Date: December 10, 2010

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

SUBMITTED ELECTRONICALLY

Subject: Comments on: "Proposed, Revised Green Guides, 16 CFR Part 260, Project No. P954501"

Dear Madam or Sir:

Please consider the enclosed recommendations when incorporating public comments into the proposed, revised Green Guides (16 CFR Part 260, Project No. P954501).

Our comments are focused on Section 206.2 and statements on "competent and reliable scientific evidence." We have provided a strikethrough version of our changes, along with the rationale for the proposed changes in Appendix 1.

We appreciate the opportunity to comment on this proposed regulation. Thank you for your consideration.

Sincerely,

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Page 195, § 260.2 states:
"In the context of environmental marketing claims, a reasonable basis often requires competent and reliable scientific evidence. Such evidence consists of tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results."[1]

Proposed change:
"In the context of environmental marketing claims, a reasonable basis often requires competent and reliable scientific evidence. Such evidence consists of tests, analyses, research, or studies that have been conducted **in accordance with Good Laboratory Practice standards and a validated testing guideline, if available** ~~and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results~~."

Rationale:
Good Laboratory Practice standards
Studies performed under Good Laboratory Practices (GLP) require among other things that all of the raw data[2] "...necessary for the reconstruction and evaluation of the report of [the] study" are retained.[3]

Regulatory and intergovernmental organizations have issued guidance or policies on the central importance of having all of the raw data for a study. For example, the European Chemicals Agency (ECHA) consider "[t]he availability of the raw data from [a] study" as one of several key points when evaluating data reliability.[4] Similarly, the U.S. Environmental Protection Agency's (EPA)'s policy is to reject a study if the researchers failed to record and archive raw data or if the available data are inadequate for reconstructing the study.[5] Finally, the Organisation for

[1] FTC (2010), *Proposed Revisions to the Green Guides*, 229 pp., at p. 195.

[2] See, *e.g.*, 40 CFR Part 792, *Good Laboratory Practice Standards*, at §792.3 Definitions ("*[r]aw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study...").

[3] *Id.*

[4] ECHA (2008), *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.4: Evaluation of available information*, GUIDANCE FOR THE IMPLEMENTATION OF REACH, 23 pp., at p. 10, European Chemicals Agency, Helsinki, Finland, available at http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r4_en.pdf?vers=20_08_08 (accessed on December 9, 2010).

[5] EPA (1995), Memorandum dated April 8, 1995; Subject: Guidelines for study rejection based on GLP considerations; From: Dan Barolo, Director, Office of Pesticide Programs; To: All Division Directors, Office of Pesticide Programs, 4 pp., at p. 2, U.S. Environmental Protection Agency, Washington, DC.

Economic Co-operation and Development considers "[n]ot preserving primary data" or "[w]ithholding data from the scientific community" as data-related scientific misconduct.[6]

Validated Testing Guidelines
Performing studies according to validated testing guidelines[7,8] ensure that endpoints are evaluated, which have been proven to confirm a specific effect or to be present along a continuum of changes that leads to the specific effect. Therefore, validated testing guidelines should be followed whenever they are available for a particular type of evaluation.

Competent and Reliable Scientific Evidence
Studies performed according to GLP and validated testing guidelines are internationally recognized as the highest quality and most reliable data available. For example, the U.S. EPA states the following in their information quality guidelines: "[o]ur test guidelines and Good Laboratory Practices (GLPs) [footnote omitted] describe sound scientific practices for conducting studies needed to assess human and environmental hazards and exposures. Such studies are not required to be peer-reviewed."[9] Similarly, the ECHA adopted a tiered system for ranking studies based on data quality and reliability. Tier 1 studies are those performed according to GLP and validated testing guidelines, and are considered "reliable without restriction."[10]

At a minimum, GLP should be required by the "Green Guides" to meet the threshold determination of competent and reliable scientific evidence. If GLP is not required, laboratories that do not follow these standards may not adequately document or retain underlying data used to support specific claims. For example, if a marketer wishes to make a non-toxic[11] claim, all of the

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[6] OECD (2007), *Unofficial Report on Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*, Organisation for Economic Co-operation and Development Global Science Forum, 13 pp., at p. 3., Organisation for Economic Co-operation and Development, Paris Cedex, France.

[7] See, *e.g.*, EPA (2010), *Harmonized Test Guidelines*, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Washington, DC, available at http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm (accessed December 9, 2010).

[8] See, *e.g.*, OECD (2010), *OECD Guidelines for the Testing of Chemicals*, Organisation for Economic Co-operation and Development, Paris Cedex, France, available at http://www.oecd.org/document/40/0,3343,en_2649_34377_37051368_1_1_1_1,00.html (accessed December 9, 2010).

[9] EPA (2002), *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02-008, 61 pp., at p. 50, Office of Environmental Information, U.S. Environmental Protection Agency, Washington, DC.

[10] ECHA (2008), *supra* note 4, at p. 9 ("*studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.*").

raw data used in support of that claim should be available, upon request. Another possible scenario could be that an outside group challenges the "non-toxic" claim for a product, based on a summarized study that was published in the peer-reviewed literature. Since publication in the peer-reviewed literature does not ensure quality[12] or the retention or production of the underlying raw data for the study, the results and conclusions may be immune from critical review, especially if the study authors are not willing to provide the raw data.[13,14,15,16]

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[11] FTC (2010), *supra* note 1, at p. 210.

[12] Jennings CG (2006), *Quality and Value: The True Purpose of Peer Review*, NATURE, DOI:10.1038/nature05032 (publication in the peer-reviewed literature "...provides only a minimal assurance of quality..."), available at http://www.nature.com/nature/peerreview/debate/nature05032.html (accessed December 9, 2010).

[13] See, *e.g.*, EPA (2008a), *Toxicological Review of Decabromodiphenyl Ether (BDE-209) (CAS No. 1163-19-5)*, EPA/635/R-07/008F, at p. 32 (footnote 1: "[a]ttempts to obtain numerical values and other information on the data from the authors were not successful"), U.S. Environmental Protection Agency, Washington, DC, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190307#Download (accessed December 9, 2010).

[14] See, *e.g.*, EPA (2008b), *Toxicological Review of 2,2',4,4',5,5'-Hexabromodiphenyl Ether (BDE-153) (CAS No. 68631-49-2)*, EPA/635/R-07/007F, at p. 22 (footnote 1: "[a]ttempts to obtain numerical values and other information on the data from the neurobehavioral studies were not successful"), U.S. Environmental Protection Agency, Washington, DC, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190308#Download (accessed December 9, 2010).

[15] See, *e.g.*, EPA (2008c), *Toxicological Review of 2,2',4,4',5-Pentabromodiphenyl Ether (BDE-99) (CAS No. 60348-60-9)*, EPA/635/R-07/006F, at pp. 30-31 (footnote 1: "[a]ttempts to obtain numerical values and other information on the data from the neurobehavioral studies were not successful"), U.S. Environmental Protection Agency, Washington, DC, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190309#Download (accessed December 9, 2010).

[16] See, *e.g.*, EPA (2008d), *Toxicological Review of 2,2',4,4'-Tetrabromodiphenyl Ether (BDE-47) (CAS No. 5436-43-1)*, EPA/635/R-07/005F, at p. 29 (footnote 1: "[a]ttempts to obtain numerical values and other information on the data were not successful"), U.S. Environmental Protection Agency, Washington, DC, available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190310#Download (accessed December 9, 2010).