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1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202) 337-4508
www.gmabrands.com

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BY *HAND* DELIVERY

Documents 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Re: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Docket No. OOD-1598

Dear Sir or Madam:

The undersigned, on behalf of the Grocery Manufacturers of America ("GMA"), the Food Marketing institute ("FMI"), the American Frozen Food Institute ("AFFI"), the International Dairy Foods Association ("IDFA"), the National Food Processors Association ("NFPA"), and the Snack Food Association ("SFA") (hereinafter "Joint Food Industry"), submit these comments on the above-captioned proceeding. It involves the issuance of the referenced Draft Guidance and a related focus group survey conducted by the Food and Drug Administration ("FDA" or the "agency") entitled "Report on Consumer Focus Group on Biotechnology" (hereinafter "Focus Group Survey") as part of an associated Federal Register notice. See generally 66 Fed. Reg. 4839 (2001).

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $450 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The Association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

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FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. FMI's membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $300 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. The Association's international membership includes 200 members from 60 countries.

AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's more than 550 members are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. AFFI represents nearly all frozen fruit and vegetable processors in the U.S., as well as manufacturers of frozen juice, meat and poultry further processed products, baked goods and other prepared products.

IDFA is America's leading trade association representing the dairy industry. IDFA's approximately 600 member companies manufacture the entire range of dairy products and include processors, manufacturers, marketers, distributors, and suppliers. IDFA consists of three constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. Member companies in these groups account for 85 percent of the dairy products consumed in the United States.

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruits and vegetables, meat and poultry, seafoods, drinks, and juices or provide supplies and services to food manufacturers.

SFA is the international trade association of the snack food industry representing snack manufacturers and suppliers. Founded in 1937, SFA represents over 800 companies worldwide. SFA business membership includes, but is not limited to, manufacturers of potato chips, tortilla chips, crackers, corn chips, pretzels, popcorn, extruded snacks, meat snacks, pork rinds, snack nuts, party mix, fruit snacks, cereal snacks, snack bars, and various other snacks. Retail sales of snack foods in the U.S. total more than $30 billion annually.

Turning now to a discussion of the Draft Guidance, we note at the outset that it reiterates many of the points made in the Joint Food Industry Citizen Petition submitted on May 5, 2000 (Docket No. 00P-1284/CP1). This Joint Citizen Petition reviewed applicable law and FDA food labeling precedent in the context of modern biotechnology-produced foods. It particularly focuses on claims about food that is not produced using bioengineering. The comments herein therefore generally support FDA's Draft Guidance and it is in this respect that we provide some additional suggestions for how the Draft Guidance could be changed and improved. We specifically recommend that FDA generally support the use of claims that are production oriented, such as "This food contains cornmeal that was produced using bioengineering." Claims such as "bioengineered cornmeal" may be misleading without further qualification if, for example, they imply that significant changes in the composition of the food have occurred, even if that is not the case. Moreover, composition-based claims may be misleading, if not false, because the food itself is not bioengineered. Only the plant is from which the food is produced.

We also believe that the Draft Guidance is firmly grounded in law and policy. It is consistent with past agency announcements regarding the use of old and new genetic methods as part of plant breeding practices. With respect to labeling, we realize that some consumers are interested in information in this area and that food manufacturers may want to respond to this interest. These Joint Food Industry comments therefore also continue to support FDA's voluntary labeling approach, as did the Joint Food Industry Citizen Petition. We, too, generally endorse truthful and non-misleading statements about foods developed with or without bioengineering, although the Joint Food Industry Citizen Petition only covers the latter topic. Finally, we recommend that the positions reflected in the Draft Guidance, as discussed below, be used in various international forums, such as the Codex Alimentarius proceedings on labeling.

For ease of review, we serially address the topic areas for comment according to the format used in the Draft Guidance. The areas can be divided broadly into the Background section and the Guidance section pertaining to claims about (1) foods developed using bioengineering and (2) foods that are not developed using bioengineering. The substantiation of claims is discussed at the end of this correspondence.

BACKGROUND

FDA seems to draw no distinction between the use of the terms "genetically engineered," "biotechnology," or "bioengineered," which are used interchangeably throughout the Draft Guidance to refer to recombinant DNA methods. It appears the agency is therefore suggesting that consumers equate such terms with the use of recombinant DNA or modern genetic techniques, although there seems to be no direct evidence to support this notion. See Focus Group Survey at 5.

In the Joint Food Industry Citizen Petition, however, we emphasize the use of the term "modern biotechnology" or "recombinant DNA" to eliminate confusion and to preserve technical accuracy. Joint Food Industry Citizen Petition at 7. As a practical matter, though, we understand that more technical terms, such as "recombinant DNA", may be confusing to some consumers. We therefore support the use by FDA of these alternate terms, provided they are actually understood to refer to the use of modern genetic methods, not to the use of traditional, e.g., plant breeding, techniques. Otherwise, they at least may be misleading without further qualification.

These comments further support a number of other FDA positions. Specifically, we endorse most of the statements that follow up on or reiterate, or both, policy positions adopted by FDA in its 1992 Statement of Policy entitled "Foods Derived From New Plant Varieties," 57 Fed. Reg. 22984 (1992). See also 58 Fed. Reg. 25837 (1993) (FDA requests additional information about whether any type of labeling should be required for foods produced from new plant varieties). These past positions of the agency, as reflected now in the Draft Guidance and previously in the Joint Food Industry Citizen Petition, all emphasize that there is no legal or scientific basis to establish across-the-board special mandatory labeling requirements for foods produced by bioengineering.

The Joint Food Industry also endorses FDA's position that the agency has no basis for concluding that foods produced by bioengineering differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater concern than foods developed by traditional plant breeding. In other words, there is no information available to suggest that the application of recombinant DNA techniques to develop new plant varieties will result in foods which, as a class, exhibit attributes different from foods produced from other methods of plant breeding. See 58 Fed. Reg. at 25839; Joint Food Industry Citizen Petition at 9; and Draft Guidance at 2.

In this context, we particularly agree with FDA's conclusion that the method of development of a new plant variety is not normally material information that must be disclosed in labeling under sections 403(a)(l) and 201(n) of the Federal Food, Drug, and Cosmetic Act ("Act"). Draft Guidance at 2; Joint Food Industry Citizen Petition at 9; and 57 Fed. Reg. at 22991. We also endorse the view that the materiality concept typically has been interpreted to mean attributes of the food itself, such as color or texture, and not how it is produced, such as its method of agricultural production, including plant breeding. Joint Food Industry Citizen Petition at 9; Draft Guidance at 3; 58 Fed. Reg. at 25839.

These comments further agree that the labeling requirements which apply to all foods could apply to foods produced from the use of bioengineering, such as in the following circumstances:

- where a food is significantly different from its traditional counterparts so that the common or usual name no longer adequately describes the food;
- where an issue exists for a food or a constituent of food regarding how the food is to be used or the consequences of its use; or
- where a food produced by genetic engineering has significantly different nutritional properties or contains allergens.

Draft Guidance at 4; see Joint Food industry Citizen Petition at IO-I 1; and 57 Fed. Reg. at 22991.

With respect to legal considerations, the Joint Food Industry also endorses FDA's position that, in determining whether a food is misbranded, sections 403(a)(l) and 201(n) of the Act apply. Draft Guidance at 2-3; Joint Food Industry Citizen Petition at 1 I-12; and 57 Fed. Reg. at 22991. Section 403(a)(l) provides that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) states that labeling may be misleading if it fails to disclose facts that are material in light of the representations made about a product or facts that are material with respect to consequences that may result from use of the product. To determine whether labeling is false or misleading in any particular, the entire label and labeling must be reviewed.

STATEMENTS ABOUT FOODS DEVELOPED USING BIOENGINEERING

In contrast to the preference expressed in the Joint Food Industry Citizen Petition, the agency permits foods themselves to be described as "genetically engineered." We have explained previously that claims such as "bioengineered corn" can be construed to be composition or source/production claims, or both. Joint Food Industry Citizen Petition at 16. The Petition, however, clearly makes the point that foods (particularly fabricated foods), including food ingredients, are themselves not typically genetically engineered; rather, they are the result or product of genetic engineering. Compare Draft Guidance at 7 with id. at 15. In other words, such foods are produced from plants (or other organisms) that are bioengineered, whether by traditional or modern biotechnology methods. Even where significant changes occur in food produced from modern biotechnology, again, the food itself is not bioengineered. Other labeling may be required in such cases, however, to note the material differences in the product compared to other food.

This point about the use of bioengineering being appropriately framed as a production claim, rather than as a compositional claim, would especially seem to be valid where plants are altered with respect to agronomic traits, which are not apparent to the consumer, such as herbicide tolerance. Joint Food Industry Citizen Petition at 15. Moreover, from a practical standpoint, as FDA notes in its Draft Guidance primarily in the context of "free" claims, compositional claims (1) can be harder to substantiate because they are more likely to be based on testing rather than on handling procedures and validated testing methods do not yet exist for many foods; and (2) can involve difficult threshold issues (discussed below). See Draft Guidance at 12-13, 15. Claims not otherwise qualified and not framed as production or source claims can therefore be construed as compositional claims, which may be misleading, if not false. They may

imply material changes in the food's composition, Then, too, such composition claims can be viewed as "off-putting." Focus Group Survey at 8.

In those instances where voluntary claims are being made about the goals of bioengineering, such as in the context of the claim "This food is produced using bioengineering to improve texture," we also endorse the use of additional labeling to ensure that the consumer is not misled. For example, in the situation where a claim about a change in texture alone does not involve a noticeable difference in the processed product, labeling may be required to make clear that a change in texture relates to processing characteristics to avoid misleading the consumer about the purpose of the change. Id. at 9. The above-referenced claim involving texture may therefore need to be changed to "This food is produced using bioengineering to improve texture for processing."

STATEMENTS ABOUT FOODS THAT ARE NOT BIOENGINEERED

The Draft Guidance also adopts almost all of the recommendations in the Joint Food Industry Citizen Petition regarding the use of claims such as "GM free," "non-GM," "GMO free," "non-GMO." For example, FDA agrees with the message of the Joint Food Industry Citizen Petition that terms such as "GMO free," and "GM free may be confusing or misleading." Joint Food Industry Citizen Petition at 15-I 8; Draft Guidance at 11. Moreover, terms like "not genetically modified" and "GMO free" that include the word "modified" do not accurately describe most foods, including those that are not produced through bioengineering, because the terms encompass all types of genetic modification, including traditional methods, such as breeding. Since most, if not all, cultivated food crops are produced through some form of genetic modification, it would be misleading to claim that those crops are not genetically modified. Id. The term "GMO free," which refers to organisms, may also be misleading, because most foods do not contain organisms. Draft Guidance at 12, Joint Food Industry Citizen Petition at 16.

We also agree with the Draft Guidance that terms involving the word "free" may be inaccurate and therefore misleading if they imply a "zero" presence of ingredients or components that are produced through the use of bioengineering. Given the potential for the adventitious presence of components derived from bioengineering, even foods that are not intentionally produced through genetic engineering may contain components from bioengineered sources. Therefore, a "free" claim may be misleading unless FDA establishes a threshold level above which a food containing such adventitious presence may not be labeled with such free-type claims.

The Joint Food Industry notes in this regard that FDA's Focus Group Survey states that consumers interpreted claims such as "GM free" as deceptive where a threshold level is allowed. Focus Group Survey at 15. An additional complexity pertaining to the use of thresholds is the necessity for validated standardized testing methods. FDA appropriately recognizes such testing methods are not generally available at this time. Draft Guidance at 12. See also Joint Food Industry Citizen Petition at 20-21.

We agree with FDA, as noted previously in the Joint Food Industry Citizen Petition, that

- it may be false and misleading to claim that a whole food or food ingredient itself is not produced through the use of bioengineering when no market varieties of that category of food or food ingredients are so produced. Draft Guidance at 14; Joint Food Industry Citizen Petition at 17;

- claims regarding the absence of bioengineering in the production of foods may be misleading if they imply that the labeled food is superior to foods that are not so produced. Draft Guidance at 13; Joint Food Industry Citizen Petition at 18; and

- the circumstances surrounding the use of these types of label claims need to be evaluated in determining whether a label statement implies that the food is superior, such as of safer or higher quality, because it is not produced through the use of bioengineering. Draft Guidance at 13; Joint Food Industry Citizen Petition at 18-19.

As discussed in the Joint Food Industry Citizen Petition, in those cases where a label statement unlawfully expresses or implies that a food is superior, the addition of a disclaimer may ameliorate the defect. Joint Food Industry Citizen Petition at 18-l 9.

We further support the position that a claim about the presence of an ingredient not produced from the use of bioengineering could be misleading if there is another ingredient present in the food that is produced through the use of bioengineering. Such a claim must not misrepresent the absence of an ingredient produced through the use of bioengineering. Draft Guidance at 13. Specifically, a product made largely of corn

flour produced by bioengineering and a small amount of soybean containing a claim that the product "does not include soybean oil produced using genetic engineering" could be misleading if consumers believe that the entire product or a larger portion of it than is actually the case does not contain ingredients produced through the use of bioengineering. See id. at 4.

Similar to this situation we offer the following additional examples:

- A manufacturer of cheese claims without qualification that the product is not made with "bioengineered" ingredients. Bioengineered sources of enzymes are used as aids in the production process, although the enzymes are not present in the finished food. The claim is misleading if consumers interpret it as meaning that no bioengineering was used in the production process.

- A manufacturer of a food made largely of traditionally produced corn flour, and a small amount of bioengineered produced soy oil, claims that the product "does not contain corn produced from the use of bioengineering." This claim may not be misleading or false because it is limited to the large portion of the product that is not produced using bioengineering.

SUBSTANTIATION OF LABEL STATEMENTS

The Joint Food Industry also agrees with FDA's analysis of the requirements necessary to substantiate a bioengineering claim as truthful and not misleading. Along the lines of the Joint Food Industry Citizen Petition, FDA states that validated testing is the most reliable way to identify food or food ingredients that have been produced by the use of bioengineering. Joint Food Industry Citizen Petition at 21 and 22; Draft Guidance at 14-15. Since for many foods, however, such methods may not be available or reliable or appropriate for use, it may be important to document the claims differently. Id. Special handling and other appropriate recordkeeping requirements may be necessary to document that the food's labeling is not false or misleading. In some situations certifications or affidavits from farmers or processors and others in the food and distribution production chain may be adequate to document that foods are obtained through the use of traditional methods. Id.

We further endorse Draft Guidance statements that a claim about foods being "free" of bioengineered-produced ingredients (and, in our view, all such composition claims in general) may be difficult to substantiate without testing. Draft Guidance at 15. It therefore would be easier to document handling practices and procedures to substantiate claims about how the food was processed than to substantiate a "free" claim, consistent with the previous discussion about the importance of framing avoidance claims as production or source claims. We also support the notion that certification practices, as part of the National Organic Standards recently promulgated as final regulations (65 Fed. Reg. 80548 (2000), to be codified at 7 C.F.R. Subchapter M, Part 205) by the Agricultural Marketing Service of the United States Department of Agriculture, are sufficient and can be one way to substantiate claims that foods were not produced using bioengineering methods. Draft Guidance at 16.

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We hope these comments are useful to the agency. If we can provide any further information, please do not hesitate to contact us.

C. Manly Molpus
President and Chief Executive Officer
Grocery Manufacturers of America
1010 Wisconsin Avenue, NW, Ninth Floor
Washington, DC 20007
202/337-9400

Food Marketing Institute
655 15th Street NW
Washington, DC 20005
202/452-8444

American Frozen Food Institute
2000 Corporate Ridge, Suite 1000
McLean, VA 22102
7031821-0770

OF COUNSEL:
Edward L. Korwek, Ph.D., J.D.
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004
202/637-5600

International Dairy Foods Association
1250 H Street, NW, Suite 900
Washington, DC 20005
202/737-4332

National Food Processors Association
1350 I Street, NW, Suite 300
Washington, DC 20005
202/639-5900

Snack Food Association
1711 King Street, Suite One
Alexandria, VA 22314
703/836-4500