Center for Food Safety ❧ Consumers' Choice Council
Consumer Policy Institute/Consumers' Union
Edmonds Institute ❧ Friends of the Earth ❧ Greenpeace USA
Institute for Agriculture & Trade Policy ❧ Organic Consumers Association
Organic Independents ❧ Organic Trade Association
Pesticide Action Network North America ❧ Sierra Club
U.S. Public Interest Research Group

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21 August 2001

Dr. Bernard Schwetz, DVM, Ph.D.
Acting Principal Deputy Commissioner
U.S. Food and Drug Administration
Room14-71, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: food labeling complaint

Dear Dr. Schwetz:

The undersigned organizations are writing in response to a letter sent to you, dated August 14th, 2001, regarding labels on food not derived from or containing genetically modified organisms (GMOs).[1] The letter requests that the Food and Drug Administration (FDA) take enforcement action against companies that are using labels to inform consumers that their products do not use GMOs. We believe taking enforcement action against such products at this time would be premature, a violation of law, contrary to consumer interest and an inappropriate use of the agency's limited resources.

The August 14th letter asks the FDA to take action for violations of the FDA's draft Guidance to Industry on "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" ("Guidance"). In January of this year, the FDA published these draft guidelines for public comment. 66 Fed. Reg. 4839 (January 18, 2001). The comment period sought information from the public on how this draft guidance dealt with issues such as whether labels that use terminology such as "GMO-free" were misleading. Id. at 4840. As of August 8, 2001, the FDA has received 92,131 comments (although the count is not complete) concerning this Federal Register notice. To date, the FDA has failed to respond to those public comments and has not finalized its Guidance. Taking enforcement action against any company for its "GMO-free"[2] labeling claims prior to the agency concluding its review and substantive response to the public comments would be arbitrary and capricious. As a result, we believe it would be premature and contrary to law to conclude that "GMO-free" (and other similar labels such as "Non-GMO") are misleading.

Moreover, enforcement action against "GMO-free" labeling claims may violate constitutional rights. As the FDA is aware, companies already have a commercial free speech right (as long as it is a truthful claim) to label their foods "GMO-free." Under existing law, corporations have a free speech right to inform their customers that their products and ingredients meet exacting standards. This protection is derived from the U.S. Constitution's First Amendment, which provides in pertinent part that "Congress

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shall make no law . . . abridging the freedom of speech." U.S. Const. Amend. I. In 1976, the Supreme Court decided that certain speech involving commercial transactions merited protection under the First Amendment.[3] In protecting commercial free speech the Supreme Court has stated:

> The particular consumers interest in the free flow of consumer information . . . may be as keen, if not keener by far, than his interest in the days most urgent political debate . . . . The free flow of commercial information is indispensable . . . to proper allocation of resources in a free enterprise system . . . [and] to the formation of intelligent options as to how that system ought to be regulated or altered.[4]

Recent Supreme Court decisions have further bolstered the commercial speech doctrine and, as result, extended constitutional protection to "GMO-free" label users.[5] The undersigned believe proper exercise of this right provides the public with critical material information about the content of their food supply.

The August 14th letter also fails to support its claim that "GMO free" labels are misleading under the Federal Food Drug and Cosmetic Act. The letter lacks, inter alia, evidence of the following information:

(1) any consumer complaints that the labels are misleading;

(2) any evidence of price premiums charged for GMO-free labeled products;

(3) any evidence of products being returned or refunds being offered because of deceptive labels;

(4) any consumer focus group results showing that such labels are misleading;

(5) any complaints from competing businesses about such labels; or

(6) any enforcement actions by consumer protection agencies at any level.

Additionally, the August 14th letter's suggestion that the term "genetically modified' is misleading and not recognized as having a plain meaning that is identifiable to the public is facially incorrect. Such an assertion is refuted by numerous recent actions by regulatory bodies around the world. For instance, on July 25, 2001, the European Commission released its new proposal concerning the labeling of genetically engineered foods entitled "Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed."[6] Moreover, a search of the worldwide web reveals the terms "GMO" and "genetically modified organism" have clearly been adopted by the public, industry and governments to mean food, food ingredients or crops derived from genetic engineering. Even the FDA has acknowledged that the terms "genetic modification" and "GMO" have come to be associated with this "popular usage."[7]

Furthermore, the undersigned believe that voluntary truthful labels that differentiate food products because of an absence of the use of genetically modified ingredients are appropriate and not inherently misleading. There are significant and material differences in genetically modified foods compared to their conventionally bred counterparts. As the agency is aware, even FDA scientists have determined that "[t]here is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering"[8] More recently, these differences have been recognized in the controversy over genetically modified StarLink™ corn. Recently, the EPA's expert science panel reiterated its

finding that a novel protein in the corn created by the genetic engineering process has a medium likelihood of being a human food allergen.[9] The scientific conclusions made by the FDA's own scientists and the EPA's recent panel exemplify that genetic modification results in fundamental differences in the material nature of food. Coupled with the widespread publicity surrounding the StarLink™ incident, the public is increasingly aware of these facts. Labels providing truthful product differentiation are scientifically supportable and assist in consumers making informed choices. The FDA should be supportive of such actions.

Lastly, the FDA has a number of pending issues before it concerning genetically modified food to which it is legally obligated to respond. These issues should take precedence over the actions requested by the August 14th letter. First, the FDA is reminded that StarLink™ corn has not been approved for human consumption. Therefore, the agency should be continuing to test food products for the presence of this potential allergen and initiating food recalls for all products testing positive for its presence. Second, the agency should respond to the public comments it has received concerning regulatory proposals on genetically modified food. This includes responding to the legal petition filed by over 50 organizations requesting the adoption of a mandatory pre-market safety testing and labeling regulatory regime.[10] This citizen petition has received 434,979 comments in support of the actions requested. In addition, the agency has received approximately 176,000 comments concerning its proposals on its voluntary labeling guidelines and pre-market notification.[11] Thus, the agency has pending regulatory decisions on genetically modified food with over 600,000 public comments to consider and provide substantive responses. The agency should focus it resources on responding to these comments and making its final regulatory determinations. If the FDA is truly concerned about misleading the public about genetically modified foods, the agency will move quickly to adopt the regulatory approach overwhelmingly favored by those 600,000+ public comments - mandatory pre-market safety testing, mandatory environmental review and mandatory labeling.

Sincerely,

Joseph Mendelson III, Center for Food Safety
Cameron Griffith, Consumers' Choice Council
Jean Halloran, Consumer Policy Institute/Consumers' Union
Beth Burrows, Edmonds Institute
Brent Blackwelder, Friends of the Earth
Charles Margulis, Greenpeace USA
Kristin Dawkins, Institute for Agriculture & Trade Policy
Ronnie Cummins, Organic Consumers Association
James Riddle, Organic Independents
Katherine DiMatteo, Organic Trade Association
Ellen Hickey, Pesticide Action Network North America
Laurel Hopwood, Sierra Club
Richard Caplan, U.S. Public Interest Research Group

CC: Via Fax (301) 443-1863
Docket 00D-1598, Dockets Management Branch, FDA
Dr. Michael Jacobson, Center for Science in the Public Interest

Endnotes:

1. Letter to FDA Seeking Enforcement Against Misbranding of Foods that Manufacturers Claim Do Not Contain Contain [sic] Genetically Engineered Ingredients, sent by the Center for Science in the Public Interest, dated August 14, 2001.

2. "GMO free" is used throughout this letter to include other label claims such as "Non-GMO," "No GMOs".

3. Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 758, 48 L.Ed.2d. 346, 96 S.Ct. 1817 (1976).

4. Id. at 763-765.

5. See Rubin v. Coors Brewing Co., 514 US 476, 131 L.Ed2d 532, 115 S.Ct. 1585 (1995) (Federal regulations banning beer labels from displaying alcohol content violated the First Amendment. The Court found that Coors disclosure of a truthful, verifiable, and non-misleading factual information about alcohol content on its beer label was provided First Amendment protection).

6. See http://europa.eu.int/comm/food/fs/biotech/biotech_index_en.html (emphasis added). See also, Codex Committee on Food Labelling (CCFL) Draft Recommendations for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (emphasis added).

7. See http://www.cfsan.fda.org/~dms/bioresp.html. Letter from US Codex Manager Regarding Elaboration of Standards, Guidelines or Other Principles for Foods Derived from Biotechnology, dated December 27, 1999.

8. Document from Dr. Louis J. Pribyl, "Comments on Biotechnology Draft Document," dated March 6, 1992.

9. FIFRA Sceintific Advisory Panel Report No. 2001-09 (July 25, 2001) at 31.

10. FDA Docket 00P-1211, Center for Food Safety, et al., "Legal Petition Seeking the Establishment of Mandatory Pre-Market Safety Testing, Pre-Market Environmental Review & Labeling for All Genetically Engineered Foods," filed March 21, 2000. The FDA has established regulations in which a reasonable period for agency response to citizen petitions can be no more than 180 days. The agency's delay in answering the current petition amounts to a refusal to act, with sufficient finality and ripeness to permit judicial review.

11. FDA Dockets 00D-1598, "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering,"and 00N-1396, "Premarket Notice Concerning Bioengineered Foods."

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