American Crop Protection Association®
Jay J. Vroom
President

March 19, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, Docket No. 00D-1598

Dear Sir/Madam:

The American Crop Protection Association (ACPA) is submitting these comments in response to the availability of a draft guidance for industry entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering", published in the *Federal Register* on January 18, 2001.11

ACPA is a not-for-profit trade organization representing the major manufacturers, formulators and distributors of crop protection, pest control, and biotechnology products. ACPA member companies produce, sell and distribute virtually all the scientific technology products used in crop production by American farmers. Since ACPA members are heavily involved in the development and use of modern biotechnology methods in the initial stages of the "agri-food chain", they are vitally interested in the application of guidance to all foods developed using recombinant DNA technology.

ACPA commends the Food and Drug Administration (FDA) for conducting a thorough and transparent stakeholder involvement process. We agree with FDA's reaffirmation that there is no scientific basis for requiring special labeling of foods derived via modern biotechnology, because there are no data or other pertinent information that would justify such labeling. We concur with FDA that no data were presented during the hearings or comment period that would support a scientific basis for requiring special labeling of all foods resulting from the use of modern biotechnology techniques based upon any health effects.

1/ 66 Fed. Reg. 4839 (2001).

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With respect to claims about foods or food ingredients that are not derived via biotechnology, we agree with FDA that terms such as "GMO Free" and "GM Free" are potentially confusing to consumers and therefore should not be used. 2/ We agree that such terms are technically inaccurate because most foods are derived from plants that have been genetically modified in some way. Additionally, the lack of validated diagnostic methods to test for biotech materials in foods also is a problem in establishing thresholds and in substantiating such a "free" claim. ACPA is seeking to develop standards for programs involving such diagnostic testing for grain produced from biotechnology-derived crops, as are other organizations such as the Association of Official Seed Certifying Agencies, the American Seed Trade Association, and the Grain Inspection, Packers, and Stockyards Administration (GIPSA), 3/ as part of the USDA. Even with the development and use of future detection methods, test results will still have to be linked to substantiation through validated testing, and/or through other documentation pertaining to the use of production method (e.g., organic), handling, segregation, and source of such foods.

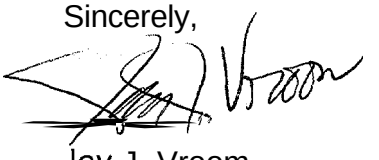
ACPA strongly agrees with FDA that a so - called avoidance claim about a food not derived via modern biotechnology may be misleading if it implies that the labeled food is superior to foods that are not so labeled. Disclaimer language should be required to qualify such claims to make clear that there are no implications of superiority. Additionally, we agree with FDA that a label statement expressing or implying superiority of a food developed without the use of modern biotechnology, such as it is safer or of higher quality than food developed using this technology would be at least misleading, if not false. Therefore, we strongly encourage FDA to review food labels to determine in context whether an avoidance claim implies that a food is superior, and, if the label claim does indicate or suggest superiority, take appropriate action under the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

ACPA is committed to working with FDA and other stakeholders in developing scientifically -sound and legally supportable regulations for products of crop biotechnology consistent with provisions of the FFDCA. We hope these comments are useful in this regard.

2/ Levy, A.S., Derby, B.M., "Report on Consumer Focus Groups on Biotechnology", Consumer Studies Team, Center for Food Safety and Nutrition, Food and Drug Administration, Washington, DC. 2000.

3/ See 65 Fed. Reg. 71272 (2000).

Sincerely,



Jay J. Vroom
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