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Food and Drug Administration
Department of Health and Human Services
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CITIZEN PETITION

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"), submits this petition to the Food and Drug Administration ("FDA" or "the agency"), under section 403 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act" or "Act"), 1/and 21 C.F.R. § 10.30 (1999), to request the Commissioner of Food and Drugs to issue a guidance document and take other action as it deems appropriate that will clarify the circumstances and conditions under which language may be used on food labels and in food labeling about the lack of use of modern biotechnology methods in the production of foods.

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

1/ 21 U.S.C. § 343 (1994).

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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.

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

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 \$21 billion annually.

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A. ACTION REQUESTED

Petitioners hereby request that FDA issue a guidance document and take other action as it deems appropriate pertaining to the general requirements applicable to making certain specific "GM Free" type claims in the labels of food or in labeling 2/ for food about the lack of use of modern biotechnology in the production of foods. In particular, Petitioners request that FDA promulgate a guidance document that duplicates the wording of, or in substance encompasses the principles that appear in, Appendix A attached hereto with respect to claims such as "GM Free," "GMO Free," "Non-GM," "Non-GMO," "No genetically engineered ingredients," and "No ingredients derived through biotechnology," and any other claims of similar import and wording. 3/ Claims that do not comport with any guidance issued by FDA that incorporates the principles enunciated in Appendix A should be considered by FDA to result in the misbranding of food, in accordance with section 403(a)(1) of the FD&C Act 4/ prohibiting false or misleading labeling.

2/ Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. Label means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity. 21 C.F.R. § 1.3 (1999).

3/ The following are possible brief explanations of these ambiguous terms: "GM Free": genetically modified free, implying the food is free of genetic modification; "GMO Free": genetically modified organism free, implying that a food is free of genetically modified organisms; "Non-GM": Non-genetically modified food; "Non-GMO": Non-genetically modified organism food. It is unclear how the first two "Free" claims are different in meaning from the last two "Non-" claims. In this context, the claims may be confusingly similar. See also note 39 *infra* and accompanying text.

4/ 21 U.S.C. § 343(a)(1).

B. STATEMENT OF GROUNDS

Most foods are products of biotechnology in some way. Vegetables as seemingly different as cabbage, Brussels sprouts, broccoli, and cauliflower are all genetically derived from the mustard plant. Most commercial corn varieties are hybrids, with seeds produced by breeding different varieties or different species. Food animals, such as cows and pigs, and edible bacteria, such as those in yogurt, also are further examples of traditional biotechnology or traditional genetic methods such as breeding or selection. ^{5/}

In the last few decades, modern biotechnology, such as recombinant DNA ("rDNA") technology, has allowed developers to transfer specific genes or combinations of genes from a variety of sources, such as bacteria, plants, and animals. Recombinant DNA techniques are used to achieve the same types of goals as traditional methods. They are used in the development of food from plants, animals, and bacteria with enhanced agronomic and quality characteristics.

For example, the modern methods of effecting genetic changes have resulted in plants that are resistant to pests, diseases, and chemical herbicides, or that have improved drought tolerance. These are agronomic (input) traits most valuable to the farmer. Other, output, traits of more obvious value to the consumer include those for improved food processing, texture and flavor, and nutritional content. These last types of foods may contain higher levels of desirable nutrients, such as Vitamin C A, and less saturated fats.

The trend today in the U.S. is not to label food from plants with rDNA-derived input traits differently from other foods, but instead to label their traditionally derived food as not

^{5/} FDA itself has recognized the widespread use of breeding and selection in agriculture. 21 C.F.R. § 170.30(f)(1) and (2).

having been derived from the use of "genetic engineering." These claims about the absence of the use of rDNA are characterized here as avoidance claims. They are meant to convey information to the consumer who may want foods that are not derived from the use of rDNA.

Modern Biotechnology Defined

Numerous commentators, reports, and federal policy statements have defined or discussed such related terms as "biotechnology," "genetic engineering," "deliberately modified heredity traits," "modern biotechnology," "traditional biotechnology," and "bioengineering." 6/ Many of these terms or definitions have appeared in policy statements published by the federal agencies as to how they would regulate products of "biotechnology." 7/ The term "modern biotechnology," as used here, typically refers to recombinant DNA methods. 8/

6/ See, e.g., Genetically Modified Pest-Protected Plants, Science and Regulation, Committee on Genetically Modified Pest-Protected Plants, Board on Agriculture and Natural Resources, National Research Council (National Academy Press, 2000); The President's Council on Competitiveness, Report on National Biotechnology Policy (February 1991); Administrative Conference of the United States, "Biotechnology and the Design of Regulation" (1989); "Field Testing Genetically Modified Organisms: Framework for Decisions," Committee on Scientific Evaluation of the Introduction of Genetically Modified Microorganisms and Plants into the Environment, Report on Biology, Commission on Life Sciences, National Research Council (National Academy Press, 1989); General Accounting Office, "Biotechnology, Managing the Risks of Field Testing Genetically Engineered Organisms," Report to the Chairman, Subcommittee on Oversight Investigations, Committee on Energy and Commerce, House of Representatives (June 1988); Office of Technology Assessment, Congress of the United States, New Developments in Biotechnology, Rpts. 1-5 (1987-1989).

7/ See, e.g., Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986); Principles for Federal Oversight of Biotechnology: Planned Introductions Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 31,118 (1990) (proposed scope document); and Exercise of Federal Oversight Within The Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6,753 (1992) (final policy on agency oversight).

8/ The Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) define recombinant DNA molecules to be either (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) molecules

FDA Biotech Food Policy

On May 29 1992, 9/ FDA issued a statement of policy on the regulation of foods derived from new plant varieties, including plants developed by both old and new methods of biotechnology, such as by rDNA techniques. The May 1992 notice clarifies FDA's interpretation of how plant food products resulting from modern and other methods of biotechnology will be subject to oversight under the FD&C Act.

In the May 1992 notice, FDA provides detailed information about how the agency would be involved in oversight of foods derived from new plant varieties, including premarket clearances. With respect to labeling, FDA states that it "does not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information. . . , and would not usually be required to be disclosed in labeling for the food." 10/ FDA reasons that it "has not considered the [traditional] methods used in the development of a new plant variety (such as hybridization, chemical or radiation-induced mutagenesis, protoplast fusion, embryo rescue, somaclonal variation, or any other method) to be material information within the meaning of section 201(n) of the act." 11/ The agency further adds that it "is not aware of any information showing that foods derived by these new methods differ from other foods

that result from the replication of those described in (1). See section I-B at www.NIH.gov/od/orda/toc.htm. Although GMA believes that "recombinant DNA" need not be defined for purposes of issuance of a guidance document, this NIH definition might be useful, if one should become necessary. The United States Department of Agriculture does not define the term recombinant DNA, even though its regulations govern recombinant DNA-derived plants. 7 C.F.R. § 340.1 (definition of "genetic engineering" refers to recombinant DNA techniques, but does not define what these techniques are).

9/ Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (1992).

10/ *Id.* at 22,991.

11/ *Id.*

in any meaningful or uniform way, or that, as a class, foods developed by these new techniques present any different or greater safety concern than foods developed by traditional plant breeding." 12/ Petitioners agree with this May 1992 position.

In a subsequent April 1993 notice, FDA requested additional information about whether any type of labeling should be required for foods derived from new plant varieties. 13/ The agency again stated that it was "not aware of any information to suggest that the application of recombinant DNA techniques, commonly referred to as genetic engineering, to the development of new plant varieties would result in foods which, as a class, exhibit attributes different from foods derived by other methods of plant breeding." 14/ FDA also reflected on its conclusion in May 1992, that the method of development of a new plant variety is not material information under section 201(n) of the Act, stating that it "is consistent with the agency's historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling." 15/ More importantly, in terms of this petition, FDA also asked for information on voluntary labeling, specifically on niche markets for labeled food indicating it was not derived from the use of rDNA methods. 16/

12/ *Id.*

13/ Food Labeling; Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837 (1993).

14/ *Id.* at 25,839.

15/ *Id.*

16/ *Id.* at 25,841.

Recently, FDA announced and held three public meetings 17/ covering scientific and safety issues, as well as public information issues. Of particular relevance to this petition is the public information part of these hearings. While GMA, FMI, IDFA, and NFPA have filed specific comments to the docket pertaining to these public hearings and GMA and NFPA have presented testimony at one or more of the hearings, it is in the context of the agency's latest request for information on labeling-related issues that this petition is submitted.

Scope

This petition only addresses general principles about the use of certain avoidance claims such as "GMO Free" that food manufacturers may want to make in labels and in labeling about the lack of use of modern biotechnology in the production of foods. Identical principles can apply to other claims of similar import and wording that signify the absence of modern biotechnology in the production of foods; nonetheless, because there are a multitude of possible variations in such claims and their plain meanings can differ significantly, this petition does not address all of the detailed criteria that may apply to specific claims.

Nor does it address mandatory labeling requirements or changes in foods introduced through traditional or modern biotechnology that result in material differences in composition or in the nature of a "bioengineered" food compared to its traditional counterpart. For example, traditional and modern genetic methods can introduce allergens into foods or significantly change the nutritional content of foods. These types of changes in foods require different labeling from that for other foods to convey the nature of any such differences that might exist. These foods and others are also subject to a variety of labeling

17/ Biotechnology in the Year 2000 and Beyond; Public Meetings, 64 Fed. Reg. 57,470 (1999).

regulations applicable to all foods, such as FDA's nutrient content regulations, 18/ health claims, 19/ nutrition labeling, 20/ and standardized food 21/ requirements.

Legal Considerations

FDA has extensive authority under the adulteration and misbranding provisions of the FD&C Act over all foods, including foods derived by the use of modern biotechnology, such as by recombinant DNA methods. Claims made directly or by implication in labels or labeling of foods are within FDA's jurisdiction.

Section 403 of the FD&C Act, 22/ the statutory workhorse pertaining to the labeling of any food, contains roughly 25 different provisions. Of importance is the requirement of section 403(a)(1) that the food shall not contain labeling that is false or misleading in any particular. In determining whether a food is misbranded because its labeling is misleading, the law states that:

[T]here shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also to the extent to which the labeling . . . fails to reveal facts material in

18/ 21 C.F.R. Part 101, Subpart D.

19/ *Id.*, Subpart E.

20/ *Id.*, Subpart C.

21/ 21 C.F.R. Part 130.

22/ 21 U.S.C. § 343.

light of such representations or material with respect to consequences which may result from use of the article. . . . 23/

FDA's regulations further state that the materiality of a fact will be considered:

- (1) in light of other representations made or suggested by statement, word, design, device, or any combination thereof; or
- (2) with respect to consequences which may result from use of the article under (i) the conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual. 24/

Reviewing courts and FDA have generally upheld a high standard of consumer protection in interpreting sections 403 and 201(n) of the Act. As one court put it, the statute's comprehensive terms "condemn every statement design and device which may mislead or deceive, including those statements that are not technically false or which may be literally true." 25/ In short, "[t]he aim of the statute is to prevent that resulting from indirection and ambiguity, Those [statements] which are ambiguous and liable to mislead should be read" to accomplish the purposes of the law. 26/ In determining whether statements are false or misleading, the labeling must be considered as a whole. A label

23/ FD&C Act § 201(n), 21 U.S.C. § 321(n) (emphases added).

24/ 21 C.F.R. § 1.21(a).

25/ *U.S. v. 95 Barrels of . . . Apple Cider Vinegar*, 265 U.S. 438 (1924); see also *Taylor v. U.S.*, 80 F.2d 604, 605-606 (5th Cir. 1936) ("Deception may result from statement not literally false.")

26/ *U.S. v. 95 Barrels of . . . Apple Cider Vinegar*, 265 U.S. at 443.

must be evaluated not by fragmentizing it or "isolating statements claimed to be false from the label in its entirety, since such statements may not be deemed misleading when read in light of the label as a whole." 27/ At the same time, however, a false statement will not necessarily be cured or neutralized by a true statement. 28/ In determining whether a label is false or misleading, it is not necessary to show that anyone will actually be misled or deceived. 29/ Moreover, it is not required to prove that all the label representations are false or misleading, only that one representation is. 30/

Insofar as FDA's regulation of implied claims is concerned, the claims that are primarily the subject of this petition, the agency's implementation of the Nutrition Labeling and Education Act 31/ is particularly relevant. FDA defines implied nutrient content claims as "claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount." 32/ The definition of an implied claim was "not intended to be a quantitative standard to determine the number of consumers who have a particular conception about an individual claim but is intended to focus on what the claim is saying." 33/ While the agency was willing to consider a manufacturer's intent and consumer surveys, FDA was not persuaded that direct consumer survey information was

27/ *U.S. v. 432 Cartons . . . Candy Lollipops*, 292 F.Supp. 839 (S.D.N.Y. 1968).

28/ *Id.* at 841.

29/ See *U.S. v. An Article of Food . . . Nuclomin*, 482 F.2d 581 (8th Cir. 1973) and *U.S. v. An Article of Food . . . Manischewitz . . . Diet Thins*, 377 F.Supp. 746 (E.D.N.Y. 1974).

30/ See *An Article of Food . . . Manischewitz . . . Diet Thins*, 377 F.Supp. at 749.

31/ Pub. L. No. 101-535, 104 Stat. 2353.

32/ 21 C.F.R. § 101.65(c).

33/ 58 Fed. Reg. at 2371.

always needed as guidance on whether a statement was an implied claim. The agency took a similar position regarding implied health claims. It reiterated its position that the agency would consider the manufacturer's intent and consumer perception, but that the focus of the inquiry would be on "what the claim is saying." 34/

Finally, in terms of FDA's approach to the regulation of claims, the courts have generally embodied a preference for disclosure of information over outright suppression or banning of a claim. 35/ In short, the government may not "completely suppress information when narrow restrictions on expression would serve its interest as well." 36/ While inherently misleading speech may be prohibited in its entirety, potentially misleading information may not be prohibited if the information can be presented in a way that is not deceptive. 37/

Avoidance Claims

This petition generally addresses "GM Free," "Non-GM," "GMO Free," and "Non-GMO" and similar avoidance claims that imply the absence of the use of modern biotechnology methods in the production of foods. 38/ At the least, GM or GMO types of

34/ Food Labeling: Health Claims, General Principles, 58 Fed. Reg. 2478, 2483 (1993).

35/ See, e.g., *In Re RMJ*, 455 U.S. 191, 203 (1982).

36/ *Hudson Gas and Electric Corp. v. Public Service Commission*, 447 U.S. 557, 565 (1980).

37/ *In Re RMJ*, 455 U.S. at 203. See also *Pearson v. Shalala*, 164 F. 3d. 650 (D.C. Cir. 1999).

38/ While FDA has allowed various types of "free" avoidance claims involving, for example, the lack of fat, sodium, and sugar, these are not pertinent to the discussion here because these and other terms are defined, or are well understood, or both, and often are used in conjunction with nutrition labeling information, which can provide context to nutrient content and other types of "free" related claims. See, e.g., 21 C.F.R. §§ 101.60(c) (sugar-free); 101.61(b) (sodium-free); 101.62(b) (fat-free); and 101.62(d) (cholesterol-free).

"Free" or "Non-" claims may be confusingly similar and seem not to be synonymous. ^{39/} Indeed, they may even engender misunderstanding based on their literal meanings, unless they are at least qualified. For these and other reasons discussed below, while these types of claims may not necessarily be inherently misleading and, thus, without protection from the First Amendment, they may be misleading, if not false. They may need to be qualified or clarified before they can be legally made in accordance with sections 403 and 201(n) of the FD&C Act.

The reasons for this position are several-fold. Few foods are themselves genetically modified; rather, such foods are derived from plants or animals that are genetically modified, whether by traditional or modern biotechnology methods. Therefore, it may be misleading, if not false, to suggest without qualification that foods with such GM avoidance claims are not themselves genetically modified since most foods are not so modified anyway. In other words, it may be misleading to suggest that a food itself is free of genetic modification, when ordinarily it is not genetically modified. A current analogous example would be to suggest that celery is free of fat when ordinarily it has no fat. Accordingly, FDA's regulations prohibit a "fat-free" claim for a specific brand of celery, although a statement of more general applicability is allowed, e.g., "celery, a fat-free food." ^{40/}

Even if such claims are qualified to imply instead that the foods are derived from plants or animals that are not genetically modified, the claims still may be misleading, if not

^{39/} By way of analogy, FDA has stated that "alcohol-free" may be used only when the product contains no detectable alcohol, whereas "non-alcoholic" beverages could actually contain traces (less than 0.5% by volume) of alcohol. Dealcoholized Wine and Malt Beverages Labeling. Compliance Policy Guideline 7101.04, section 510.400.

^{40/} See 21 C.F.R. § 101.60(b)(2)(ii).

false. Most foods have been derived from sources that are genetically modified through cultivation or domestication. Similarly, with regard to the claim "GMO Free," few foods, except products like yogurt, contain entire "organisms." It therefore may also be misleading, if not false, to suggest that a food which ordinarily would not contain entire organisms is "Organism Free," regardless of whether the acronym "GM" accompanies such a claim. Also, such claims, standing alone, can improperly imply a compositional difference rather than a difference in the way the food was produced or developed. 41/

Petitioners therefore request that FDA adopt the following positions and conditions for labeling food with GMO and GM "Free" and "Non-" claims and similar claims; each bulleted sentence (also appearing in Appendix A) contains the general requirements for making such claims and the accompanying indented paragraph contains the basis for such claims:

- Claims such as "GM Free" that imply the absence of "genetic modification" in the production of foods (including food ingredients) may be truthful and not misleading when such terms are qualified, or explained as necessary in an appropriate context, so that consumers understand that the words "genetic modification" refer to recombinant DNA methods.

Most, if not all, cultivated food crops, as well as animals and bacteria used in the production of food, have been genetically modified in some way. The use of such claims therefore can imply that no genetic modification whatever has been used in the production of the food or food ingredients, which is not the

41/ The implied claim of a compositional difference has been dealt with previously by FDA in the context of avoidance claims involving bovine growth hormone. See note 43 *infra* and accompanying text.

case for most foods. Such claims therefore need to be modified, depending upon consumer understanding of the meaning of such claims, to clarify that the claims refer to recombinant DNA.

- It is false and misleading to claim that a whole food or food ingredient is "GMO Free" or "Non-GMO" where the food or ingredient does not ordinarily contain entire organisms.

Only certain foods contain entire "organisms;" for example, yogurt contains the edible bacteria, *Lactobacillus acidophilus*, among other organisms. Other foods, such as raw agricultural commodities, 42/ a category including fruits and vegetables, contain seeds. Most foods, however, do not contain entire "organisms," dead or alive, recombinant DNA-derived or not.

- It is false and misleading to claim that a whole food or food ingredient is "GM Free" or "Non-GM" where the whole food or food ingredient is not ordinarily modified by recombinant DNA techniques.

Corn and soy are often derived today from the use of recombinant DNA, although many foods do not contain corn or soy and most food ingredients today are not derived from the use of recombinant DNA. Appropriate qualification may be necessary to clarify that the food on which such claims appear is not ordinarily derived by recombinant DNA methods.

- When appropriately qualified, claims that a whole food or food ingredient is "GM Free" or "Non-GM" may be truthful and not misleading provided their meaning is clear in terms of whether they refer to compositional differences or to source differences, or both.

42/ The term "raw agricultural commodity" is any food in its raw or natural state, including fruits, that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. FD&C Act § 201(r), 21 U.S.C. § 321(r).

The terms could refer (1) to a compositional difference in the recombinant DNA-derived food compared to other foods or (2) to the use of recombinant DNA methods, or both. Both "GM Free" and "Non-GM" can imply that recombinant DNA methods are not used in the production of the food or its ingredients, or that the food does not contain any detectable levels of food components or ingredients made from the use of rDNA methods, or both.

Implied Superiority Claims

Another important aspect of this petition is whether GM or GMO "Free" or "Non-" claims, or other claims about the lack of modern biotechnology in the production of foods, constitute implied superiority claims, for example, with respect to food quality or safety. The circumstances surrounding the use of these terms will dictate whether superiority is claimed. When superiority is claimed, FDA's analysis in the 1994 interim guidance on the labeling of milk and milk products in cows that have not been treated with recombinant bovine somatotropin (rBST) may be relevant. ^{43/} Citing sections 403(a) and 201 of the FD&C Act, FDA stated that claims such as "rBST-free" may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Moreover, without proper context, such statements may be interpreted to imply that milk from untreated cows is safer or of higher quality than milk from treated cows. The agency therefore required that a disclaimer be used in conjunction with such "free" claims, stating that "No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows."

^{43/} Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin, 54 Fed. Reg. 6279 (1994).

In line with this reasoning, a similar disclaimer may be appropriate for GMO and GM "Free" and "Non-" claims. The compositional, safety and quality considerations discussed above may apply to these types of claims as well. Disclaimer language such as "No significant difference has been shown between foods that are derived from plants modified by recombinant DNA techniques and those that are derived from plants developed by traditional plant breeding methods" may be appropriate under some circumstances. The following bulleted sentence (also appearing in Appendix A) and indented paragraph again contain the recommended conditions for making GM and GMO "Free" and "Non-" claims and the reasons therefore in light of FDA's treatment of claims concerning the absence of rBST:

- Claims that a whole food or food ingredient is "GM Free" or "Non-GM" may be truthful and not misleading if they do not imply superiority.

The circumstances surrounding the use of these types of claims are important in deciding whether superiority is implied. If superiority is implied, such an implication could be false or misleading. FDA addressed implied superiority claims in the *"Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin (rBST)."* In this Interim Guidance, FDA stated that food companies not using milk from cows supplemented with rBST may voluntarily inform consumers of this fact in their product labels or labeling, provided any statements that are made are truthful and not misleading. FDA was concerned that claims, such as "From cows not treated with rBST," without proper context, might imply that milk from untreated cows is safer or of higher

quality than milk from treated cows. If unqualified "GM Free" or "Non-GM" statements or other similar claims imply that food made by traditional breeding practices is safer or of higher quality than food made from recombinant DNA techniques, appropriate qualification may be necessary to avoid misleading consumers.

Threshold *De Minimis* and Testing Considerations

Closely related to the use of GMO and GM "Free" and "Non-" claims and similar statements is the level, if any, of adventitious rDNA-derived material that is allowable before a food cannot be labeled with these types of claims or with terms of similar import. This *de minimis* level has sometimes been called the "threshold" above which a food containing such rDNA-derived material may not be labeled with claims such as "GMO Free." ^{44/} The *de minimis* presence of unavoidable rDNA-derived materials could occur during cultivation, harvesting, transport and storage, or processing. A further complication is that "Free" type claims seem to suggest a zero threshold, whereas "Non-" type claims seem to allow an undefined level of rDNA-derived materials. ^{45/} Finally, an additional complexity pertaining to the use of thresholds is the necessity for validated, standardized testing methods, with appropriate sensitivity and reference materials, to detect the level of adventitious materials.

Petitioners believe at this time that, in light of the difficult issues associated with the establishment of thresholds, it is inappropriate for Petitioners to define a threshold level in

^{44/} The European Union has adopted a 1% per food ingredient "threshold" before a food would have to be labeled as "genetically modified." See Commission Regulation (EC) No. 49/2000 (2000).

^{45/} See also note 39 *supra* in the context of "free" and "non" claims for alcoholic beverages.

this petition that might be applicable to different types of GMO and GM claims. Petitioners are willing to work with FDA to define further specific threshold levels that might be useful for these types of claims. Perhaps another approach that could be useful in this area is to specify a percentage level which reflects the lack of rDNA-derived materials, such as, perhaps, "99% free from recombinant DNA-derived ingredients."

The use of validated testing methods is the preferable way to establish the source of foods or food components, particularly the presence of rDNA adventitious materials. Since validated methods are not yet commercially available for all foods and for different types and levels of rDNA-derived materials, a combination of testing and certification schemes may be necessary to verify and document the source of food and food components throughout the food chain to ensure, for example, that "Free" and "Non-" type claims are substantiated and therefore not false. In this general regard, the following bulleted sentence (also appearing in Appendix A) and indented paragraph contain the recommended substantiation requirements for making GM and GMO "Free" and "Non-" claims and the reasoning therefore:

- Claims that a food or its ingredients, including foods such as raw agricultural commodities, are not derived from or made through the use of recombinant DNA techniques can be truthful and not misleading when adequate testing records, or other appropriate documentation as may be necessary, or both, exist to establish the source and handling of the food or its ingredients.

Validated, reliable testing is the preferable way to identify foods or food components derived from the use of rDNA methods. For many foods, however, particularly for highly processed foods such as oils, it may be

difficult to differentiate by validated analytical methods between foods and food components obtained from the use of recombinant DNA techniques and those obtained from traditional methods. For example, if validated test methods are not available or reliable because of the way foods are produced or processed, it may be necessary to document the source of such foods differently. Special handling and other appropriate recordkeeping requirements that are consistent with the FD&C Act may be necessary not because of any safety concern, but to ensure that the food's labeling is not false or misleading. In some situations, certifications or affidavits from farmers, processors, and others in the food production chain may be adequate to document that foods are obtained from the use of traditional methods.

C. ENVIRONMENTAL IMPACT

Neither an environmental impact statement nor an environmental assessment is required for this citizen petition, in that the FDA action requested consists of the issuance of guidelines. 46/

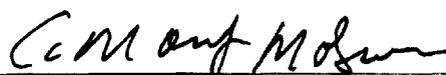
D. ECONOMIC IMPACT

No request has been made by the Commissioner for this information. It will be supplied upon request.

46/ 21 C.F.R. § 25.30(h).

E. CERTIFICATION

The undersigned to this citizen petition certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the petition.



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GUIDANCE FOR INDUSTRY

**GENERAL INFORMATION FOR MAKING CLAIMS
ABOUT THE LACK OF USE OF
MODERN BIOTECHNOLOGY IN THE PRODUCTION OF FOODS**

- Claims such as "GM Free" that imply the absence of "genetic modification" in the production of foods (including food ingredients) may be truthful and not misleading when such terms are qualified, or explained as necessary in an appropriate context, so that consumers understand that the words "genetic modification" refer to recombinant DNA methods.
- It is false and misleading to claim that a whole food or food ingredient is "GMO Free" or "Non-GMO" where the food or ingredient does not ordinarily contain entire organisms.
- It is false and misleading to claim that a whole food or food ingredient is "GM Free" or "Non-GM" where the food or food ingredient is not ordinarily modified by recombinant DNA techniques.
- When appropriately qualified, claims that a whole food or food ingredient is "GM Free" or "Non-GM" may be truthful and not misleading provided their meaning is clear in terms of whether they refer to compositional differences or to source differences, or both.
- Claims that a whole food or food ingredient is "GM Free" or "Non-GM" may be truthful and not misleading if they do not imply superiority.

- Claims that a food or its ingredients, including foods such as raw agricultural commodities, are not derived from or made through the use of recombinant DNA techniques can be truthful and not misleading when adequate testing records, or other appropriate documentation as may be necessary, or both, exist to establish the source and handling of the food or its ingredients.