal was therefore moot. The Staff disagreed, finding that “Hanesbrands’ public disclosures [did not] compare favorably with the guidelines of the proposal” and the company could not rely on Rule 14a-8(i)(10) for exclusion. In other words, the existence of a general company policy that fails to address the proponent’s concerns is an insufficient basis on which to exclude a proposal requesting a descriptive report on those same matters.

Moreover, even where a company policy specifically discusses the very concerns raised by a proposal, the company must be in compliance with that policy to rely on Rule 14a-8(i)(10) for exclusion. In *Johnson & Johnson*, 2010 WL 5317485 (Feb. 4, 2011), the proponent requested that the company “[a]dopt available non-animal methods whenever possible and incorporate

them consistently throughout all the Company's operations" and "[e]liminate the use of animals to train sales representatives." The supporting statement discussed that certain Johnson & Johnson facilities used live pigs for training medical professionals while others used simulators for the same purpose and that the company used live animals to train sales representatives, including non-employee interns.

At the time of the proposal, the company's Guidelines for the Use of Animals in Teaching & Demonstrations ("Guidelines") required that:

- Live animals shall be used for teaching or demonstration purposes only when actual participation by the trainee is required to learn the proper usage of a product in a medical or surgical procedure.
- Participation in a training session shall be limited to only those individuals for whom the training experience is considered essential.
- Alternative methods shall be employed whenever possible.

The proponent argued that if the Guidelines were in fact being followed, the instances discussed in the supporting statement could or should not have occurred: "[F]or the Company to assert that the Guidelines, to which it fails to adhere, demonstrate that the proposal has been substantially implemented, is to make precisely the opposite point." The Staff agreed, finding that Johnson & Johnson failed to meet its burden of establishing it may exclude the proposal under Rule 14a-8(i)(10). "Although the company has adopted its [Guidelines]," it concluded, "the proposal addresses not only 'standards' but also requests that the company adopt 'methods' and that it 'incorporate them consistently.'" See also *Wal-Mart Stores, Inc.*, 2011 WL 304198 (Mar. 29, 2011) (finding that the company could not exclude a proposal regarding supplier sustainability reports as substantially implemented where "the Proposal's underlying concern [was] . . . the gap between company policies and the actual implementation of such policies in a company's supply chain"); *Chevron Corp.* (March 22, 2008) (finding that the company could not exclude a proposal requesting that the company adopt a comprehensive, transparent, verifiable human rights policy where, although the company had a "paper policy," the company had not implemented the policy).

Here, the Company's Policy does not specifically address the essential objective of the Proposal, as it provides no specific procedures whatsoever to ensure that the animals used by the Company receive proper care. Even assuming, *arguendo*, that the Policy was sufficient on its face, the Company is not in compliance with it and therefore may not rely on it for excluding the Proposal under Rule 14a-8(i)(10).

First, Merck cites its accreditation by AAALAC as "another way the Company exemplifies it [sic] commitment to animal welfare." AAALAC accreditation is maintained through the payment of an annual fee and a prearranged site visit once every three years. Of course, this does not ensure proper animal care or that the law is being followed. In one example of the countless instances in which AAALAC-accredited facilities have been cited by the USDA for the failure to provide proper animal care, a PETA undercover investigation at a Covance, Inc. laboratory revealed that workers struck, choked, and tormented monkeys and that sick and injured monkeys received no veterinary care. Other primates circled frantically in their cages and self-mutilated as

a result of Covance's failure to provide psychological enrichment and socialization and treat injuries. Based on PETA's documentation, Covance was cited and fined by the USDA for serious violations of the AWA. See PETA, *Covance Fined for Violations of the Animal Welfare Act*, <http://www.covancecruelty.com/feat-fined.asp>.

Furthermore, the Company's allegations that it "holds similar expectations for standards of animal care and use for our contract laboratories," that it "performs due diligence and monitors external laboratories," and that contract laboratories are "subject to" the AWA, do not ensure proper animal care at those laboratories. First, while the Company has attempted to place a great deal of importance on its own AAALAC accreditation, it is noteworthy that Professional Laboratory and Research Services (PLRS)—a North Carolina contract laboratory used by Merck before it was closed, investigated by the USDA, and its employees charged with felony cruelty to animals following a PETA undercover investigation—*was not AAALAC accredited*. Moreover, despite the appalling conduct that occurred over the course of a nearly year-long investigation, there was no alleged "due diligence" or "monitor[ing]" by Merck that caused the Company to sever its relationship with PLRS prior to its closure. Merck's relationship with PLRS is discussed further in Section III.

As the Staff found in *Hanesbrands Inc.*, 2011 WL 6425339, and *Johnson & Johnson*, 2010 WL 5317485 (Feb. 4, 2011), a company's policy about how it holds itself and its contractors to high standards is simply not enough to find that a proposal requesting a report on specifically how that policy is implemented—i.e., what the standards entail, how they are reached, *and how they are enforced*—has been substantially implemented, particularly where that policy has not even been followed.

The cases on which Merck relies for support of its argument that the Proposal has been substantially implemented by means of the Policy not only fail to support exclusion under Rule 14a-8(i)(10) here, but in fact reveal the woeful inadequacy of the Policy to address the essential objectives of the Proposal. See No-Action Request at 2; *Wal-Mart Stores, Inc.*, 2010 WL 1256519 (Mar. 30, 2010) (finding a proposal urging the board "to adopt principles for national and international action to stop global warming" to be substantially implemented where the company had detailed and specific climate change policy, took "a variety of concrete actions" in implementing the policy, and referenced 46 pages of environmental initiatives in its annual Global Sustainability Report that addressed the concerns raised in the proposal); *Aetna Inc.*, 2009 WL 890014 (Mar. 27, 2009) (finding a proposal requesting a report "describing our Company's policy responses to public concerns about gender and insurance" to be substantially implemented where the company had published a policy paper explaining the role of gender in setting premiums, addressed the reasons for considering gender, its effect on premiums, and the ability of the insurance industry to eliminate gender considerations); *PG&E Corporation*, 2010 WL 128062 (Mar. 10, 2010) (finding a proposal requesting a report disclosing information regarding the company's charitable contributions to be substantially implemented where the company specifically provided most of the requested information on its website).

In sum, the existence of Merck's Policy, *which is cited in the Proposal itself as failing to address the Proposal's concerns and objectives*, is an insufficient basis on which to exclude the Proposal

requesting a report to shareholders on the “*procedures used to ensure proper animal care,*” i.e., compliance with that policy and all other relevant policies, laws, and regulations.

### **III. The Proposal Does Not Contain Materially False or Misleading Statements And Therefore May Not Be Excluded Pursuant to Rule 14a-8(i)(3).**

Rule 14a-8(i)(3) permits the exclusion of a stockholder proposal that is “contrary to any of the Commission’s proxy rules, including Rule 14a-9, which prohibits materially false or misleading statements in proxy soliciting materials.” *See* Rule 14a-9. According to the Staff, companies may rely upon Rule 14a-8(i)(3) to exclude or modify a statement where “the company demonstrates objectively that a factual statement is materially false or misleading.” Staff Legal Bulletin No. 14B (Sept. 15, 2004). However, a company *may not exclude* supporting statement language or an entire proposal in reliance on Rule 14a-8(i)(3) where the company objects to factual assertions because they do not include a citation; because, while not materially false or misleading, they may be disputed or countered; or because they may be interpreted by shareholders in a manner that is unfavorable to the company. *Id.* Rather, companies may appropriately address these objections in their statements of opposition. *Id.* Every statement Merck cites as false or misleading, addressed in turn below, is supported by objective fact.

*Merck “has been repeatedly cited by the government for improper care of animals used in laboratory experiments.”*

As discussed in Section II.A. above, each violation of the AWA cited in the supporting statement is supported by USDA documentation, attached hereto as exhibits B – F. If the Company objects to the mention of these violations in the supporting statement because the Inspection Reports were not cited, or because it is unfavorable to the Company, it may respond appropriately in its statement of opposition. *See* Staff Legal Bulletin No. 14B(4).

*“In the last three years, our Company used more than 41,000 animals in-house . . . . More than 16,000 of these animals were used in painful experiments and more than 2,000 were given no pain relief whatsoever.”*

The Company correctly assumes that these numbers were obtained from the Company’s Form 7023, filed with APHIS annually pursuant to the AWA. No-Action Request at 5. First, it takes issue with the way in which these numbers were calculated, but does not even attempt to demonstrate objectively that the numbers are incorrect or are materially false or misleading and has therefore failed to meet its burden under Rule 14a-8(i)(3).<sup>3</sup>

In addition, it appears that Merck takes issue with the very fact that the Proposal discusses the number animals used in painful experiments in its facilities. No-Action Request at 6. As

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<sup>3</sup> If the Staff finds that the way in which these numbers were presented are false or misleading despite the Company providing no evidence that they are incorrect, we respectfully request that it exercise its “long-standing practice of issuing no-action responses that permit shareholders to make revisions that are minor in nature and do not alter the substance of the proposal.” Staff Legal Bulletin No. 14B. While we do not believe there is any basis on which to conclude that any of the statements in the Proposal are false or misleading or are in any way subject to exclusion, as discussed herein, we would appreciate the opportunity to make minor revisions as the Staff may deem necessary.

discussed in the Company's own submission, the number provided in Category D of Form 7023 represents those non-rodent animals used in painful and distressing experiments for which anesthetic, analgesic, or tranquilizing drugs were used. Category E on that form represents the number of non-rodent animals used in painful and distressing experiments for which no anesthetic, analgesic, or tranquilizing drugs were administered. These statistics were submitted to the USDA by the Company itself. If the Company would like to include a discussion of its alleged mitigation of pain experienced during experiments "where possible" and that it "keeps to a minimum" the number of animals who are used in painful experiments without any anesthetic, analgesic, or tranquilizing drugs whatsoever, it may do so in its statement of opposition. "[I]t would not be appropriate for companies to exclude supporting statement language and/or an entire proposal in reliance on rule 14a-8(i)(3)" in these circumstances. See Staff Legal Bulletin No. 14B(4).

*"These figures do not include animals used in Merck experiments in contract laboratories . . . ."*

Merck alleges that it "would not be able to report on third party animal usage because the Company would not have the required information and even if it did, it would be a violation of law for Merck to disclose."<sup>4</sup> No-Action Request at 6. It is not clear exactly how the Company is alleging that the challenged clause is false or misleading, as its response in fact confirms that the numbers reported on Form 7023 do not include animals used in Merck experiments in contract laboratories. Furthermore, the Company's response implies that the Proposal requests that these numbers be disclosed, when in fact this statement was made only to convey that the animals reported on Form 7023 are not inclusive of all experiments conducted on Merck's behalf. Again, the Company has not even attempted to demonstrate objectively that this undisputed statement is materially false or misleading and therefore cannot rely upon Rule 14a-8(i)(3) to exclude or modify it.

*"Animals used in laboratory experiments experience pain, fear, and stress. . . ."*

In its challenge of this paragraph, the Company has again attempted to rely on alleged AWA compliance, its IACUC, and AAALAC accreditation, all addressed in detail above as failing to ensure that the animals used in Merck laboratories receive proper care. It is also remarkable that the Company's single example of how "most animals are socially housed and not deprived of companionship" is that "non-human primates have environmental enrichment plans that include social housing." No-Action Request at 6. As discussed above, *the Company was cited in 2011 for individually housing primates in isolation in violation of the AWA*. See USDA, Merck Inspection Report (Apr. 6, 2011).

#### *Professional Laboratory and Research Services (PLRS)*

The Company alleges that the supporting statements discussion of the appalling conditions and abuses found at PLRS are "not only materially false and misleading," but also "inflammatory

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<sup>4</sup> One must seriously question the extent of the Company's alleged due diligence, monitoring, and oversight of research conducted on its behalf at contract laboratories if it does not even know the number of animals used in Merck experiments.

and impugning.” No-Action Request at 6. Its reasoning offered in support of this allegation—that “PRLR [sic] was an unaffiliated third party contract laboratory and the statements made by the Proponent regarding PRLR [sic] have nothing to do with the Company”—is itself deceptive, misleading, and demonstrably false.

Local news articles reporting on the closure of PLRS after PETA’s investigation highlighted the fact that both Merck and Schering-Plough (which have since merged) were among the clients of the company. *See, e.g.,* IBJ Staff & AP, *Lab Used by Lilly, Peers Accused of Animal Cruelty*, Indianapolis Bus. J. (Sept. 8, 2010), available at <http://www.ibj.com/lab-used-by-lilly-other-drugmakers-accused-of-animal-cruelty/PARAMS/article/22154> (“The lab has tested flea and tick preventatives and other products for numerous companies, including . . . Merck, Schering-Plough . . .”). In fact, this longstanding relationship dates back to at least as early as 1996. *See* FDA, NADA 141-078 Heartgard for Cats (Dec. 23, 1996) (Merck), <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm116793.htm>; FDA, NADA 140-841 Ivomec Pour-On for Cattle (June 5, 1997) (Merck), <http://www.guinealynx.info/fda/NADA140-841.html>; *see also* FDA, NADA 141-286 PANACUR Plus (May 9, 2008) (Schering-Plough), <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm062342.pdf>. Moreover, upon information and belief, Schering-Plough retained PLRS to perform testing on animals during the course of the undercover investigation that led to the surrender of the animals and closure of the facility. The Company’s attempt to characterize itself as “unaffiliated” with PLRS is specious.<sup>5</sup>

Merck’s further objection that PLRS “has not been in business since 2010” is precisely the point. During the undercover investigation, PETA’s investigator found laboratory workers yelling and cursing at cowering dogs and cats, using pressure hoses to spray water (as well as bleach and other harsh chemicals) on them, dragging dogs who were too frightened to walk through the facility, and viciously slamming cats into the metal doors of cages and attempting to rip their nails out. Many dogs had raw, oozing sores from being forced to live constantly on wet concrete, often in pools of their own urine and waste. In fact, PLRS didn’t have a veterinarian on staff, instead bringing in its primary veterinarian in for only one hour most weeks. Animals endured bloody feces, worm infestations, oozing sores, abscessed teeth, hematomas, and pus- and blood-filled infections without receiving adequate veterinary examinations and treatment.

The conditions were so appalling at the facility that one week after PETA released its undercover video and filed a complaint with the USDA—which resulted in an initial investigation, citations for dozens of violations of federal animal welfare laws, and an ongoing investigation by the agency’s Investigative Enforcement Service—the facility surrendered nearly 200 dogs and more than 50 cats and shut its doors. Four employees, including a supervisor, have since been indicted on fourteen felony cruelty to animals charges.

Merck was a client of PLRS despite the Company’s broad policy that requires “due diligence” and “monitor[ing]” of all contract laboratories. This suggests a glaring lack of oversight and the failure to ensure that contract laboratories used by the Company provide even the basic animal

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<sup>5</sup> To the extent that Merck’s use of the term “affiliate” is intended to deny any control of, control by, or being under common control with PLRS, this statement is irrelevant. The Proposal does not allege that PLRS was an affiliate in such a sense, but merely that the Company contracted with PLRS to perform animal testing on its behalf.

care—whether or not the cruelty observed during the investigation occurred while conducting Merck-commissioned experiments. If the Company would like to argue to shareholders that it adequately monitored PLRS, consistent with its Policy, it is free to do so in its statement of opposition.

*“92% of drugs deemed safe and effective when tested on animals fail in human clinical trials....”*

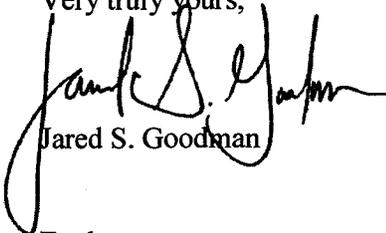
Finally, the Company challenges this statement on the ground that the website referenced in its citation is no longer available. *See* No-Action Request at 7. While a direct citation to the transcript of the FDA Commissioner’s speech has since been taken down by the agency, there are many secondary citations to this statement. When contacted by Merck prior to the Company filing its no-action request, PETA offered such an alternative citation.<sup>6</sup> In any event, again, the Company may not exclude this factual assertion or the Proposal in its entirety in reliance on rule 14a-8(i)(3) simply because a functioning link is not included. *See* Staff Legal Bulletin No. 14B(4).

#### **IV. Conclusion**

As the Proposal has not been substantially implemented and does not contain any false or misleading statements, we respectfully request that the Staff decline to issue a no-action response to Pfizer and inform the company that it may not omit the Proposal from its proxy materials in reliance on Rules 14a-8(i)(10) or 14a-8(i)(3).

Should the Staff need any additional information in reaching its decision, please contact me at your earliest convenience.

Very truly yours,



Jared S. Goodman

Enclosures

cc: Jimmy Yang, Legal Director, Merck

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<sup>6</sup> *See* Food and Drug Administration (2004) *Innovation or Stagnation, Challenge and Opportunity on the Critical Path to New Medical Products*. Rockville, MD, USA.

**Exhibit A**

## TRANSPARENCY IN ANIMAL RESEARCH

**RESOLVED**, to prevent repeated government citations and promote transparency in animal use, 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.

### Supporting Statement

Our Company has been repeatedly cited by the government for improper care of animals used in its laboratory experiments, including caging primates in isolation, issues relating to expired drugs and inadequate anesthesia, untrained personnel, inadequate housing of animals, and lack of proper veterinary care.

In the last three years, our Company used more than 41,000 animals in-house. This number includes almost 6,600 dogs and 13,500 primates. More than 16,000 of these animals were used in painful experiments and more than 2,000 were given no pain relief whatsoever.<sup>1</sup> A number of animals died in their cages without being humanely euthanized.

These figures do not include animals used in Merck experiments in contract laboratories nor the vast numbers of animals who are most commonly used in experiments and, though not legally required to be counted, suffer as well.

Animals used in laboratory experiments experience pain, fear and stress. They spend their lives in unnatural settings—caged and deprived of companionship—and are subjected to painful experiments. This is reality for animals in laboratories.

What should not be the norm is outright cruelty towards defenseless animals.

Our Company's animal welfare policy states that "Merck performs due diligence and monitors external laboratories performing in vivo [animal] studies on our behalf."<sup>2</sup> Yet documentation of sadistic treatment at a contract laboratory used by our Company, Professional Laboratory and Research Services (PLRS), resulted this year in 14 felony cruelty charges against its employees.<sup>3</sup>

The government issued a report confirming the appalling conditions at the facility and PLRS is now out of business. The abuses included:

- Sick and injured animals—including dogs with ear and eye infections, diseased gums, facial lacerations, and inflamed feet—were routinely denied veterinary care;

<sup>1</sup> [http://www.aphis.usda.gov/animal\\_welfare/efoia/7023.shtml](http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml)

<sup>2</sup> <http://www.merckresponsibility.com/priorities-and-performance/access-to-health/research-and-development/animal-research/home.html>

<sup>3</sup> <http://www.peta.org/features/professional-laboratory-and-research-services.aspx>

- An untrained worker used pliers to pull a tooth from a struggling, under-sedated dog;
- Dogs and cats were slammed into cages, thrown, kicked and dragged;
- Dogs and cats were pressure-hosed with a bleach solution;
- A worker attempted to rip out a cat's nails by forcing the cat to clutch a chain-link fence and then violently pulling her away.

Our Company has the ability and the obligation to ensure that no animal suffers from lack of veterinary care, poor housing, or outright mistreatment.

Given that 92% of drugs deemed safe and effective when tested on animals fail in human clinical trials, there is also a clear scientific imperative for improving testing methods.<sup>4</sup>

Shareholders cannot monitor what goes on behind the closed doors of animal testing laboratories, so our Company must. Our Company has an ethical and fiscal obligation to implement this socially important proposal.

We urge shareholders to vote **FOR** the proposal.

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<sup>4</sup> FDA Commissioner: <http://www.fda.gov/oc/speeches/2006/fdateleconference0112.html>

**Exhibit B**



### Inspection Report

MERCK SHARP & DOHME CORP

Customer ID: 178

Certificate: 22-R-0030

Site: 005

MERCK RESEARCH LABORATORIES

126 E LINCOLN AVENUE

Type: ROUTINE INSPECTION

RAHWAY, NJ 07065

Date: Apr-06-2011

**3.81 (a) (3)**

**ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.**

Section 3.81(a)(3) Social grouping: Individually housed nonhuman primates must be able to see and hear nonhuman primates of their own or compatible species unless the attending veterinarian determines that it would endanger their health, safety, or well-being.

There were six individually housed nonhuman primates housed in enclosures on one side of room 1-221. These animals could not readily see each other. During the inspection the nonhuman primates were moved to a room with mirrors mounted on the wall so they could see each other. The facility needs to ensure individually housed nonhuman primates are housed in enclosures and/or rooms that allow them to see other non-human primates of their own or compatible species for the well-being of the animals.  
Correct by April 14, 2011.

**3.125 (a)**

**FACILITIES, GENERAL.**

Section 3.125(a) Structural strength: Animal housing facilities shall be structurally sound and maintained in good repair to protect the animals from injury and to contain the animals.

In room 2-246 the last enclosure housing one mini-pig had a broken door latch. The chain used to close the door allowed the door to move slightly back and forth, creating more space between the door and the enclosure frame. A foot or leg could get injured in the gap. The door was replaced during the inspection. The facility needs to ensure that future maintenance problems are adequately fixed to keep the facility in good repair to protect the animals from injury.  
Correct by April 14, 2011.

An exit briefing was conducted with the facility representatives.

Prepared By:

MARY E GEIB, D V M                      USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Apr-07-2011

Received By:



(b)(6), (b)(7)(C)

Date:

Title:

Apr-07-2011



## Inspection Report

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Note: This inspection conducted on April 6, 2011 and April 7, 2011 covered buildings 44, 44E and 46; the IACUC records; and the animal records.

A copy of the inspection report was left at the facility at the time of the inspection. Registrant elected not to sign the inspection report but signed the PS Form 3811 for article number 7004 0550 0000 8903 0887 which was for the hand delivered copy of the inspection report.

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**Prepared By:**

MARY E GEIB, D V M                      USDA, APHIS, Animal Care

**Title:**                      VETERINARY MEDICAL OFFICER Inspector 1021

**Date:**

Apr-07-2011

**Received By:**

(b) (6), (b) (7) (c)

**Date:**

Apr-07-2011

**Title:**

## **Exhibit C**



### Inspection Report

MERCK SHARP & DOHME CORP

Customer ID: 178

Certificate: 22-R-0030

Site: 005

MERCK RESEARCH LABORATORIES

126 E LINCOLN AVENUE

PO BOX 2000 RY80M-101

Type: ROUTINE INSPECTION

Date: Feb-22-2010

RAHWAY, NJ 07065

2.31 (d) (1) (ii)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC: The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources used to determine that alternatives were not available.

Amendment 2 for animal activity proposal 09028544080152 does not include a written narrative description of the methods and sources used to determine that alternatives were not available for the relieved painful procedure included in the amendment. The principal investigator needs to provide the required information to the Institutional Animal Care and Use Committee for its review and to comply with the Animal Welfare regulations. Correct by April 1, 2010.

Note: This inspection conducted on February 22, 2010 and February 23, 2010 covered buildings 44, 44E and 46; the IACUC records; and the animal records.

A copy of the inspection report was left at the facility at the time of the inspection. Registrant elected not to sign the inspection report but signed the PS Form 3811 for article number 7009 0820 0000 3056 1928 which was for the hand delivered copy of the inspection report.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Feb-23-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Feb-23-2010

**Exhibit D**



### Inspection Report

MERCK SHARP & DOHME CORP

Customer ID: 178

Certificate: 22-R-0030

Site: 001

LINCOLN AVENUE SITE

126 E LINCOLN AVENUE

Type: ROUTINE INSPECTION

RAHWAY, NJ 07065

Date: Jun-30-2010

2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Item Veterinary Care 2.33 b 5

Each research facility shall establish and maintain programs of adequate veterinary care that include: Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

At the time of inspection for protocol 09-136 canine Id 1320484 and protocol 09-113 canine Id 5129923 the investigator failed to document the monitoring of the animals during the induction phase of the procedure.

For canine 1320484 the investigator failed to document the amount of propofol that was administered to the animal as part of the anesthesia protocol.

Facility needs to insure records are documented and complete in order to insure adequate veterinary care for the animals.

Correct from this day 6/30/10

2.33 (b)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Item Veterinary Care 2.33 b

Each research facility shall establish and maintain programs of adequate veterinary care

At the time of inspection Mebendazole exp 10/09 was found.

Facility removed outdated drug at time of inspection.

Corrected at time of inspection.

At the time of inspection canine 4854373 was noted to have what appeared to be interdigital cysts on the left front paw.

While the animal was placed on a mat in the pen there was no documentation that the veterinarian was notified about this condition.

Facility needs to insure communication is given to the veterinarian about medical conditions so that treatment can be performed.

Before the end of inspection the veterinarian instituted a course of treatment for the canine.

Prepared By:

JOHN LOPINTO, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1008

Jun-30-2010

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jun-30-2010



## Inspection Report

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Corrected at time of inspection

Inspection took place over 2 days 6/29-30/10

An exit briefing was conducted at the end of inspection

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**Prepared By:**

JOHN LOPINTO, D V M                      USDA, APHIS, Animal Care

**Title:**                      VETERINARY MEDICAL OFFICER Inspector 1008

**Date:**

Jun-30-2010

**Received By:**

(b) (6), (b) (7) (c)

**Date:**

Jun-30-2010

**Title:**

**Exhibit E**



## Inspection Report

MERCK & COMPANY INC

Customer ID: 178

Certificate: 22-R-0030

Site: 001

LINCOLN AVENUE SITE

126 E LINCOLN AVENUE

PO BOX 2000 RY80M-101

Type: ROUTINE INSPECTION

Date: Sep-09-2009

RAHWAY, NJ 07065

2.32 (c) (1) (iii)

### PERSONNEL QUALIFICATIONS.

Training and instruction of personnel must include guidance in at least the following areas: proper pre-procedural and post-procedural care of animals.

During the inspection, four dogs were observed with bleeding from their nails following routine trimming (#3921239, #3880931, #4970535, #1082800). The animal care staff needs to ensure that routine procedures are properly done to prevent injury to the animals, and that the appropriate measures are taken to remedy such problems if they occur. The dogs were brought to the veterinarians attention and immediately treated.

\*\*\*Corrected during the inspection\*\*\*

Prepared By:

NADIRA R WILLIAMS, V M D USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1060

Sep-09-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-09-2009

**Exhibit F**



### Inspection Report

MERCK & COMPANY INC

Customer ID: 178

Certificate: 22-R-0030

Site: 005

MERCK RESEARCH LABORATORIES

126 E LINCOLN AVENUE

Type: ROUTINE INSPECTION

RAHWAY, NJ 07065

Date: Aug-11-2008

3.31 (a) (2)

**SANITATION.**

Section 3.31(a)(2) Cleaning and sanitation of primary enclosures: In the event a primary enclosure becomes soiled or wet to a degree that might be harmful or uncomfortable to the animals therein due to leakage of the watering system, discharges from dead or dying animals, spoiled perishable foods, or moisture condensation, the guinea pigs or hamsters shall be transferred to clean primary enclosures.

In room A306 there was one enclosure housing three guinea pigs with excessively wet bedding. The guinea pigs were moved to a clean enclosure during the inspection.  
Corrected during the inspection.

Note: This inspection conducted on August 11, 2008 and August 12, 2008 covered buildings 45, 45A and 81; the IACUC records; and the animal records.

A copy of the inspection report was left at the facility at the time of the inspection. Registrant elected not to sign the inspection report but signed the PS Form 3811 for article number 7006 0100 0006 4358 6819 which was for the hand delivered copy of this inspection report.

Prepared By:

MARY E GEIB, D V M                      USDA, APHIS, Animal Care  
Title: VETERINARY MEDICAL OFFICER Inspector 1021

Date:  
Aug-12-2008

Received By:

(b)(6), (b)(7)(c)

Date:  
Aug-12-2008

**Exhibit G**



U.S. Department of Agriculture

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Office of Inspector General  
Western Region

# **Audit Report**

## **APHIS Animal Care Program Inspection and Enforcement Activities**

Report No. 33002-3-SF  
September 2005

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UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



September 30, 2005

REPLY TO

ATTN OF: 33002-3-SF

TO: W. Ron DeHaven  
Administrator  
Animal and Plant Health Inspection Service

ATTN: William J. Hudnall  
Deputy Administrator  
Marketing and Regulatory Programs

FROM: Robert W. Young /s/  
Assistant Inspector General  
for Audit

SUBJECT: APHIS Animal Care Program – Inspection and Enforcement Activities

This report presents the results of our audit of the subject program. Your September 28, 2005, response to the draft report, excluding attachments, is included as exhibit E of the report. Excerpts from your response and the Office of Inspector General's positions have been incorporated into the relevant sections of the report.

We agree with your management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

In accordance with Department Regulation 1720-1, please furnish a reply within 60 days describing the corrective action taken or planned and the timeframes for implementation of those recommendations for which management decision has not yet been reached. Please note that the regulation requires a management decision to be reached on all recommendations within a maximum of 6 months from report issuance.

We appreciate the cooperation and assistance provided by your staff during our audit.

# Executive Summary

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## Results In Brief

Animal care and use in the United States is a controversial topic with varying points of view from the public, animal rights groups, breeders, research laboratories, and others. In 1966, the Secretary of Agriculture was given the statutory authority to enforce the Animal Welfare Act (AWA), which set minimum standards of care and treatment for certain warm-blooded animals<sup>1</sup> bred for commercial sale, used in research, transported commercially, or exhibited to the public.

This report presents the results of our audit of the Animal and Plant Health Inspection Service's (APHIS) Animal Care (AC) unit, which has the responsibility of inspecting all facilities covered under the AWA and following up on complaints of abuse and noncompliance. We also reviewed AC's coordination with the Investigative and Enforcement Services (IES) staff, which provides support to AC in cases where serious violations have been found. In addition, we evaluated the effectiveness of the Institutional Animal Care and Use Committees (IACUCs)—the self-monitoring committees at the research facilities responsible for ensuring compliance with the AWA.

We found that most AC employees are highly committed to enforcing the AWA through their inspections and are making significant efforts to educate research facilities and others on the humane handling of regulated animals. However, we identified several ways in which AC should improve its inspection and enforcement practices to ensure that animals receive humane care and treatment and that public safety is not compromised.

- Due to a lack of clear National guidance, AC's Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA.<sup>2</sup> We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES.<sup>3</sup> In contrast, the Western Region declined action against 18 of 439 violators.

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<sup>1</sup> Regulated animals are any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warmblooded animal. It excludes birds, rats of the genus *Rattus*, mice of the genus *Mus*, bred for use in research; horses not used for research; and other farm animals such as livestock and poultry under certain circumstances.

<sup>2</sup> The data in this section, which we compiled from IES records, may include some Horse Protection Act cases, for which AC is also responsible.

<sup>3</sup> IES estimates that these cases cost APHIS at least \$291,000 to investigate.

We found cases where the Eastern Region declined to take enforcement action against violators who compromised public safety or animal health. For example, one AC inspector requested an investigation of a licensee whose primate had severely bitten a 4-year-old boy on the head and face. The wounds required over 100 stitches. Although this licensee had a history of past violations, IES has no record of a referral from AC. In another case, the Eastern Region did not take enforcement action when an unlicensed exhibitor's monkey bit two pre-school children on separate occasions. The exhibitor failed to provide a sufficient public barrier and failed to handle the animal to ensure minimal risk to the public.

As a result, the two regions are inconsistent in their treatment of violators; the percentage of repeat violators (those with 3 or more consecutive years with violations) is twice as high in the Eastern Region than in the Western Region. Eastern Region inspectors believe the lack of enforcement action undermines their credibility and authority to enforce the AWA.

- Discounted stipulated fines assessed against violators of the AWA are usually minimal. Under current APHIS policy, AC offers a 75-percent discount on stipulated fines<sup>4</sup> as an incentive for violators to settle out of court to avoid attorney and court costs. In addition to giving the discount, we found that APHIS offered other concessions to violators, lowering the actual amount paid to a fraction of the original assessment. An IES official told us that as a result, violators consider the monetary stipulation as a normal cost of conducting business rather than a deterrent for violating the law.<sup>5</sup>
- Some VMOs did not verify the number of animals used in medical research or adequately review the facilities' protocols and other records.<sup>6</sup> We found that 13 of 16 research facilities we visited misreported the number of animals used in research. In reviewing the protocols, some Veterinary Medical Officers (VMOs) did not ensure that the facilities provided them with a complete universe of protocols from which to select their sample. These VMOs told us that the selection process was based on "good faith" and that they relied on the facilities to provide them with accurate records. In addition, a VMO did not review readily available disposition records that disclosed unexpected animal deaths at a research facility.
- Some IACUCs are not effectively monitoring animal care activities or reviewing protocols. During FYs 2002 through 2004, the number of research facilities cited for violations of the AWA has steadily increased

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<sup>4</sup> These fines are not mandatory but agreed to by the violator.

<sup>5</sup> This was also discussed in OIG Audit No. 33600-1-Ch issued in January 1995.

<sup>6</sup> Protocols are the researchers' proposals for the use of animals in research.

from 463 to 600 facilities. Most VMOs believe there are still problems with the search for alternative research, veterinary care, review of painful procedures, and the researchers' use of animals.

- *AC's Licensing and Registration Information System (LARIS) does not effectively track violations and prioritize inspection activities.* The LARIS database records AC inspections and archives violation histories for all breeders, exhibitors, research facilities, and others. We determined that the system generates unreliable and inaccurate information, limiting its usefulness to AC inspectors and supervisors.
- *FMD and IES did not follow the law and internal control procedures in their processing and collection of penalties.* APHIS' Financial Management Division (FMD) did not transfer 81 of 121 delinquent AC receivables totaling \$398,354 to the U.S. Department of Treasury for collection as required by the Debt Collection Improvement Act of 1996 (see exhibit A). In addition, IES did not comply with APHIS' internal cash controls to secure the collection of fines.

## **Recommendations In Brief**

To ensure consistent treatment of violators, we recommend that AC incorporate specific guidance in AC's operating manual that addresses referrals and enforcement actions. We also recommend that AC review all cases where the regions decline to take enforcement actions against violators.

To increase the effectiveness of stipulated fines, we recommend that APHIS eliminate the automatic 75-percent discount for repeat violators or direct violations,<sup>7</sup> calculate fines based on the number of animals affected per violation, and seek legislative change to increase fines up to \$10,000 for research facilities.

AC needs to emphasize the need for more detailed reviews of protocols, including those where animals are not present at the facility during the inspection. AC also needs to require research facilities to identify annually the number of protocols in their annual reports, and require the VMOs to verify the number of animals used in research.

To reduce the number of violations, AC needs to modify regulations to require IACUCs to conduct more frequent reviews of facilities identified as repeat violators (3 or more consecutive years with violations). We also recommend that AC require IACUCs to implement policies to fully train committee members on protocol review, facility inspections, and the AWA.

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<sup>7</sup> Direct violations have a high potential to adversely affect the health and well-being of the animal.

For LARIS, AC needs to implement temporary measures to address system deficiencies until the new system is operational. Finally, IES and FMD need to follow APHIS policies for internal controls over cash collection, and FMD must timely process receivables for collection.

**Agency  
Response**

In its September 28, 2005, written response to the draft report, the APHIS National Office concurred with the report findings and recommendations, except for Recommendation 13. APHIS' response is included in exhibit E of this report.

**OIG Position**

We accept APHIS' management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

**Exhibit H**



**U.S. Department of Agriculture**

**Office of Inspector General**



**Animal and Plant Health Inspection Service  
Animal Care Program  
Inspections of Problematic Dealers**

**Audit Report 33002-4-SF  
May 2010**



U.S. Department of Agriculture  
Office of Inspector General  
Washington, D.C. 20250



DATE: May 14, 2010

REPLY TO  
ATTN OF: 33002-4-SF

TO: Cindy J. Smith  
Administrator  
Animal and Plant Health Inspection Service

ATTN: Joanne Munno  
Acting Deputy Administrator  
Marketing and Regulatory Programs Business Services

FROM: Gil H. Harden /s/  
Assistant Inspector General  
for Audit

SUBJECT: APHIS Animal Care Program – Inspections of Problematic Dealers

This report presents the results of the subject review. Your written response to the official draft report is included at the end of the report. Excerpts from the response and the Office of Inspector General's (OIG) position are incorporated into the relevant sections of the report. Based on the information in your written response, we have accepted your management decision on Recommendations 1, 2, 3, 5, 6, 7, 8, 9, 10, 12, 13 and 14. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

Based on your written response, management decision has not been reached on Recommendations 4 and 11. The information needed to reach management decision on these recommendations is set forth in the OIG Position section after each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days providing the information requested in the OIG Position section. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance, and final action to be taken within 1 year of each management decision.

We appreciate the courtesies and cooperation extended to us by members of your staff during the review.

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# ***Animal Care Program – Inspections of Problematic Dealers***

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## **Executive Summary**

In the last 2 years, there has been significant media coverage concerning large-scale dog dealers (i.e., breeders and brokers)<sup>1</sup> that failed to provide humane treatment for the animals under their care. The breeders, negatively referred to as “puppy mills,” have stirred the interest of the public, Congress, animal rights groups, and others. Accordingly, we conducted an audit of the Animal and Plant Health Inspection Service’s (APHIS) Animal Care (AC) unit, which is responsible for enforcing the Animal Welfare Act (AWA). The audit focused on AC’s inspections of problematic dealers. It is the latest in a series of audits related to AWA.<sup>2</sup>

In our last audit on animals in research facilities,<sup>3</sup> we found that the agency was not aggressively pursuing enforcement actions against violators of AWA and that it assessed minimal monetary penalties against them.<sup>4</sup> APHIS agreed to take corrective action by incorporating more specific guidance in its operating manual to address deficiencies in enforcement actions. It also agreed to revise its penalty worksheet to generate higher and more appropriate penalties.

In this audit, one objective was to review AC’s enforcement process against dealers that violated AWA. Accordingly, we focused on dealers with a history of violations in the past 3 years.<sup>5</sup> Another objective was to review the impact of recent changes the agency made to the penalty assessment process. We identified the following major deficiencies with APHIS’ administration of AWA:

- ***AC’s Enforcement Process Was Ineffective Against Problematic Dealers.*** AC’s enforcement process was ineffective in achieving dealer compliance with AWA and regulations, which are intended to ensure the humane care and treatment of animals. The agency believed that compliance achieved through education<sup>6</sup> and cooperation would result in long-term dealer compliance and, accordingly, it chose to take little or no enforcement action against most violators.

However, the agency’s education efforts have not always been successful in deterring problematic dealers from violating AWA. During FYs 2006-2008, at the re-inspection of 4,250 violators, inspectors found that 2,416 repeatedly violated AWA, including some that ignored minimum care standards. Therefore, relying heavily on education for serious or repeat violators—without an appropriate level of enforcement—weakened the agency’s ability to protect the animals.

- ***AC Inspectors Did Not Cite or Document Violations Properly To Support Enforcement Actions.*** Many inspectors were highly committed, conducting timely and thorough

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<sup>1</sup> Breeders are those that breed and raise animals on the premises; brokers negotiate or arrange for the purchase, sale, or transport of animals in commerce.

<sup>2</sup> Refer to the Background section for more information on related prior audits.

<sup>3</sup> Audit No. 33002-3-SF, “APHIS Animal Care Program Inspection and Enforcement Activities” (September 2005).

<sup>4</sup> AWA refers to monetary penalties as civil penalties.

<sup>5</sup> APHIS synonymously used the terms violations, alleged violations, and noncompliant items in its documents. For simplicity, we used the term violations in this report.

<sup>6</sup> Education was generally provided through the inspectors’ interaction with dealers during routine inspections as well as periodic seminars.

inspections and making significant efforts to improve the humane treatment of covered animals. However, we noted that 6 of 19 inspectors<sup>7</sup> did not correctly report all repeat or direct violations (those that are generally more serious and affect the animals' health). Consequently, some problematic dealers were inspected less frequently.

In addition, some inspectors did not always adequately describe violations in their inspection reports or support violations with photos. Between 2000 and 2009, this lack of documentary evidence weakened AC's case in 7 of the 16 administrative hearings involving dealers.<sup>8</sup> In discussing these problems with regional management, they explained that some inspectors appeared to need additional training in identifying violations and collecting evidence.

- *APHIS' New Penalty Worksheet Calculated Minimal Penalties.* Although APHIS previously agreed to revise its penalty worksheet to produce "significantly higher" penalties for violators of AWA, the agency continued to assess minimal penalties that did not deter violators. This occurred because the new worksheet allowed reductions up to 145 percent of the maximum penalty. While we are not advocating that APHIS assess the maximum penalty, we found that at a time when Congress tripled the authorized maximum penalty to "strengthen fines for violations," the actual penalties were 20 percent less using the new worksheet as compared to the worksheet APHIS previously used.
- *APHIS Misused Guidelines to Lower Penalties for AWA Violators.* In completing penalty worksheets, APHIS misused its guidelines in 32 of the 94 cases we reviewed to lower the penalties for AWA violators. Specifically, it (1) inconsistently counted violations; (2) applied "good faith" reductions without merit; (3) allowed a "no history of violations" reduction when the violators had a prior history; and (4) arbitrarily changed the gravity of some violations and the business size. AC told us that it assessed lower penalties as an incentive to encourage violators to pay a stipulated amount rather than exercise their right to a hearing.
- *Some Large Breeders Circumvented AWA by Selling Animals Over the Internet.* Large breeders that sell AWA-covered animals over the Internet are exempt from AC's inspection and licensing requirements due to a loophole in AWA. As a result, an increasing number of these unlicensed breeders are not monitored for their animals' overall health and humane treatment.

## Recommendation Summary

To ensure dealer compliance with AWA, AC should modify its *Dealer Inspection Guide* (Guide) to require enforcement action for direct and serious violations. We also recommend that "no action" be deleted as an enforcement action in the Guide.

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<sup>7</sup> In 2008, AC employed 99 inspectors. We accompanied 19 on their inspections of dealer facilities.

<sup>8</sup> During this period, administrative law judges or the Department's Judicial Officer rendered decisions in 16 cases involving dealers. We reviewed all 16.

To increase the effectiveness of inspections, AC should provide more comprehensive training and detailed guidance to its inspectors and supervisors on direct and repeat violations, enforcement procedures, and evidentiary requirements (e.g., adequately describing violations).

To calculate more reasonable penalties, APHIS should limit total reductions on its penalty worksheet to less than 100 percent. We also recommend that the agency ensure its penalty guidelines are consistently followed and that it include instructions to count each animal as a separate violation in cases involving animal deaths and unlicensed wholesale activities.

To prevent large breeders from circumventing AWA requirements, APHIS should propose that the Secretary seek legislative change to exclude these breeders from the definition of "retail pet store," and require that all applicable breeders that sell through the Internet be regulated under AWA.

### **Agency Response**

In its written response, dated April 23, 2010, APHIS concurred with the reported findings and recommendations. APHIS' response is included at the end of this report.

### **OIG Position**

We accept APHIS' management decision on Recommendations 1, 2, 3, 5, 6, 7, 8, 9, 10, 12, 13 and 14. The actions needed to reach management decision on Recommendations 4 and 11 are provided in the OIG Position section after these recommendations.

January 20, 2012



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 2012 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 10, 2012. 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 the Proposal may properly be excluded from our Proxy Materials for the following reasons, each of which in and of itself, should be sufficient:

- Pursuant to Rule 14a-8(i)(10) because the Company already has substantially implemented the Proposal.
- Pursuant to Rule 14a-8(i)(3) because the Proposal contains materially false or misleading statements.

#### **BACKGROUND**

On November 14, 2011, 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, to prevent repeated government citations and promote transparency in animal use, 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.

A copy of the Proposal is attached hereto as Exhibit 1.

## ANALYSIS

### **The Proposals 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 "disclosur[e] of procedures to ensure proper animal care, including measures to improve the living conditions of all animals used in-house and at contract laboratories." The Company's website has an entire page devoted to the essential objective of the proposal. The website is cited in the Proposal and can be found at:

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

A printed copy of the content found on that page 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:

[t]he 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.

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 discusses Merck's Institutional Animal Care and Use Committees and Bioethics 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 Merck animal welfare policies and animal welfare regulations."

Furthermore, as stated on the Company's website:

Merck holds similar expectations for standards of animal care and use for 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 Merck 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 (“Form 7023”). 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 facilities also have attained and maintained accreditation from the Association for Accreditation and Assessment for Laboratory Animal Care (“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.

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 model, 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 Lutticken 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 excludable pursuant to Rule 14a-8(a)(i)(10).

### **The Proposals May Be Excluded Pursuant to Rule 14a-8(i)(3)**

Under Rule 14a-8(i)(3), a proposal may be omitted from a registrant's proxy statement if "the proposal or supporting statement is contrary to any of the Commission's proxy rules, including Rule 14a-9, which prohibits materially false or misleading statements in proxy soliciting materials." Rule 14a-9 provides, in pertinent part, that "No solicitation subject to this regulation shall be made by means of any proxy statement, form of proxy, notice of meeting or other communication, written or oral, containing any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." The Staff has stated that it would concur in a company's reliance on Rule 14a-8(i)(3) to exclude a proposal where a company "demonstrates objectively that the proposal is materially false or misleading." See Staff Legal Bulletin 14B (September 15, 2004).

The opening sentence of the Proponent's supporting statement begins "[o]ur Company has been repeatedly cited by the government for improper care of animals used in its laboratory experiments...." However, the Proponent does not cite even a single example of a violation by the Company of applicable rules or regulations. The Proponent's opening paragraph to their supporting statement gives shareholders the false and misleading impression that the Company is repeatedly not in compliance with its regulatory obligations.

The Proponent's second paragraph of their supporting statement states "In the last three years, our Company experimented on more than 41,000 animals in-house ... more than 16,000 of these animals were used in painful experiments and more than 2,000 were given no pain relief whatsoever." Presumably, the Proponent is referring to the Company's Form 7023 as filed with the Animal and Plant Health Inspection Service. There are a number of false and misleading statements made in connection with this paragraph. First, the numbers cited apparently have been aggregated, meaning the Proponent has simply added together all relevant numbers over a three year period to come up with the numbers used. However, it should be noted that these reports are filed annually. If an animal lives three years, over that three year period, the animal is counted once each year. Adding up the numbers together would give the false impression that three animals were used over a three year period, where in this example, there was only a single animal. Second, as stated above, the form has various columns and clearly differentiates between experiments where the subject animals experienced pain or distress and which anesthetics, analgesics or tranquilizers were used and experiments where the use of any anesthetics,

analgesics or tranquilizers would “have adversely affected the procedures....” The Company mitigates any pain or distress that an animal may experience whenever possible and keeps to a minimum animal usage where mitigation efforts cannot be used due to its adverse affect on the related research. The Proponent has decided not to include any discussion of this in their supporting statement.

The Proponents’ third paragraph of their supporting statement states “[t]hese figures do not include animals used in Merck experiments in contract laboratories....” As stated above, each applicable facility, including third party contract laboratories, are required to comply with AWA’s reporting requirements. Merck would not be able to report on third party animal usage because the Company would not have the required information and even if it did, it would be a violation of law for Merck to disclose. The Company and its affiliates regularly enter into service agreements with research laboratories that conduct animal research on the Company’s behalf. A significant number of agreements are subject to mutual confidentiality agreements which prohibit both parties thereto from disclosing information exchanged in the course of that relationship. Therefore, a proposal requiring the Company to disclose third-party information that is subject to existing confidentiality agreements would cause the Company to be in breach of the related agreements.

The Proponent’s fourth paragraph of their supporting statement also includes the following statement:

Animals used in laboratory experiments experience pain, fear and stress. They spend their lives in unnatural settings – caged and deprived of companionship – and subjected to painful experiments. This is reality for animals in laboratories.

This statement is materially misleading because is does not apply to the Company’s practices. First, as noted above, not all animals used in laboratory experiences experience pain, fear or stress. Further, all caging of animals done by the Company complies with USDA regulatory standards for caging as well as the standards noted in the Guide for the Care and Use of Laboratory Animals (National Academy Press, 2011). The Company’s research facilities are inspected annually by the USDA to verify compliance with all caging standards and other USDA regulations. Additionally, most animals are socially housed and not deprived of companionship. For example, non-human primates have environmental enrichment plans that include social housing. The veterinary staff developed the plans and they are reviewed by the Institutional Animal Care and Use Committee as well as by the USDA. The Institutional Animal Care and Use Committee (IACUC) is a self-regulating entity that, according to U.S. federal law, must be established by institutions that use laboratory animals for research or instructional purposes to oversee and evaluate all aspects of the institution’s animal care and use program. Also, as stated earlier, the Company’s research facilities also have attained and maintained accreditation from the AAALAC, a well respected international private nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

The Proponent’s fourth paragraph of their supporting statement includes a lengthy discussion about its undercover investigation of Professional Research Laboratory and Research Services (“PRLR”). This entire paragraph is not only materially false and misleading, it is inflammatory and impugning. PRLR was an unaffiliated third party contract laboratory and the statements made by the Proponent regarding PRLR have nothing to do with the Company. As far as the Company is aware, PRLR has not been in business since 2010 and the footnote to PETA’s website which includes video of various animals in distress has not been linked to the Company or any of its research efforts. In this regard, the entire discussion of PRLR is also excludable under Rule 14a-9 on the basis that it is inflammatory and is impugning, which, as indicated by Staff Legal Bulletin 14B, Section B.4, provides a separate basis for exclusion.

Lastly, the Proponent states that "92% of drugs deemed safe and effective when tested on animals fail in human clinical trials, there is a also [sic] clear scientific imperative for improving testing methods." The Proponent has included a website reference for this sentence, however, the reference does not contain any information. "PAGE NOT FOUND" shows up on the FDA website, and a search of the sentence yielded no applicable results.

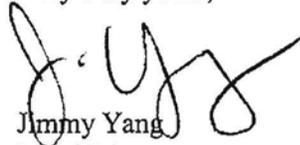
It is clear that Proposal contains numerous false and misleading statements, thereby making it excludable pursuant to Rule 14a-8(i)(3).

### 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 908-423-5744. 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 "Jimmy Yang", written over a printed name.

Jimmy Yang  
Legal Director

EXHIBIT 1

November 14, 2011

Celia A. Colbert  
Senior Vice President, Secretary and Assistant General Counsel  
Merck & Co., Inc.  
1 Merck Dr.  
Whitehouse Station, NJ 08889

Dear Secretary:

Attached to this letter is a shareholder proposal submitted for inclusion in the proxy statement for the 2012 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 was 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 2012 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. 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,

A handwritten signature in black ink, appearing to read "David Byer". The signature is fluid and cursive, with the first name "David" and last name "Byer" clearly distinguishable.

David Byer, Manager  
PETA Corporate Affairs

Enclosures: 2012 Shareholder Resolution  
Morgan Stanley Smith Barney letter

November 14, 2011

Celia A. Colbert  
Senior Vice President, Secretary and Assistant General Counsel  
Merck & Co., Inc.  
1 Merck Dr.  
Whitehouse Station, NJ 08889

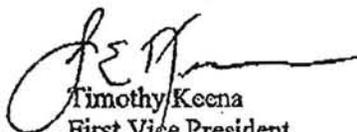
Re: Shareholder Proposal for Inclusion in the 2012 Proxy Material

Dear Secretary:

This letter confirms 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) 394-1997.

Sincerely,



Timothy Keena  
First Vice President  
Global Wealth Management Group  
Morgan Stanley Smith Barney

## TRANSPARENCY IN ANIMAL RESEARCH

**RESOLVED**, to prevent repeated government citations and promote transparency in animal use, 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.

### Supporting Statement

Our Company has been repeatedly cited by the government for improper care of animals used in its laboratory experiments, including caging primates in isolation, issues relating to expired drugs and inadequate anesthesia, untrained personnel, inadequate housing of animals, and lack of proper veterinary care.

In the last three years, our Company used more than 41,000 animals in-house. This number includes almost 6,600 dogs and 13,500 primates. More than 16,000 of these animals were used in painful experiments and more than 2,000 were given no pain relief whatsoever.<sup>1</sup> A number of animals died in their cages without being humanely euthanized.

These figures do not include animals used in Merck experiments in contract laboratories nor the vast numbers of animals who are most commonly used in experiments and, though not legally required to be counted, suffer as well.

Animals used in laboratory experiments experience pain, fear and stress. They spend their lives in unnatural settings—caged and deprived of companionship—and are subjected to painful experiments. This is reality for animals in laboratories.

What should not be the norm is outright cruelty towards defenseless animals.

Our Company's animal welfare policy states that "Merck performs due diligence and monitors external laboratories performing in vivo [animal] studies on our behalf."<sup>2</sup> Yet documentation of sadistic treatment at a contract laboratory used by our Company, Professional Laboratory and Research Services (PLRS), resulted this year in 14 felony cruelty charges against its employees.<sup>3</sup>

The government issued a report confirming the appalling conditions at the facility and PLRS is now out of business. The abuses included:

- Sick and injured animals—including dogs with ear and eye infections, diseased gums, facial lacerations, and inflamed feet—were routinely denied veterinary care;

<sup>1</sup> [http://www.aphis.usda.gov/animal\\_welfare/efoia/7023.shtml](http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml)

<sup>2</sup> <http://www.merckresponsibility.com/priorities-and-performance/access-to-health/research-and-development/animal-research/home.html>

<sup>3</sup> <http://www.peta.org/features/professional-laboratory-and-research-services.aspx>

- An untrained worker used pliers to pull a tooth from a struggling, under-sedated dog;
- Dogs and cats were slammed into cages, thrown, kicked and dragged;
- Dogs and cats were pressure-hosed with a bleach solution;
- A worker attempted to rip out a cat's nails by forcing the cat to clutch a chain-link fence and then violently pulling her away.

Our Company has the ability and the obligation to ensure that no animal suffers from lack of veterinary care, poor housing, or outright mistreatment.

Given that 92% of drugs deemed safe and effective when tested on animals fail in human clinical trials, there is also a clear scientific imperative for improving testing methods.<sup>4</sup>

Shareholders cannot monitor what goes on behind the closed doors of animal testing laboratories, so our Company must. Our Company has an ethical and fiscal obligation to implement this socially important proposal.

We urge shareholders to vote **FOR** the proposal.

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<sup>4</sup> FDA Commissioner: <http://www.fda.gov/oc/speeches/2006/fdateleconference0112.html>

EXHIBIT 2

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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 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, 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 Merck's commitment to the highest level of animal care, Merck Research Laboratories' 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 \(AAALAC\)](#). Merck also advocates for the development of best practices and dissemination of information by supporting and participating with non-governmental organizations such as the Scientist Center for Animal Welfare, the Institute for Laboratory Animal Research at the National Academy of Science, and the American College of Laboratory Animal Medicine Foundation.

Merck's standing Institutional Animal Care and Use Committees (IACUC)/Bioethics committees or equivalent, 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, which is globally accountable for compliance with all Merck animal welfare policies and animal welfare 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 regulations, policies, the use of animal research alternatives, the role of the IACUC/Bioethics committees and how to raise any concerns. Merck places high value on its animal welfare stewardship responsibility, and violating of 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 for 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 Merck 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.

### **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, Merck subscribes 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, 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 model, and analgesics or tranquilizers are used whenever possible)

Training in the 3Rs is part of the 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 has extensive *in vitro* expertise and investments, as the *In Vitro* department develops and utilizes non-animal 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 like the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) and 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 rodents and monitor the long-term effectiveness of new treatments in a non-invasive manner. In addition, Merck employs internal and external information specialists in our research library, trained by the Animal Welfare Information Center of the U.S. National Agriculture Library, to assist Merck scientists in identifying potential animal alternatives.

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

To support the 3Rs philosophy, since 1994, Merck has annually presented an Animal Alternative Award to the teams of Merck scientists who develop new techniques to support the alternative principle and published their work to share with the scientific community.

The 2009 Animal Alternative Award went to two teams that used state of the art imaging in cancer research studies, which represented a refinement in techniques and resulted in an overall reduction in the number of animals needed for studies while enhancing the data collected.

The 2008 Animal Alternatives Award went to two teams that demonstrated a refinement in study techniques and a reduction in the number of animals needed through the use of quantitative 3D-Micro-Ultrasound in mice for hypertensive model development and atherosclerosis biomarker studies.

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

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

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>\*</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.

The 2009 award went to a European team that developed an in vitro potency test for the routine quality control of inactivated Newcastle Disease Virus (NDV) vaccines. Previously, quality control of NDV vaccines included an in vivo potency assay in chickens. The new method avoids the use of chickens and has now been included in the respective European Pharmacopoeia monograph as an additional potency assay to release NDV vaccines.

<sup>\*</sup>Reference: 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