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OF THE
UNITED STATES OF AMERICA

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Dockets Management Branch (HFA-305)
Docket Number 00D-1598
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Guidance for Industry on Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

Dear Sir or Madam:

These comments are being filed on behalf of the U.S. Chamber of Commerce ("U.S. Chamber"), which is the world's largest business federation, representing more than three million businesses of every size, sector, and region. The U.S. Chamber serves as the principal voice of the American business community.

Many of the U.S. Chamber's members are food producers and manufacturers, and these members would be directly subject to the Food and Drug Administration ("FDA" or "Agency") guidance on 'voluntary labeling indicating whether foods have or have not been developed' using bioengineering.[1] These members would also be affected by any subsequent rulemaking on the subject.

Food labels required by the FDA typically warn consumers of risks based on scientific analysis or provide certain specific nutritional information. By law, these food labels must be truthful and not misleading. If manufacturers use a labeling term the FDA considers misleading, FDA could consider the product misbranded or adulterated and request a recall or even seize the product. This standard must be upheld while at the same time allowing companies to satisfy a market segment composed of consumers who want to avoid bioengineered foods.

FDA released a policy in 1992 regarding foods derived from new plant varieties[2] which states that the agency will not regulate recombinant DNA ("rDNA" or "bioengineered")

[1] 66 FR 4839 (January 18, 2001)
[2] 57 FR 22984 (May 29, 1992)

foods as a class any more stringently than conventionally produced foods. FDA maintains that, use of rDNA technology is not a "material fact" with respect to labeling, rDNA foods do not differ from other foods in any meaningful or uniform way, and that they as a class do, not present different or greater safety concern than'traditional food varieties.3 FDA's policy is supported by all the available science, and consistent with existing law.4

The U.S. Chamber supports the Agency's posit&that bioengineered foods as a class do not require special' labeling. Mandatory labels based on the process by which a food is produced, rather than on the composition of the final product, could force producers and manufacturers to separate - based solely on the use of bioengineering - commodities, ingredients and final products. This would requireseparate storage, transportation and processing facilities, adding costs that would be passed along to the consumer. Perhaps more importantly, if there are no changes to the nutritional content or safety of the product itself, this type of labeling will not result in any additional protection of our food supply.

Government labeling requirements are intended to provide consumers with significant information about a food, Mandating labeling relating to the process of food development or 'preparation, rather than the product itself, could inappropriately signal to a consumer that safety or nutrition has been compromised in the product, or that there is a nutritional or health benefit associated with one process over another.

Voluntary label claims regarding the use of bioengineering that are not misleading can be difficult to develop under this guidance, as the FDA has indicated. To address these problems, FDA has identified, through focus group testing; neutral labeling terms that inform and educate the consumer. This is an excellent goal for all types of labeling, and one that the US,. Chamber hopes the Agency will continue to achieve. , The labeling guidance . provides opportunities to inform consumers without unduly restricting their choices, and gives businesses the freedom to differentiate their products in a changing marketplace. We commend the Agency for spelling out which types of label claims are acceptable and which are not, which will facilitate informed consumer choices about food.

The US. Chamber supports the suggestion in the guidance that in the absence of validated testing to substantiate label claims; manufacturers should document handling practices &proof that no bioengineered materials are present. 'The request for either testing or documentation to verify the absence of bioengineered materials for a label claim places the burden and costs of testing or record-keeping squarely on those who want to use the label and capture the 'market for non-bioengineered foods.

The FDA is correct that "free" type statements suggest zero content of the ingredient

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[3] *I b i d ,*

[4] 21 USC 9 (Federal Food, Drug, and Cosmetic Act)

referred to on t,he label., If "free". does not mean zero, that is a material fact, and must be treated as a material fact when developing labeling statements. Furthermore, statements like "no genetically engineered materials"' would be misleading on a processed product (oils, sucrose, etc.) where no genetic material or protein of any sort is present to indicate bioengineered or non-bioengineered starting materials. A clarifying statement could resolve the discrepancy, but would be likely to confuse consumers, because of the redefinition of commonly used terms. While clarifying statements may make a label more accurate, the additional information may be lost on consumers already saturated with the data content of food labels.

Stating a product is "free" of a particular ingredient, further implies that ingredient is unsafe or unhealthy and should be avoided. Voluntary label claims developed under this guidance are purely for marketing purposes, not to indicate health or safety. There are no significant health, safety or nutritional differences between bioengineered foods and conventional varieties; thus, there is nothing to be avoided. A "free" claim implies a benefit 'where none exists. A clarifying statement would be of limited use, as it would not be an explanation, but a disclaimer. Clarifying a label claim is one thing; retracting it is another.

The U.S. Chamber agrees that in the absence of a legal or scientific mandate to label 'bioengineered foods based solely on the use of technology,[5] voluntary label statements are one appropriate and effective means of addressing consumer's desire for information regarding biotechnology. The U.S.' Chamber supports voluntary truthful and'non-misleading labeling of food products as an appropriate way for businesses to differentiate their products in the marketplace according to their own business strategies and market research.

The U.S. Chamber appreciates the opportunity to submit these comments and thanks FDA for soliciting the opinion of the business community.

Sincerely,

William L. Kovacs

[5] From a statement by Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, before the Health, Education, Labor, and Pensions Committee of the U.S. Senate on September 26, 2000