DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549-0402

January 30, 2004

Thomas J. Spellman III
Assistant Corporate Secretary and
Senior Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Act: 1934
Section:
Rule: 14A-8
Public
Availability: 1-30-2004

Re: Johnson & Johnson
Incoming letter dated December 18, 2003

Dear Mr. Spellman:

This is in response to your letter dated December 18, 2003 concerning the shareholder proposal submitted to Johnson & Johnson by Joan Lewis. We also have received a letter by the proponent dated January 5, 2004. Our response is attached to the enclosed photocopy of your correspondence. By doing this, we avoid having to recite or summarize the facts set forth in the correspondence. Copies of all of the correspondence also will be provided to the proponent.

In connection with this matter, your attention is directed to the enclosure, which sets forth a brief discussion of the Division's informal procedures regarding shareholder proposals.

Sincerely,

Martin P. Dunn

Martin P. Dunn
Deputy Director

Enclosures

cc: Joan Lewis
3473 Mandeville Canyon Road
Los Angeles, CA 90049

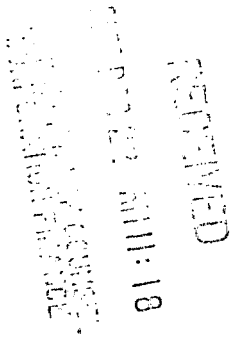
Johnson & Johnson

OFFICE OF THE CORPORATE SECRETARY
THOMAS J. SPELLMAN III
ASSISTANT SECRETARY

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933-

December 18, 2003

VIA FEDERAL EXPRESS



Office of the Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, D.C. 20549

Re: *Johnson & Johnson Shareholder Proposal of Joan Lewis*
Securities Exchange Act of 1934—Rule 14a-8

Ladies and Gentlemen:

This letter is to inform you that it is the intention of Johnson & Johnson, a New Jersey corporation (the "Company"), to omit from its proxy statement and form of proxy for its 2004 Annual Meeting of Shareholders (collectively, the "2004 Proxy Materials") a shareholder proposal and statement in support thereof (collectively, the "Proposal") received from Joan Lewis (the "Proponent") relating to animal testing. The Proponent's letter, dated November 28, 2003, setting forth the Proposal, is attached hereto as Exhibit A.

The Company respectfully requests that the staff of the Division of Corporation Finance (the "Staff") of the Securities and Exchange Commission (the "Commission") concur in our view that the Proposal may be excluded from the 2004 Proxy Materials on the grounds set forth below. In the alternative, the Company requests that the Staff require the Proponent to revise the Proposal in order to comply with the proxy rules.

Pursuant to Rule 14a-8(j) under the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), enclosed are six (6) copies of this letter and its attachments. Also in accordance with Rule 14a-8(j), a copy of this letter and its attachments are being mailed on this date to the Proponent, informing her of the Company's intention to omit the Proposal from the 2004 Proxy Materials.

The Company expects to file its definitive 2004 Proxy Materials with the Commission on or after March 10, 2004. Accordingly, pursuant to Rule 14a-8(j), this letter is being submitted not less than 80 calendar days before the Company expects to file its definitive 2004 Proxy Materials with the Commission. In order to allow the Company to complete its mailing of the 2004 Proxy Materials in a timely fashion, we would appreciate receiving your response as soon as practicable.

The Company is requesting that the Proposal be excluded from the proxy statement for the reasons cited below:

1. The substance of the Proposal has already been implemented. Rule 14a-8(i)(10) provides that a proposal may be excluded if the company has substantially implemented the proposal.

   - The Company has already committed to using non-animal tests wherever those tests have proven reliable enough to assure the safety of the Company's products, which include cosmetics, pharmaceutical products and medical devices.

   - Where there are no adequately reliable non-animal tests currently available, the Company is at the forefront of funding and developing alternative non-animal tests.

   - Until such alternative non-animal tests are developed, the Company has a policy against inflicting any unnecessary pain on animals and uses analgesics, anesthetics and tranquilizers wherever possible. In fact, mistreatment of animals or failure to abide by the Company's policies on the humane treatment of animals is grounds for dismissal of the Company's employees.

   - The Company continues to spend over $37 million each year using and developing non-animal tests and will continue to substitute non-animal tests for animal tests as reliable systems are developed and accepted by the applicable regulatory authorities.

2. The Proposal contains statements that are materially false or misleading and Rule 14a-8(i)(3) states that a proposal may be excluded if it contains materially false or misleading statements.

3. The Proposal, if implemented, would cause the Company to violate the law. In addition, the Company lacks the power or authority to implement the Proposal. Rule 14a-8(i)(2) indicates that a proposal may be excluded if, upon implementation, it would cause a company to violate the law. Rule 14a-8(i)(6) states that a proposal may be excluded if a company lacks the power or authority to implement it.

In the alternative, we believe that the Proposal should be revised substantially in order to comply with the Commission's proxy rules.

I. Substantially Implemented—Rule 14a-8(i)(10)

The Company believes that the Proposal may properly be excluded from its 2004 Proxy Materials pursuant to Rule 14a-8(i)(10) because the Company has already substantially implemented it.

The Proponent urges the Company to use alternative testing methods for five specific conditions: 1) skin corrosion, 2) skin irritation, 3) skin absorption, 4) phototoxicity and 5) pyrogenicity. Testing for skin corrosion does not apply to our businesses. Skin corrosion could arise in connection with products like detergents and household cleaners – products that the Company does not market or sell. Skin irritation and absorption testing is already conducted by the Company using a variety of commercially available, validated *in vitro* alternatives such as the Epi-Derm skin equivalent method advocated by the Proponent, as well as the Franz-cell system and the trans-epithelial permeability assay. Phototoxicity testing is performed using the *in vitro* alternative neutral red uptake, when necessary. Pyrogenicity testing is also accomplished using an *in vitro* alternative – the limulus amebocyte lysate test.

The Proponent also requests that the Company "generally commit to elimination of product testing on animals in favor of validated *in vitro* alternatives." The Company has already publicly committed itself to substituting alternative non-animal testing in place of live animal testing wherever possible. See Exhibit B; Exhibit C; and Industry Charter in Support of Global Alternatives to Animal Testing (available at www.colipa.com/alternatives). In the limited areas in which there currently are no non-animal tests that are reliable enough to assure the safety of the Company's products for its customers, the Company is working actively and funding the work of a number of organizations to develop adequate non-animal tests. In fact, the Company's cumulative total spending is more than $37 million each year for using and developing non-animal tests.

The Proponent also asks that the Company "request that relevant regulatory agencies accept validated *in vitro* tests as replacements for animal tests." The Company has already committed itself to "[p]roactively support European and international initiatives to develop alternative testing methods and promote their use around the world." See Industry Charter in Support of Global Alternatives to Animal Testing, Article 6. The Company is also at the forefront in the U.S. and internationally of developing non-animal testing methods.

The Company acknowledges that the Staff did not permit American Home Products ("AHP") to exclude an animal testing proposal even though AHP argued that it had substantially implemented the proposal's substance because it already was minimizing the use of animal testing not required by law and reducing the impact of testing on animals. See American Home Products Corporation (February 25, 1993). The Proposal is distinguishable from the AHP proposal, however, because the Proposal is narrower in focus, relating specifically to tests for skin corrosion, skin absorption, skin irritation, phototoxicity and pyrogenicity. As a result, the Company believes that it has already substantially implemented the Proposal in these areas.

II. Materially False or Misleading—Rule 14a-8(i)(3)

The Company believes that the Proposal should be excluded from the Company's 2004 Proxy Materials because it contains a number of materially false or misleading statements such that the Proposal would require detailed and extensive editing in order to bring it into compliance with the proxy rules. In the alternative, the Company respectfully requests that the Staff require the Proponent to revise the Proposal to remove any materially false or misleading statements.

Rule 14a-8(i)(3) permits a company to exclude a shareholder proposal from its proxy materials if the proposal is materially false or misleading. The Staff has commented, "when a proposal and supporting statement will require detailed and extensive editing in order to bring them into compliance with the proxy rules" because the proposal contains so many materially false or misleading statements, "we may find it appropriate for companies to exclude the entire proposal, supporting statement, or both, as materially false or misleading." See Staff Legal Bulletin No. 14 (July 13, 2001).

The Staff has permitted companies in the past to exclude portions of proposals relating to animal testing on the grounds that they were materially false or misleading. See, e.g., McDonald's Corporation (March 20, 2002) (permitting the company to exclude portions of a shareholder proposal that the board issue a report to shareholders reviewing the company's animal welfare standards because those portions were materially false or misleading); The Gillette Company (January 4, 1996) (permitting the company to exclude portions of a shareholder proposal that the company provide a report on its efforts to eliminate all animal testing because those portions were materially false or misleading); American Home Products Corporation (February 25, 1993) (permitting the company to exclude portions of a shareholder proposal that the company eliminate animal testing because those portions were materially false or misleading); PepsiCo., Inc. (March 9, 1990) (permitting the company to exclude portions of a shareholder proposal that the company establish a committee to investigate the effects of factory farming of animals whose meat is used in the company's products and make recommendations on how the company can encourage the development of more humane farming techniques because those portions were materially false or misleading); Avon Products, Inc. (March 30, 1988) (permitting the company to exclude portions of a shareholder proposal that the company make certain disclosures concerning animal testing because those portions were materially false or misleading).

The Proposal contains a number of statements that are materially false or could mislead shareholders. In the introduction, the Proponent argues for *in vitro* tests "as an alternative to...unnecessary animal testing." The Company does not use any unnecessary animal tests. In fact, the Company is at the forefront of phasing out animal testing where it is not required by law and not necessary to assure the safety of the Company's products. Although *in vitro* systems have contributed to reducing animal use in product testing, they cannot at this time obviate the need entirely for animal studies. Testing in animals is required to understand the

complex interactions between the body's organ systems and the physiological and pathological consequences of exposure to drugs, chemicals and medical devices. Both U.S. and foreign regulators require a certain amount of animal testing in order to protect consumers. See, e.g., 21 C.F.R. Section 312.23(a)(8)(i) (providing that a company must include in an application to the U.S. Food and Drug Administration for authorization to conduct a clinical trial of an Investigational New Drug Application in humans "a section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known"); European Federation of Pharmaceutical Industries and Associations, Policy Statement on the Use of Animals in Research and Development ("[A]ll countries which regulate the approval of new medicines demand evidence from animal studies before they will allow the medicines . . . to be tested and used in patients.")

When American Home Products received a shareholder proposal that the company eliminate animal testing, the company argued, among other things, that the portion of the proposal claiming that animal testing is an "unnecessary expense" was excludable as false or misleading. The Staff agreed with the company and required the proponent to revise the proposal to delete the reference. See American Home Products Corporation (February 25, 1993). In light of the Staff's determination in response to the request for a no-action letter from American Home Products, the Company believes that the Proponent's characterization of animal testing as "unnecessary" should be omitted from the Company's 2004 Proxy Materials

The Proposal also misleadingly suggests that the Company conducts tests on animals for skin corrosion, irritation, absorption, phototoxicity and pyrogenicity, as follows:

- "Testing for skin corrosion, irritation, absorption, phototoxicity, and pyrogenicity on animals is no longer necessary, and can be tested using non-animal methods."
- "Testing for skin corrosion can be accomplished using skin equivalent tests such as EpiDerm and EpiSkin."
- "Chemical absorption through the skin can be determined using isolated human skin tissue instead of applying substances to the skin of living animals."
- "Once a chemical has been determined to be non-corrosive, its potential to cause mild irritation can be tested using a clinical skin patch test."
- "Phototoxicity, an inflammatory reaction caused by interaction of a chemical with sunlight, can be evaluated using 3T3 Neutral Red Uptake ("NRU") test."

- "Pyrogenicity, the inflammatory reaction and fever that can occur when intravenous drugs and pharmaceuticals interact with the immune system can be evaluated using blood from healthy human donors. . . . The *in vitro* pyrogen test validated in Europe is a total replacement for the rabbit test. The *in vitro* test [for pyrogenicity] is more accurate, and results more quickly attainable."

Testing for skin corrosion does not apply to our businesses. Skin corrosion could arise in connection with products like detergents and household cleaners – products that the Company does not market or sell. Skin irritation and absorption testing is already conducted by the Company using a variety of commercially available, validated *in vitro* alternatives, such as the Epi-Derm skin equivalent method advocated by the Proponent, as well as the Franz-cell system and the trans-epithelial permeability assay. Phototoxicity testing is performed using the *in vitro* alternative neutral red uptake, when necessary. Pyrogenicity testing is also accomplished using an *in vitro* alternative – the limulus amebocyte lysate test. Since the Company is already using alternative tests for each of these conditions, it is misleading to shareholders to suggest that there are alternative tests available that the Company is not already using.

The Proposal also contains various false or misleading claims about the current state of foreign laws relating to animal testing.

- "Canada, the European Union, and most countries in the Organization for Economic Cooperation and Development (OECD) accept the *in vitro* tests as total replacements for animal tests."

- "This *in vitro* approach is accepted as an OECD Test Guideline, and is the default approach for skin absorption testing in several European nations."

- "This test is accepted by Regulators in Canada as a valid replacement for animal based skin irritation testing."

- "The NRU test is accepted throughout Europe and by the OECD as the official test guideline for phototoxicity."

- "The *in vitro* pyrogen test validated in Europe is a total replacement for the rabbit test."

The Company acknowledges that the European Union has validated three alternative test methods: 1) the EPISKIN™ test for skin corrosion, 2) the Transcutaneous Electrical Resistance Assay (TER) for chemical absorption and 3) the 3T3 Mouse Fibroblast Neutral Red Uptake Phototoxicity (NRU-PT) for phototoxicity. Since the European Union validated these alternative test methods, the Company has not used animal testing in Europe to evaluate the safety of these parameters of its finished cosmetic products. The Company has

relied on existing data, historic databases, information from suppliers, computer systems and *in vitro* tests.

However, European regulators still require companies to conduct certain amounts of animal testing. See European Federation of Pharmaceutical Industries and Associations, Policy Statement on the Use of Animals in Research and Development ("[A]ll countries which regulate the approval of new medicines demand evidence from animal studies before they will allow the medicines . . . to be tested and used in patients.") Where the Company is still currently required to conduct animal testing, the Company has committed itself publicly to work to develop additional non-animal testing methods. See Industry Charter in Support of Global Alternatives to Animal Testing.

Alternative tests are not accepted as total replacements for animal tests in Canada either, as the Proponent claims. In determining whether companies are required to conduct animal testing on products marketed and sold in Canada, Health Canada, the relevant regulatory agency, is guided by the International Conference on Harmonization (ICH) guidelines. The ICH guidelines require companies to conduct a certain amount of animal testing, such as testing for the systemic toxicity of a product. The Company acknowledges that Health Canada has expressed general support for alternative testing methods, but has not adopted regulations that formally validate alternative testing methods for all of the Company's products.

When Gillette received a shareholder proposal that the company provide a report on its efforts to eliminate animal testing, Gillette argued that the proposal was excludable as false or misleading because it suggested that Gillette would be required to eliminate animal testing or cease exports to Europe pursuant to a directive of the European Community Council of Ministers. Gillette noted that the directive contained an exception to the ban where adequate non-animal test methods have not been developed yet for a particular product. The Staff required the proponent to revise the proposal to discuss the exception to the directive. See The Gillette Company (January 4, 1996). Similarly, the Proposal mischaracterizes the state of European and Canadian law on animal testing. As a result, the Company believes that the statements contained in the Proposal about European and Canadian law are excludable as materially false or misleading.

The Proposal also asks the Company to "request that relevant regulatory agencies accept validated *in vitro* tests as replacements for animal tests." The Proposal misleads shareholders by suggesting that the relevant regulatory agencies do not already accept certain validated *in vitro* tests as replacements for animal tests. In fact, regulatory agencies in the U.S. and internationally have already accepted a number of validated *in vitro* tests as replacements for animal tests. For example, in February 2000, the European Commission formally accepted three alternative testing methods: 1) the EPISKIN™ test for skin corrosion, 2) the Transcutaneous Electrical Resistance Assay (TER) for chemical absorption and 3) the 3T3 Mouse Fibroblast Neutral Red Uptake Phototoxicity (NRU-PT) for phototoxicity. In the U.S., the Food and Drug Administration has validated the limulus amebocyte lysate test used by the Company to test for

pyrogenicity of certain products. Accordingly, the Company currently uses these alternative methods. As a result of these and other regulations that permit our Company to use certain non-animal tests, our affiliates around the world currently use more than 160 different alternative tests in research.

Furthermore, the Proposal misleads shareholders by suggesting that the Company is not already taking steps to encourage regulators to validate additional alternative testing methods. The Company joined in an Industry Charter in Support of Global Alternatives to Animal Testing in Europe and committed itself to, "[p]roactively support European and international initiatives to develop alternative testing methods and promote their use around the world." See Industry Charter in Support of Global Alternatives to Animal Testing. Where there are no currently validated *in vitro* tests for product safety, the Company is at the forefront of developing and funding the development of replacements for live animal testing. For example, we are a corporate sponsor of the Johns Hopkins Center for Alternatives to Animal Testing and the Institute for In Vitro Sciences. In total, we spend more than $37 million each year using and developing non-animal tests.

The Proposal also incorrectly suggests that animal testing is always "painful" to the animals. The Company has consistently committed itself publicly to developing procedures that limit the potential for discomfort to the animals. See Exhibit B and Industry Charter in Support of Global Alternatives to Animal Testing. In the Company's Policy on the Humane Care & Use of Laboratory Research Animals, the Company commits that, "[n]o laboratory animal shall be subjected to unnecessary pain and/or distress. Where pain and/or distress are unavoidable, appropriate analgesics, anesthetics and tranquilizers shall be used." See Exhibit C. Failure by the Company employees to abide by this policy is grounds for dismissal. Id.

The Company acknowledges that the Staff did not permit Greyhound to exclude the statement "some tests cause pain" from an animal testing proposal it had received on the grounds that the statement was materially false or misleading. See The Greyhound Corporation (March 24, 1987). The Proposal, however, is distinguishable from the Greyhound proposal because the Greyhound proponent submitted reports filed by Greyhound with the United States Department of Agriculture showing that in the two prior years Greyhound had used several species of animals in acute toxicity and other testing involving pain or distress without the administration of appropriate anesthetic, analgesic or tranquilizer drugs. In contrast, the Company has a policy that "[n]o laboratory animal shall be subjected to unnecessary pain and/or distress. Where pain and/or distress are unavoidable, appropriate analgesics, anesthetics and tranquilizers shall be used." See Exhibit C. As a result, the Company believes that the Proposal's suggestion that all animal testing is "painful" should be omitted from the Proposal.

In addition, the Proposal misleadingly claims that non-animal test methods are necessarily "reliable." The Company has substituted non-animal test methods for live animal testing wherever those methods have been proven reliable and have been permitted by regulatory authorities and will continue to do so as new tests are developed. Unfortunately, there currently

do not exist sufficiently reliable non-animal test methods that can be used to assure the safety of all of the Company's products. The Proposal misleads shareholders by suggesting that there are reliable non-animal test methods currently available to the Company that the Company is choosing not to use.

Furthermore, the Proposal falsely claims that non-animal tests are "often faster and more economical." This statement is not supported. Nonetheless, the Company remains committed to substituting alternative non-animal systems in place of live animal testing, even if these methods are slower and more costly to the Company because the Company is committed to a policy of humane treatment of animals. In fact, the Company spends more than $37 million each year using and developing non-animal tests.

When Avon challenged a shareholder proposal that the company make certain disclosures about animal testing by arguing that the proposal contained a number of false or misleading statements, including allegations that animal tests are more costly, the Staff determined that such allegations were excludable absent revision by the shareholder to characterize the allegations as an opinion. See Avon Products, Inc. (March 30, 1988). As a result, the Company believes that the Proponent's claim that non-animal testing is "more economical" should be excluded from the Company's 2004 Proxy Materials or, at the least, the Proponent should be required to recast the claim as an opinion.

The Proposal states, "[i]t is in the Company's best interest that it commit to utlizing [*sic*] validated *in vitro* methods of testing as a humane alternative to unnecessary animal tests." The Company already uses alternative non-animal test methods where those methods have proven adequate to sufficiently assure product safety and been approved for use by applicable regulatory authorities. The Company is committed to substituting non-animal test methods for live animal systems in the future if possible, but it is not in the best interest of the Company to use *in vitro* methods where those methods may not serve to adequately ensure the safety of the Company's products and customers or may constitute a violation of the Company's legal obligations.

As discussed above, the Proposal contains many false or misleading statements and it would require substantial revision in order to be in compliance with Rule 14a-8(i)(3). As a result, the Company believes that the Proposal should be excluded from its 2004 Proxy Materials in its entirety. The Staff has made clear that "when a proposal and supporting statement will require detailed and extensive editing in order to bring them into compliance with the proxy rules, we may find it appropriate for companies to exclude the entire proposal, supporting statement, or both, as materially false or misleading." See Staff Legal Bulletin No. 14 (July 13, 2001). In the alternative, the Company requests the Staff to require the Proponent to revise the Proposal to remove all materially false or misleading statements.

III. Violation of the Law—Rule 14a-8(i)(2) and Lack of Authority or Power—Rule 14a-8(i)(6).

The Company believes that the Proposal may be excluded from the Company's 2004 Proxy Materials because, if implemented, it would result in a violation of the law pursuant to Rule 14a-8(i)(2) and because the Company lacks the power and authority to implement the Proposal pursuant to Rule 14a-8(i)(6).

The Staff has often considered the application of these rules to a particular shareholder proposal in tandem. See, e.g., The Greyhound Corporation (March 24, 1987) (considering in tandem the application of Rule 14a-8(i)(2) and Rule 14a-8(i)(6) to a shareholder proposal on animal testing).

The Proposal requests that the Company commit to "elimination of product testing on animals in favor of validated *in vitro* alternatives" and to "commit to use *in vitro* tests for assessing skin corrosion, skin absorption, skin irritation, phototoxicity and pyrogenicity." The Company is required under U.S. and foreign laws to conduct a limited amount of animal testing to assure the safety of its products, which include pharmaceuticals and medical devices, prior to their marketing and sale. If the Company eliminated all animal testing, as the Proposal requests, the Company would be in violation of the law.

In the United States, the Company is required to test new ingredients in or new formulations of pharmaceutical products for safety in animals prior to final validation in human tests. See 21 C.F.R. Section 312.23(a)(8)(i) (providing that a company must include in an application to the U.S. Food and Drug Administration for authorization to conduct a clinical trial of an Investigational New Drug Application in humans "a section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known").

In The European Union, European regulators require "evidence from animal studies before they will allow the medicines . . . to be tested and used in patients." See European Federation of Pharmaceutical Industries and Associations, Policy Statement on the Use of Animals in Research and Development.

Canadian regulators are guided by the International Conference on Harmonization (ICH) guidelines. The ICH guidelines require companies to conduct a certain amount of animal testing, such as testing for the systemic toxicity of a product.

The Company acknowledges that the Staff did not permit Greyhound Corporation to exclude an animal testing proposal even though Greyhound argued that the proposal was excludable because the company was required to conduct animal testing by law and implementing the proposal would cause the company to violate the law. See The Greyhound Corporation (March 24, 1987). However, the Proposal is distinguishable from the Greyhound

proposal because the Greyhound proposal, if approved, would only have committed Greyhound to eliminate animal testing not required by law. With respect to animal testing required by law, Greyhound would only have been committed to make disclosures and phase-out product lines.

In contrast, the Proposal, if approved, would commit the Company to cease animal testing in the development of products that the Company is required to test on animals prior to the marketing and sale of those products.

As a result, the Company believes that the Proposal may be excluded from its 2004 Proxy Materials because the Company would be forced to violate the law if the Proposal were implemented.

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For the foregoing reasons, we respectfully request that the Staff concur in our opinion that the Proposal may be properly omitted from the 2004 Proxy Materials.

If you have any questions with respect to the foregoing or if you need any additional information, please feel free to give me a call at Johnson & Johnson at (732) 524-3570. If for any reason the Staff does not agree with the conclusions expressed herein, we would appreciate an opportunity to confer with the Staff before issuance of its response.

We request that you acknowledge receipt of this letter and the enclosures by stamping and returning the enclosed additional copy of the cover page of this letter using the enclosed self-addressed stamped envelope.

Thank you for your prompt attention to this matter.

Very truly yours,

Thomas J. Spellman III
Assistant Corporate Secretary and
Senior Counsel

TJS/dr
Enclosures
cc: Joan Lewis, Esq.
3473 Mandeville Canyon Road
Los Angeles, California 90049

Exhibit A

JOAN LEWIS, ESQ.
3473 Mandeville Canyon Road
Los Angeles, California 90049
Tel. (310) 476-5065
Fax (310) 476-3457

November 28, 2003

BY REGULAR MAIL

Mr. Michael H. Ullmann
Secretary, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Re: Shareholder Resolution for Inclusion in the 2004 Proxy Statement

Dear Mr. Ullmann:

I am in receipt of your letter dated November 19th and am responding accordingly.

Attached to this letter is a revised Shareholder Proposal submitted for inclusion in the proxy statement for the 2004 annual meeting. The revised Proposal complies with the Section 14a-8(d) limitation on length and is submitted within the time frame required by Rule 141-8(f)(1).

Thank you for your consideration.

Very truly yours,

Joan Lewis

Joan Lewis

Enclosure

SHAREHOLDERS' RESOLUTION

This Proposal is submitted by Joan Lewis, owner of 200 shares of stock.

It relates to availability of validated *in vitro* tests for assessing dermal and pyrogenic affects, as an alternative to painful and unnecessary animal testing. Johnson & Johnson ("J&J" or "the Company") should commit to utilizing validated *in vitro* tests in place of live animal assays whenever possible.

RESOLVED, the shareholders of J&J request that the Board:

1. Commit to use *in vitro* tests for assessing skin corrosion, skin absorption, skin irritation, phototoxicity and pyrogenicity, and generally commit to elimination of product testing on animals in favor of validated *in vitro* alternatives;
2. Request that relevant regulatory agencies accept validated *in vitro* tests as replacements for animal tests; and
3. Form a Shareholders Advisory Committee to counsel the Board on these issues and report annually to shareholders on the Company's progress.

Supporting Statement: J&J has a responsibility to use non-animal test methods, because they are reliable, often faster and more economical, and more humane. Testing for skin corrosion, irritation, absorption, phototoxicity, and pyrogenicity on animals is no longer necessary, and can be tested using non-animal methods.

Testing for skin corrosion can be accomplished using skin equivalent tests such as EpiDerm™ and EpiSkin™. In the animal test, rabbits are locked into full body restraints and the chemical applied to shaved skin for several hours. Canada, the European Union, and most countries in the Organization for

Economic Cooperation and Development (OECD) accept the *in vitro* tests as total replacements for animal tests.

Chemical absorption through the skin can be determined using isolated human skin tissue instead of applying substances to the skin of living animals. This *in vitro* approach is accepted as an OECD Test Guideline, and is the default approach for skin absorption testing in several European nations.

Once a chemical has been determined to be non-corrosive, its potential to cause mild irritation can be tested using a clinical skin patch test. This test is accepted by Regulators in Canada as a valid replacement for animal based skin irritation testing.

Phototoxicity, an inflammatory reaction caused by interaction of a chemical with sunlight, can be evaluated using 3T3 Neutral Red Uptake ("NRU") test. The animal based test involves applying different concentrations of a chemical on the shaved skin of guinea pigs, and exposing half of the animals to ultraviolet radiation for at least two hours. The NRU test is accepted throughout Europe and by the OECD as the official test guideline for phototoxicity.

Pyrogenicity, the inflammatory reaction and fever that can occur when intravenous drugs and pharmaceuticals interact with the immune system can be evaluated using blood from healthy human donors. The animal test consists of locking rabbits in full-body restraints, injecting test substances into their blood stream, and monitoring temperature. The *in vitro* pyrogen test validated in Europe is a total replacement for the rabbit test. The *in vitro* test is more accurate, and results more quickly attainable.

It is in the Company's best interest that it commit to utlizing validated *in vitro* methods of testing as a humane alternative to unnecessary animal tests.

Exhibit B

Johnson & Johnson

STATEMENT ON PRODUCT SAFETY & ANIMAL TESTING

Johnson & Johnson companies, as diversified health care products manufacturers, have a responsibility to assure that products are safe for intended use and in the event of accidental misuse.

Judicious and ethical use of animal and *in vitro* (test tube) tests continue to be a primary means of assuring that we are providing safe and efficacious products to our customers. Product safety is both a moral obligation and a requirement imposed by various government regulatory agencies.

Johnson & Johnson companies recognize that humane concern for animals is mandatory in scientific testing. The Johnson & Johnson companies' Policy on the Humane Care and Use of Animals for Laboratory Research emphasizes our commitment to the humane treatment of laboratory animals. It encourages the conservation of animal resources and promotes the use of alternative testing whenever possible.

Babies and young children traditionally have been one of the most important user groups for Johnson & Johnson companies. To assure their safety, the companies have an obligation to produce the mildest, gentlest products possible. This necessitates a minimum number of animal tests to demonstrate that new ingredients or new formulations are safe, prior to final validation in human tests, and to provide information required by physicians in emergency rooms and by poison control center personnel.

Johnson & Johnson companies are committed to the three "R" principles – **replacement, reduction and refinement** – as they apply to animal testing.

REPLACEMENT

Substituting alternative non-animal systems in place of live animal testing

We have substituted, wherever possible, test tube/cell culture *(in vitro)* alternative methods for much testing that in the past was done with animals; we carefully monitor, on a worldwide basis, all reported developments utilizing *in vitro* methods to determine their applicability to our products. We actively pursue validation, acceptance and adoption of applicable alternative tests by the scientific community and regulatory agencies. We share our alternative test methods with the scientific community through publications and presentations at symposia.

We provide substantial financial support for outside research programs that develop and validate *in vitro* alternatives. We are a corporate sponsor of the Johns Hopkins Center for Alternatives to Animal Testing and the Institute for *In Vitro* Sciences. We supported a major program at the University of Texas to develop alternatives to skin and eye irritation testing.

REDUCTION

Using the fewest number of animals possible

The Johnson & Johnson companies overall research investment increased almost 250% in the last ten years. Despite this large increase, there has been a significant reduction in our use of laboratory animals. Comparing 1990 with 2000 we reduced by more than 99.3% all laboratory animals used in worldwide testing of non-medical products (personal care, toiletries), including eye and skin irritation studies.

(over)

Exhibit C

Johnson & Johnson

POLICY ON THE HUMANE CARE & USE OF LABORATORY RESEARCH ANIMALS

It is the policy of the Johnson & Johnson Family of Companies to use animals in laboratory research to the minimum extent necessary to assess the safety and efficacy of our products for use in humans and animals. Consistent with this policy, Johnson & Johnson laboratory research animal care and use programs and facilities meet or exceed inspection agency standards; all animals are treated humanely and cared for in accordance with the Animal Welfare Act (7 USC 2131) and the National Institutes of Health *Guide for the Care and Use of Laboratory Animals.*

Although *in vitro* systems have contributed to reducing animal use, they cannot at this time obviate the need for animal studies. Testing in animals is required to understand the complex interactions between the body's organ systems and the physiological and pathological consequences of exposure to drugs, chemicals, vaccines and medical devices. The use of animals, therefore, remains an essential element in the conduct of biomedical research and development. The following principles confirm our commitment to the conservation and humane treatment of animals used for laboratory research:

- To involve animals in a research study, there must be the reasonable expectation that such studies will contribute significantly to knowledge which may eventually lead to the protection and improvement of the health and welfare of humans and animals.

- The number of animals utilized for each study shall be the minimum necessary to obtain scientifically valid data and/or to meet official requirements for regulatory or registration purposes.

- Methods requiring fewer or no animals shall be utilized whenever feasible.

- The Johnson & Johnson companies are committed to the three "R" principles – *replacement, reduction* and *refinement* – as they apply to animal testing. Replacement means substituting alternative non-animal systems, including test tube cell cultures and lower organisms, in place of live animals. Reduction means using the fewest number of animals possible. Refinement means developing procedures that limit the potential for discomfort to animals.

- All laboratory research animals shall be treated humanely. They shall be housed and cared for in compliance with the Animal Welfare Act (7 USC 2131) and in a manner consistent with the NIH *Guide for the Care and Use of Laboratory Animals.*

- No laboratory animal shall be subjected to unnecessary pain and/or distress. Where pain and/or distress are unavoidable, appropriate analgesics, anesthetics and tranquilizers shall be used except where their use will interfere with the scientific results. All exceptions are reviewed and approved on a case by case basis by the Institutional Animal Care and Use Committee (IACUC).

- Only humane and appropriate methods of euthanasia will be used, as described by the American Veterinary Medical Association Panel on Euthanasia.

- Prolonged physical restraint shall only be used after alternative procedures have been considered and found inadequate.

- Mistreatment of animals or failure to abide by these principles is a serious violation of policy and will be grounds for dismissal.

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Some specific examples of our reduction in animal testing:

- We utilize modified test methods to determine the acute toxic effects of new materials or formulas, reducing by 75% or more the number of animals used.
- We have modified the standard test method for eye irritation, the Draize eye test, to reduce the number of animals per test.
- We have modified the standard Draize skin irritation test to require fewer animals, and we rely heavily on studies in human volunteers.
- We have reduced animal usage by utilizing computer databases and other informational sources that provide historical safety data and formula compatibility.
- One of our companies, Janssen Pharmaceutica, won the European Pharmaceutical Industry Research Award for developing methods to reduce animal experimentation.
- Our laboratories have had active tissue culture programs for many years, thereby reducing the need for substantial numbers of animals.

REFINEMENT

Developing procedures that limit the potential for discomfort to animals

The companies provide facilities and programs designed to improve the welfare of animals used for laboratory research. Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care – International is required, as well as strict compliance with international regulations governing laboratory animal care and use. All facilities are staffed and supervised by conscientious, highly-trained animal technicians/technologists and veterinarians. All animals are treated humanely and cared for in accordance with the National Institutes of the Health Guide for the Care and Use of Laboratory Animals. Animal Care and Use Committees monitor the care and use of animals through protocol review procedures, training programs and site inspection activities.

Examples of our external support of refinement include contributions to the Scientists' Center for Animal Welfare and the American Association for Laboratory Animal Science Foundation.

A Johnson & Johnson Corporate Office of Animal Care and Use was formed in 1988 to facilitate the companies' commitment to the three "R" principles throughout our worldwide operations and to expedite the utilization of alternative *(in vitro)* testing whenever possible. We also have a scientific committee that meets quarterly to exchange ideas on animal care and use and develop appropriate procedures and practices for our vivarium facilities. We conduct periodic symposia to update our scientists on animal welfare regulations, humane animal care and related topics.

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January 5, 2004

Office of the Chief Counsel
Division of Corporation Finance
Securities and Exchange Commission
450 Fifth St. NW
Washington, DC 20549

Re: Johnson & Johnson Shareholder Proposal of Joan Lewis
Securities Exchange Act of 1934—Rule 14a-8

Ladies and Gentlemen:

This letter is being submitted pursuant to the rules of the Securities and Exchange Act of 1934 (the "Exchange Act") in response to a letter from Johnson & Johnson ("J&J" or the "Company") dated December 18, 2003, to omit from its proxy statement and form of proxy for its 2004 Annual Meeting of Shareholders (collectively, the "2004 Proxy Materials") a shareholder proposal and statement in support thereof (collectively, the "Proposal") I submitted on November 28, 2003.

The Company's request that the Proposal be excluded from its 2004 Proxy Materials is based on the following three (3) assertions:

1. That "[t]he substance of the Proposal has already been implemented."

2. That "[t]he Proposal contains statements that are materially false or misleading..."

3. That "[t]he Proposal, if implemented, would cause the Company to violate the law. In addition, the Company lacks the power or authority to implement the Proposal."

For the reasons outlined below, I submit that none of these assertions is correct or valid and respectfully request that the staff of the SEC's Division of Corporation Finance refrain from issuing a no enforcement action letter.

1. Substantially Implemented—Rule 14a-8(i)(10)

In a letter dated December 10, 2003 (attached hereto as Exhibit A), J&J notes that its product line includes "not only certain cosmetics and toiletry products, but also medical devices and pharmaceutical products" (p. 2). Thus, in order for the Company to assert that the substance of the Proposal has been implemented, it must be able to demonstrate each of the following:

1. Its use of "*in vitro* tests for assessing skin corrosion, skin absorption, skin irritation, phototoxicity and pyrogenicity," when and where applicable, for not only cosmetics and toiletry products, but also pharmaceuticals and medical devices, together with a general commitment to the "elimination of product testing on animals in favor of validated *in vitro* alternatives."

   - The Company's December 10 letter states that "Johnson & Johnson companies do not test cosmetics and toiletry products on animals" (p. 1) and that "[w]ith regard to the five specific conditions you reference in your proposal, we can assure you that we use only *in vitro*, or alternative, methods of testing in cosmetics and toiletry products, as applicable" (p. 1, emphasis supplied). Both of these statements are carefully qualified so as to clearly limit their scope to the testing of cosmetics and toiletry products. No similar claim is made as to the Company's implementation of Point 1 of the Proposal with respect to the testing of pharmaceuticals or medical devices.

   - The Company's December 18 letter asserts that J&J "has already committed to using non-animal tests wherever those tests have proven reliable enough to assure the safety of the Company's products, which include cosmetics, pharmaceutical products and medical devices" (pp. 2, 9). However, the Company again stops short of stating which, if any, of the non-animal tests outlined in the Proposal are currently being used in the context of safety testing of pharmaceuticals and medical devices. Similarly, on page 6 of its December 18 letter, the Company reports that it "has not used animal testing in Europe to evaluate [skin corrosion, absorption and phototoxicity] of its finished cosmetic products" (p. 6), which suggests that the same may not be true (i) outside of Europe, (ii) for the raw ingredients that comprise "finished cosmetic products," or (iii) for toiletry, pharmaceutical, or other products manufactured by J&J. The Company's extensive use of caveats and qualifiers in this area suggests that its implementation of Point 1 of the Proposal may fall well short of being "substantial" in all instances—and particularly in the area of pharmaceuticals and medical devices.

   - The Company's activities in the area of funding the development and validation of non-animal test methods are commendable; however, they are separate and distinct from the Company's use of non-animal methods for the five specific endpoints in question for the safety testing of all of its product classes, which is the focus of Point

1 in the Proposal.

- The Company's statement that "[t]esting for skin corrosion does not apply to our businesses" (pp. 3, 6) is not entirely accurate. Chemically induced skin damage exists along a spectrum ranging from irreversible tissue destruction (corrosion) to milder and reversible reactions (irritation). Thus, these terms connote a difference in degree, not kind. Although the Company is correct that an assessment of skin corrosion is not a specific regulatory requirement for the classes of products it markets, it nonetheless reports using "the EpiDerm skin equivalent method"—an internationally accepted non-animal test for skin corrosion—as part of its overall testing strategy for skin irritation. I support this action wholeheartedly, and seek only to ensure that the Company makes full use of these promising non-animal methods in the safety testing of all its product classes.

2. "Hands on" advocacy to "request that relevant regulatory agencies accept validated *in vitro* tests as replacements for animal tests."

   - Unlike the highly specific and prescriptive toxicity testing requirements that exist for pesticides and certain other types of chemicals, the pre-clinical safety testing of pharmaceuticals and medical devices tends to be a more flexible and interactive process, involving extensive dialogue and negotiations between a product manufacturer and relevant regulatory bodies. This process affords companies like J&J an excellent opportunity to "request that relevant regulatory agencies accept validated *in vitro* tests as replacements for animal tests," as the Proposal suggests. Thus, neither the Company's provision of research funding nor its involvement with contract testing facilities (i.e., Institute for *In Vitro* Sciences) or academic centers (i.e., Johns Hopkins University Center for Alternatives to Animal Testing) is a substitute for the kind of direct and active liaison with regulatory agencies in the U.S. and abroad that is needed to persuade these agencies to become more accepting of validated non-animal test methods such as those outlined in the Proposal (most of which have not been widely accepted by U.S. agencies).

3. Establishment of "a Shareholders Advisory Committee to counsel the Board on these issues and report annually to shareholders on the Company's progress."

   - The Company did not address this point in its December 18 filing, which suggests that this aspect of the Proposal has also not been substantially implemented.

2. Materially False or Misleading—Rule 14a-8(i)(3)

In its December 18 letter, the Company takes exception to some of the terminology and examples included in the Proposal, arguing that they are materially false or misleading. At the outset, it should be noted that virtually all the examples cited by the Company remove statements from the carefully constructed context of the Proposal, recombining them in such a way as to make them appear quite misleading. I will address each of the Company's examples in turn:

1. "Unnecessary" animal testing (p. 4).

   - In the context of the Proposal, "unnecessary" animal testing is carefully qualified as referring to testing on animals that could otherwise be conducted using scientifically validated non-animal methods. This narrow context is clearly established at the very outset in the proposal, with the second sentence reading: "It relates to the availability of validated *in vitro* tests for assessing dermal and pyrogenic effects as an alternative to painful and unnecessary animal testing." Thus, while it is regrettable that the 500-word limit for shareholder resolutions does not permit every term to be defined for absolute clarity, I respectfully submit that there is little room for ambiguity or misinterpretation of the term "unnecessary animal testing" in this instance, given the highly specific nature of the Proposal and my careful use of qualifiers.

   - As explained above, animal testing is rightly characterized as unnecessary where validated *in vitro* or other non-animal methods exist. Thus, the latter part of Point 1 in the Proposal—that the Company "...generally commit to elimination of product testing on animals in favor of validated *in vitro* alternatives"—merely reinforces in the form of a resolution the intent that was clearly articulated in the third sentence of the Proposal—that the Company "should commit to utilizing validated *in vitro* tests in place of live animal assays wherever possible" (emphasis supplied). The Proposal does not request that J&J abandon animal testing where validated non-animal methods do not yet exist, nor does it call on the Company to violate its obligation to assure the safety of its products or to comply with applicable statutes and regulations. In my ongoing dialogue with the Company, I have offered to amend Point 1 of the Proposal in order to eliminate any possible ambiguity or misinterpretation. The amended Proposal is attached hereto as Exhibit B. Also attached as Exhibit C is my letter to J&J further attempting to clarify the focus and accommodate the Company's concerns.

2. "The Proposal also misleadingly suggests that the Company conducts tests on animals for skin corrosion, irritation, absorption, phototoxicity and pyrogenicity..." (p. 5).

   - Based on an understanding of international pre-clinical testing requirements for the types of products manufactured by the Company, there could be little doubt that J&J

performs some manner of testing for the five specific endpoints addressed in the Proposal. Indeed, the Company's December 18 letter to the SEC clearly acknowledges that J&J conducts testing for skin irritation, absorption, phototoxicity and pyrogenicity. And despite the Company's insistence that "[t]esting for skin corrosion does not apply to our business" (pp. 3, 6), it does acknowledge using the EpiDerm™ and EpiSkin™ skin corrosion assays as part of its overall testing strategy for skin irritation. The Company's desire to argue semantics on this point does not minimize the strict accuracy of the Proposal, let alone render it false or misleading.

- I am also perplexed by the Company's extraction of six statements from the Proposal as evidence in support of its assertion as cited above. The excerpts chosen are all statements of fact, the majority of which describe specific toxicity endpoints and/or validated non-animal test methods. As explained above, there could be little doubt that J&J performs some manner of testing for the five specific endpoints addressed in the Proposal; however, the Proposal does not allege or imply that the Company necessarily performs animal-based testing for all of these endpoints.

3. "[I]t is misleading to shareholders to suggest that there are alternative tests available that the Company is not already using" (p. 6).

   - The Company's December 18 letter states: "Pyrogenicity testing is also accomplished using an *in vitro* alternative—the limulus amebocyte lysate test" (p. 3). This test uses the blood of horseshoe crabs (who may or may not be killed over the course of their use as blood "donors") to test for fever-causing agents. While this test can be seen as a positive "refinement" relative to the still-common rabbit fever test, the Company fails to acknowledge the further ethical and scientific advances that could be made by switching to a test using blood from human volunteers, as advocated in the Proposal. On the basis of J&J's position on this matter, there are indeed "alternative tests available that the Company is not already using."

4. "The Proposal also contains various false or misleading claims about the current state of foreign laws relating to animal testing."

   - All statements in the Proposal concerning international acceptance of specific non-animal test methods are thoroughly accurate and supportable; however, the manner in which various statements are cited on page 6 of J&J's December 18 letter is highly suspect. Not only does J&J remove these five statements from the narrow and specific context in which they appeared in the Proposal, the Company then proceeds to interpret their meaning quite out of context, presenting its glaring misinterpretation to the SEC as "evidence" in support of its "false or misleading" claim.

For example, it is clear in the Proposal that the statement, "Canada, the European Union, and most countries in the Organization for Economic Cooperation and Development (OECD) accept the *in vitro* tests as total replacements for animal tests," is limited to "skin equivalent methods such as EpiDerm™ and EpiSkin™" for skin corrosivity testing. The Company, however, takes this statement completely out of context, misrepresenting it to the SEC as a claim on my part that Europe and Canada have totally eliminated all animal testing. The same is true of the other statements excerpted by the Company—each refers to a single, specific toxicity endpoint, not the entire universe of toxicity testing.

5. "The Proposal misleads shareholders by suggesting that the relevant regulatory agencies do not already accept certain validated *in vitro* tests as replacements for animal tests" (p. 7).

   - International acceptance of validated non-animal methods is uneven at best for any non-animal test method, and it would be misleading to suggest otherwise. For example, international agreement has been reached through the 30-member country OECD that the use of animals in the assessment of skin corrosion can be fully replaced by a weight-of-evidence determination using non-animal methods (now codified in OECD Test Guideline 431). The OECD's policy on Mutual Acceptance of Data, in turn, provides that "data generated in a Member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other Member countries for assessment purposes and other uses relating to the protection of human health and the environment." Thus, all member countries of the OECD—including the U.S.—should accept these non-animal tests for skin corrosion as total replacements for their animal-based counterparts. The U.S., however, has opted to accept these tests only as "positive screens" (i.e., negative results *in vitro* would require confirmation in an animal test) rather than total replacements, in contrast to the international consensus.

     Similar scenarios could be presented for each of the other validated non-animal tests outlined in the Proposal.

6. "[T]he Proposal misleads shareholders by suggesting that the Company is not already taking steps to encourage regulators to validate additional alternative testing methods" (p. 8).

   - The Proposal does not address the process of validating additional or new non-animal methods, but regulatory agencies' acceptance of non-animal methods that have already undergone successful validation.

7. "The Proposal also incorrectly suggests that animal testing is always 'painful' to the animals" (p. 8).

    - Detailed statistics regarding the use and suffering of animals in U.S. laboratories are incomplete with regard to the species most commonly used in toxicity testing. However, statistics published by the Canadian Council on Animal Care clearly indicate that most animal testing is painful. (Statistics available upon request.) For example, of the nearly 260,000 animals used in regulatory toxicity tests in Canada in the year 2000:

        - 22% were subjected to tests that caused "severe pain near, at, or above the pain tolerance threshold of anaesthetized conscious animals."

        - 36% were subjected to tests that caused "moderate to severe distress or discomfort."

        - 20% were subjected to tests that caused "minor stress or pain of short duration."

    - The Company's reference to its policy that "[n]o laboratory animal shall be subjected to unnecessary pain and/or distress" (p. 8) further undermines its contention on this point. Regardless of one's personal belief regarding the "necessity" of such pain and distress, the fact remains that these conditions are inextricably linked to animal-based toxicity studies.

8. "[T]he Proposal misleadingly claims that non-animal test methods are necessarily 'reliable'" (p. 8).

    - Throughout the Proposal, I have made liberal use the term "validated" in relation to the non-animal test methods I am advocating. As validation is a rigorous scientific process to evaluate a test's reliability (ability to generate reproducible results within and between labs over time) and relevance (ability to correctly measure the biological effect of interest in the species of interest), a test method that is scientifically valid is also, by definition, reliable.

9. "[T]he Proposal falsely claims that non-animal tests are 'often faster and more economical'" (p. 9).

    - There is nothing false or misleading about this statement in the Proposal. The *Handbook of Toxicology* (2nd Ed., CRC Press, 2002), documents that almost without exception, *in vitro* methods are less costly than their animal-based equivalent.

(*Handbook* available upon request.)

10. "[I]t is not in the best interest of the Company to use *in vitro* methods where those methods may not serve to adequately ensure the safety of the Company's products and customers or may constitute a violation of the Company's legal obligations" (p. 9).

    - The Proposal states: "It is in the Company's best interest that it commit to utilizing validated *in vitro* methods of testing as a humane alternative to unnecessary animal tests" (emphasis supplied). As previously discussed, an "unnecessary" animal test would be one that could otherwise be conducted using a scientifically validated non-animal method. Thus, this statement does not call on the Company to categorically eliminate all animal testing, which could constitute a violation of its legal obligations. Moreover, given that few animal-based toxicity tests have ever undergone formal scientific validation—or a level of objective review that even remotely approximates the validation process for *in vitro* methods—I am perplexed by the Company's resistance to the logic that a rigorously validated test produces results that are more relevant, reliable, and therefore consumer-protective, than those of a non-validated test.

3. Violation of the Law—Rule 14a-8(i)(2) and Lack of Authority or Power—Rule 14a-8(i)(6)

As discussed in detail above, the Company's assertion that the Proposal would cause it to violate the law (p. 10) is alarmist to say the least, and based on a highly distorted interpretation of selected elements from the Proposal. I am well aware of U.S., European, and other international regulations and policies with respect to the submission of some animal-derived pre-clinical safety data before human clinical trials are authorized to proceed. However, the Proposal focuses on five specific and narrow health effects, and does not in any way address the innumerable toxicity endpoints that would be evaluated in animals (including some non-human primates and dogs) over the course of a standard pre-clinical safety assessment. Repeated dosing studies of one-, three-, six-, and 12-month periods, targeted pharmacokinetic studies, assessments of developmental and reproductive toxicity, cancer, and other serious health effects would still be carried out on many thousands of living animals. It is all of these studies—not the five narrow endpoints targeted in the Proposal—that clearly fall within the scope of 21 CFR 312.23(a)(8)(i).

Moreover, the non-animal test methods described in the Proposal are not the first such methods to be brought forward to companies and regulatory agencies as alternatives. For example, the *in vitro* "Ames test" has been accepted by regulators in the U.S. and internationally for more than 20 years as the "gold standard" for testing chemicals for mutagenicity. Since companies in the U.S. and around the world can and do base assessments of genetic toxicity on Ames test and other *in vitro* results without allegations of having violated their statutory/regulatory obligations, it follows that even where requirements exist that some animal-based data be provided prior to

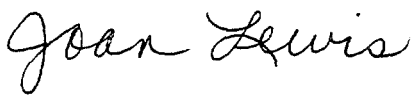
human clinical trials, this does not in any way mean that all pre-clinical data must be animal-derived.

* * * * *

I regret that J&J has chosen not to accept my narrowly-focused and carefully-worded Proposal in good faith. However, for the foregoing reasons, I respectfully request that the SEC advise the Company that it will take enforcement action if J&J fails to include the Proposal in its 2004 Proxy Materials. Should the SEC not agree with the conclusions expressed herein, I would appreciate the opportunity to confer with a member of your staff before issuance of the SEC's response.

Please feel free to contact me should you have any questions or require further information.

Sincerely,



Joan Lewis, Esq.

Encls.

cc: T. Spellman III, Johnson & Johnson (by fax)
E. Kennedy, Calvert (by fax)
T. Seidle, Scientific Consultant (by fax)

JOHNSON & JOHNSON
OFFICE OF THE CORPORATE SECRETARY
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NEW JERSEY 08933

December 10, 2003

Joan Lewis, Esq.
3473 Mandeville Canyon Road
Los Angeles, CA 20003

Dear Ms. Lewis:

I am pleased that we recently had such a productive conversation regarding the important issue of animal testing for Johnson & Johnson products. As promised, this letter will clarify a few remaining points and, I hope, provide you with the assurance you need to be confident of the Company's leadership position in this area.

As my colleague from the Corporate Office of Science & Technology explained, Johnson & Johnson companies do not test cosmetics and toiletry products in animals. Should safety data be mandated for a new, non-validated, active ingredient, then *in vitro* alternative tests, such as those methods set forth in your proposal, will be used whenever possible. We invest heavily in the development of alternative methods and in support of organizations advocating the development, validation and acceptance of these methods. In fact, last year Johnson & Johnson spent over $250,000 seeking and validating alternatives to animal testing.

With regard to the five specific conditions you reference in your proposal, we can assure you that we use only *in vitro*, or alternative, methods of testing in cosmetics or toiletry products, as applicable. Testing for skin corrosion does not apply to our businesses, as it would not be our practice to develop a product that would cause this condition. Skin corrosion could arise in connection with products like detergents and household cleaners – products that Johnson & Johnson does not market or sell. Skin absorption and irritation testing is conducted using a variety of commercially available, validated, *in vitro* alternatives such as the Epi-Derm skin equivalent method that you have advocated, as well as the Franz-cell system and the trans-epithelial permeability assay. Phototoxicity testing is performed using the *in vitro* alternative neutral red uptake, when necessary. Pyrogenicity testing is also done using an *in vitro* alternative: the limulus amebocyte lysate test. Accordingly, the alternatives that you reference in your proposal are only a few among many that we have adopted and advocated in support of our commitment to

EX. A

the three "R" principles – replacement, reduction and refinement, as they apply to animal testing.

Beyond our corporate commitment, we are active participants in the dialogue regarding the adoption of the three "R" principles by the wider scientific community, specifically through relationships with organizations such as the Center for Alternative Testing and the Institute for In Vitro Sciences. Through our contributions to these organizations (both in financial terms and in terms of active service on their respective industrial boards), we are taking diligent steps to find alternatives to animal testing. As you request in your resolution, Johnson & Johnson is already playing a very active role in presenting information to regulatory and legislative bodies that make decisions about required testing. We expect that active participation will continue with the support and encouragement of shareholders such as you.

However, our most significant commitment is to the assurance of safety of our products, which include not only certain cosmetics and toiletry products, but also medical devices and pharmaceutical products. For pharmaceutical products, for example, we are obligated to test new ingredients or new formulations for safety in animals prior to final validation in human tests. This obligation is codified in laws and regulations in the United States and elsewhere in the world. In the United States, Section 21 of the Code of Federal Regulations ("CFR") sets forth certain preclinical requirements for establishing the safety and efficacy of pharmaceutical products, including certain tests in animals.[1] In Europe, before a new compound can be administered for the first time in a human, applicable regulations require that there is no adverse effect in certain animals.[2] Of course, Johnson & Johnson is obligated to comply with the laws and regulations that govern our businesses.

We have recently enhanced the reporting of social responsibility programs on our website, www.jnj.com, and are committed to augmenting that information going forward. To that end, we can commit to you that, in light of your proposal, we will revisit the extent of information offered on our website regarding animal testing and, if it falls short with respect to disclosure of our practices and beliefs, which, again, we believe represent a leadership position in this important area, we will revise it. We are hopeful that the information set forth on our website may serve as an example for others in bringing about positive change in this area.

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[1] 21 CFR Section 312.23(a)(8)(i) provides, for example, that an Investigational New Drug Application ("IND") (which must be submitted to the U.S. Food and Drug Administration before conducting a clinical trial for a new drug in humans) must include "a section describing the pharmacological effects and mechanism(s) of action of the drug in animals, and information on the absorption, distribution, metabolism, and excretion of the drug, if known."

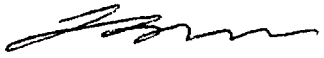
[2] The European Federation of Pharmaceutical Industries and Associations Policy Statement on the Use of Animals in Research and Development states that, "all countries which regulate the approval of new medicines demand evidence from animal studies before they will allow the medicines or vaccines to be tested and used in patients."

We hope you will agree that the commitments set out in this letter to continue to demonstrate leadership in this area, together with a fuller understanding of our posture regarding animal testing renders unnecessary a shareholder resolution. We also hope that you understand that for the reasons cited above, particularly with respect to the implication that Johnson & Johnson could be in violation of law, we cannot unequivocally commit to the elimination of animal testing as your proposal requests.

We do remain committed to the pursuit of alternatives, but until they are identified, validated and acceptable to worldwide regulatory agencies, we must occasionally and in limited scope continue to test in animals where required by law. We have elected to join with the body of industry as a single voice educating relevant agencies on this issue, and believe it is the most appropriate posture for our Company. I hope these efforts satisfy your concerns about our position regarding animal testing sufficiently so that you do not feel compelled to seek shareholder support for a resolution. Because your resolution seeks unequivocal support for commitments going forward that we are not in a position to make, we would be forced to oppose it. Not only would that not be in the best interest of our consumers and employees, it would misrepresent our longstanding and genuine commitment to humane concern for animals in testing.

I will be contacting you over the next couple of days with the hope that this issue has been resolved to your satisfaction and that you recognize our commitment to this important issue in the future. Please do not hesitate to contact me in the meantime at (732) 524-3570.

Very truly yours,



Thomas J. Spellman III
Assistant Corporate Secretary

SHAREHOLDERS' RESOLUTION

This Proposal is submitted by Joan Lewis, owner of 200 shares of stock.

The Resolution requests that Johnson & Johnson ("J&J") extend its commitment to use scientifically valid non-animal methods in the testing of cosmetics and toiletry products to the safety testing of pharmaceuticals. It does not request that J&J eliminate all animal testing, but focuses specifically on testing for dermal and pyrogenic effects, for which non-animal tests are currently accepted in other countries.

RESOLVED, the shareholders of J&J request that the Board:

1. Commit to use only non-animal methods in the pre-clinical safety testing of pharmaceutical, cosmetic and toiletry products for the following endpoints, when and where applicable: skin corrosion, skin irritation, skin absorption, phototoxicity and pyrogenicity.
2. Request that regulatory agencies requiring safety testing for the aforementioned endpoints confirm in writing their acceptance of (i) human skin equivalent tests, as described in OECD Test Guideline 431, as total replacements for animal-based testing for skin corrosion; (ii) human skin-patch tests as total replacements for animal-based skin irritation testing; (iii) studies using isolated human skin as total replacements for animal-based measures of skin absorption, per OECD Guideline 428; (iv) the 3T3 NRU Phototoxocity Test, described in OECD Guideline 432, as a total replacement for phototoxicity testing on animals; and (v) a non-animal pyrogenicity test using donated human blood as a total replacement for its animal-based counterpart.
3. Establish an independent animal testing review panel (e.g., Shell.com/testing) and provide shareholders with a detailed annual report regarding J&J's progress on implementing the foregoing resolutions.

Supporting Statement: This Resolution does not call on J&J to violate its obligation to assure the safety of its products or to comply with applicable statutes and regulations. A variety of non-animal methods have been accepted internationally as scientifically valid alternatives to animal

testing for skin corrosion (irreversible tissue damage), skin irritation (milder and reversible damage), skin absorption (the rate of chemical penetration), phototoxicity (an inflammatory reaction caused by the interaction of a chemical with sunlight), and pyrogencity (a fever-like reaction that can occur when certain intravenous drugs interact with the immune system). This Resolution does not imply that J&J currently conducts animal testing for some or all of these endpoints—only that the non-animal tests identified above should be used in lieu of animal testing when and where applicable.

The 3T3 NRU test for phototoxicity, human skin equivalent tests for corrosivity, and the human blood pyrogen test have undergone formal scientific validation by the European Centre for the Validation of Alternative Methods (http://ecvam.jrc.it/).

Several non-animal methods have also been adopted as Test Guidelines by the OECD (Organization for Economic Cooperation and Development), an alliance of 30 member countries including the US, EU, Japan, Canada and Australia. Regulatory agencies in OECD member countries are not at liberty to reject data from non-animal tests for skin corrosion, skin absorption and phototoxicity where such data have been generated in accordance with an OECD Test Guideline.

JOAN LEWIS, ESQ.
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December 22nd, 2003

BY FAX

Mr. Michael H. Ullmann
Secretary, Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Re: Shareholder Resolution by Joan Lewis

Dear Mr. Ullmann,

It was good to talk to you again. This will summarize our December 18th, 2003 conversation.

I do not believe my proposal requests Johnson & Johnson violate any law, and I am willing to amend its language to remove any ambiguity in that regard. It has also not been substantially implemented. It is not broad in its scope and does not request unequivocal elimination of animal testing. It very specifically focuses on pre-clinical dermal and pyrogenic testing of products, including pharmaceuticals. I am prepared to present my proposal, which as you know has the support of Calvert which intends to vote their proxies in its favor. However, my interest is not in publicity, nor in any public battle. My motivation as a shareholder, is that you commit to meaningful, concrete steps regarding animal testing such as those we discussed. They are consistent with and merely extend steps already taken by Johnson & Johnson and which I am respectful of. I believe it is your preference and mine that this be accomplished through friendly non-public dialogue, if possible.

First, my proposal has been mischaracterized as requesting "Johnson & Johnson to unequivocally commit to the elimination of animal testing" and requesting you violate the law. In fact, my proposal focuses specifically on five (5) specific and narrow health effects and does not address in any way the innumerable toxicity endpoints that would be tested in animals (often including non-human primates and/or dogs) over the course of a standard pre-clinical safety assessment. Repeated dosing studies for one (1), three (3), six (6) and twelve (12) months periods, targeted pharmacokinetic studies, assessments of

developmental and reproductive toxicity, cancer, and other serious health effects would still be carried out on many thousands of animals. It is these pharmacological studies—not the five narrow endpoints targeted by my proposal –that clearly fall within the scope of 21 CFR Section 312.23(a)(8)(i). Moreover, the non-animal methods described in my resolution are not the first such methods to be brought forward to companies and regulatory agencies as alternatives. For example, the *in vitro* "Ames test" has been accepted by regulators in the United States and internationally for more than twenty (20) years as the gold standard for testing chemicals for mutagenicity and genetic toxicity. Since companies in the United States and around the world can and do base assessments of genetic toxicity on *in vitro* results without allegations of having violated the law, it follows that even where requirements exist that *some* animal data be provided prior to human clinical trials, this does not in any way imply that *all* pre-clinical data must be animal-derived.

I ask that you consider this narrowly-focused request in good faith: where you use an animal-based test for any of the five (5) specified health effects for which any of the five (5) *in vitro* tests is available as an alternative, seek regulatory agency approval to use, and in fact use, the non-animal method to replace it. This is the logical extension to pharmaceuticals of your commendable position on *in vitro* testing of cosmetics and toiletry products.

Second, since you do no animal tests in your cosmetics or toiletry products, we discussed your applying for, and where appropriate, using the Corporate Standard of Compassion—the leaping bunny logo. You can apply for and receive certification on-line @leapingbunny.org. This would be a public commitment that you are doing what you claim. You would be joining over 500 corporations who've already made this public statement. Viewing this step as a shareholder, this could be positive both for the Company and the community at large. It would be a good marketing tool and enhance the Company's image. It might expand markets by reaching consumers not familiar with but supportive of your cruelty-free policy. It would distinguish your products from similar ones marketed by competitors. It is trend setting and an extension of your forward- thinking corporate image and would encourage consumers and competitors to follow your example. In our conversation you indicated Company reluctance to put another groups logo on your packaging. The logo represents independent validation and may therefore be more meaningful than self-designation. However, if you are uncomfortable at this time including the logo on packaging you might indicate in your web site that the Company applied for and met the Corporate Standard of Compassion.

Third, we discussed inclusion in your web site of specific *in vitro* tests you have found useful and are currently employing in cosmetics, toiletry and pharmaceutical products. You indicate that your subsidiaries use more than 160 different alternative tests in research. What are the names of these tests, the health effects they test for and their uses? What animal-based tests do they replace? In particular, inclusion of tests unique to Johnson & Johnson would move away from a proprietary approach and encourage others to use cruelty-free alternatives.

Fourth, we discussed Johnson & Johnson pro-actively seeking regulatory agency acceptance of *in vitro* tests such as those described in my proposal, to the extent that Johnson & Johnson is conducting animal tests for any of the specific endpoints for which those *in vitro* tests are available as alternatives. Other companies such as Procter &

Gamble, Avon, Bayer and Gillette have pursued and obtained agency acceptance on a case by case basis of certain alternative tests or testing strategies.

Fifth, commit to me that you will investigate (through executive and if necessary Board response) within a reasonable period of time, the creation of an animal testing review panel to establish independent scrutiny of Johnson & Johnson's animal testing activities. A corporate model for this oversight panel is in the Shell Oil web site (Shell.com). This would effectively communicate both internally and externally the status each year of animal testing within the Company and might generate innovation and progress. It would also inevitably build trust and credibility with consumers and shareholders.

These steps are consistent with and are extensions of your policies with regard to animal testing. I will consider it unnecessary to pursue my proposal and will withdraw it if you are willing to commit in some meaningful way to the above.

Sincerely,

Joan Lewis

Joan Lewis

cc Thomas J. Spellman III, Esq.
Ellen Kennedy, Calvert
Troy Seidle, Scientific Consultant

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.

January 30, 2004

Response of the Office of Chief Counsel
Division of Corporation Finance

Re: Johnson & Johnson
Incoming letter dated December 18, 2003

The proposal requests that the Board commit to use *in vitro* tests for assessing skin corrosion, skin absorption, skin irritation, phototoxicity and pyrogenicity, and generally commit to elimination of product testing on animals in favor of validated *in vitro* alternatives. The proposal further requests that the Board request that relevant regulatory agencies accept validated in vitro tests as replacements for animal tests and that the Board form a Shareholders Advisory Committee to counsel the Board on these issues and report annually to shareholders on the Company's progress.

We are unable to concur in your view that Johnson & Johnson may exclude the proposal under rules 14a-8(i)(2) and 14a-8(i)(6). Accordingly, we do not believe that Johnson & Johnson may omit the proposal from its proxy materials in reliance on rules 14a-8(i)(2) and 14a-8(i)(6).

We are unable to concur in your view that Johnson & Johnson may exclude the entire proposal under rule 14a-8(i)(3). There appears to be some basis for your view, however, that portions of the supporting statement may be materially false or misleading under rule 14a-9. In our view, the proponent must:

- delete the sentence that begins "Canada, the European Union . . ." and ends ". . . total replacements for animal tests"; and

- provide factual support in the form of a citation to a specific source for the statement that non-animal test methods are "often faster and more economical."

Accordingly, unless the proponent provides Johnson & Johnson with a proposal and supporting statement revised in this manner, within seven calendar days after receiving this letter, we will not recommend enforcement action to the Commission if Johnson & Johnson omits only these portions of the proposal and supporting statement from its proxy materials in reliance on rule 14a-8(i)(3).

We are unable to concur in your view that Johnson & Johnson may exclude the proposal under rule 14a-8(i)(10). Accordingly, we do not believe that Johnson & Johnson may omit the proposal from its proxy materials in reliance on rule 14a-8(i)(10).

Sincerely,

Anne Nguyen
Attorney-Advisor