November 9, 2006

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

Re: [Docket No. 2006N-0107] Food and Drug Administration - Regulated Products Containing Nanotechnology Materials; Public Meeting; Request for Comments; 71 Fed. Reg. 19523 (Apr. 14, 2006); 71 Fed. Reg. 56158 (Aug. 11, 2006); 71 Fed. Reg. 56158 (Sept. 26, 2006)

Dear Sir or Madam:

The Foods Products Association (FPA) and Grocery Manufacturers Association (GMA) (collectively, the Associations) submit the following comments on the docket referenced above.

FPA is the principal scientific and technical trade association representing the food products industry. FPA's laboratory centers, scientists, and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs, and international trade. FPA's government affairs, regulatory, communications, claims, and scientific experts work to ensure that laws and regulations governing the food industry are based on sound, modern science. FPA's members produce processed and packaged fruits and vegetables, meat and poultry, seafoods, drinks, and juices or provide supplies and services to food manufacturers.

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. 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. GMA also leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer product industry.

1. Introduction

These comments are submitted by the Associations for consideration by the FDA Nanotechnology Task Force in follow up to the public meeting on October 10, 2006, which was held to further the agency's understanding of the scientific and policy issues presented by the potential use of nanotechnology materials in FDA-regulated products. The Associations appreciate this opportunity to comment on the important issues presented by the potential use of nanotechnology materials in the production of food,[1] either as components of food (e.g., ingredients), or as components of food packaging, processing materials, or other uses in food contact materials. The Associations do recognize nanotechnology applications go beyond the food industry and currently include consumer products. We plan to provide stakeholder input on FDA-regulated consumer products in the future. The Associations commend the agency for holding the recent public meeting, and urge the agency to continue to provide such opportunities for the industry organizations having particular expertise and experience relating to nanotechnology applications in food production to contribute information and views as FDA develops policy in this area. In view of the rapidly evolving body of scientific knowledge concerning nanotechnology and the dynamic and speculative nature of forecasts concerning potential applications in food production, such contributions from industry stakeholders can provide a critical safeguard, helping to ensure that agency policies are informed by genuine, case-specific uses of nanotechnology materials, and consider the scientific methods and evidence that are relevant and meaningful under actual conditions of use.

Cooperation between the agency and industry stakeholders can aid the agency in its role to inform and educate the public on potential nanotechnology applications in food production. The Associations urge that FDA assume a leadership role in educating the public concerning the public health and consumer protection benefits from potential nanotechnology applications in food production, and in addressing questions concerning the science-based regulatory standards and procedures that are already established to ensure that food products introduced to the market are safe, regardless of the nature of the processing methods or components that are used in producing food.

2. The FD&C Act Framework Provides FDA with Ample Legal Authority

The Associations and member companies have substantial experience with the scientific and regulatory issues presented by the use of new technologies, including applications affecting agricultural production, and food processing, packaging, distribution and marketing. While new food production technologies frequently give rise to novel facts and circumstances that must be considered under the Federal Food, Drug, and Cosmetic Act (FD&C Act) standards, regardless of whether the technologies employed are new or conventional, FD&C Act standards remain constant, requiring manufacturers to establish that food is safe and labeling claims are substantiated based on sound scientific evidence developed from valid, reliable analytical methods and adequate, well controlled scientific studies. In addition, the FD&C Act provides FDA with authority to remove unsafe products from the market. The Act is expansive in scope,

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[1] 21 U.S.C. 321(f) (defining "food" to mean "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article").

and its stringent, science-based standards extend to all foods and food additives, encompassing foods developed from conventional and new technologies alike.

3. The Coordinated Framework for Regulation of Products of Biotechnology Under Existing FDA Authority Provides Useful Guidance

Based on the Associations' evaluation of potential nanotechnology applications in food, food packaging, and other food contact materials, the Associations conclude that the FD&C Act framework provides FDA with ample authority to regulate the safety and labeling of foods produced with nanotechnology materials. Moreover, the Associations believe the regulatory approach taken in the context of the interagency Coordinated Framework for Regulation of Products of Biotechnology provides useful guidance for the development of a comparable coordinated policy framework for foods produced with nanotechnology materials under existing law.[2]

The Associations have consistently supported the adequacy of the existing FD&C Act framework, within the coordinated federal regulatory framework, to regulate the safety and labeling of foods produced with new biotechnology applications. The Associations have long supported the FDA's position[3] that the agency has ample statutory authority to ensure the safety of the nation's food and feed supplies that it regulates[4], and to require that product claims be substantiated. The Associations have fully supported rigorous, science-based standards for foods produced from biotechnology, consistent with the Associations' commitment to the safety and integrity of the food products they make. Notably, while FDA has relied on a voluntary pre-market notification system to evaluate the safety of novel uses of food biotechnology before product marketing, the Associations have long urged the agency to implement existing FD&C Act provisions through a pre-market notification system that would make early food safety evaluations by FDA mandatory.[5]

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[2] 51 Fed. Reg. 23302 (June 26, 1986) (Coordinated Framework for Regulation of Biotechnology: Announcement of policy; notice for public comment).

[3] *See* 51 Fed. Reg. at 23309-13 (Coordinated Framework for Regulation of Biotechnology); 57 Fed. Reg. 22984 (May 29, 1992) (Statement of Policy: Foods Derived from New Plant Varieties); and Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, January 2001, available at: http://www.cfsan.fda.gov/~dms/biolabgu.html.

[4] FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and frozen, dried and liquid eggs, which are under the authority of the U.S. Department of Agriculture (USDA's Food Safety and Inspection Service (FSIS)).

[5] *See* the Associations' "Position Paper: Plant Biotechnology" (current) (which notes that the Associations "support the coordinated regulatory framework of USDA, EPA and FDA which assesses the safety of using science-based risk assessment and risk management," and "agree[] with the FDA's position that it has the statutory authority and the responsibility to protect the (continued…)

4. Pre-Market Notification for Novel Food Uses of Nanotechnology

Based on the Associations' evaluation of nanotechnology developments, consultation with member companies, and legal analyses of the FD&C Act, the Associations conclude that FDA has ample legal authority to regulate the safety and labeling of foods produced from nanotechnology materials, and that FDA policies governing the safety and labeling of foods derived from biotechnology under the coordinated regulatory framework generally constitute a reasonable and appropriate framework for the development of comparable nanotechnology policies. The Associations urge FDA to consider the establishment of a pre-market notification system that would make early food safety evaluations by FDA a pre-requisite for novel applications of nanotechnology materials in food, food packaging, and other food contact materials under existing FD&C Act requirements.

The Associations further urge FDA to issue guidance concerning the conditions in which the application of nanotechnology materials in food, food packaging, or other food contact materials would be regarded as "novel" for safety evaluation purposes, and thus subject to the proposed pre-market notification system for novel nanotechnology materials. For purposes of developing such guidance, the agency should avoid reliance on "nanotechnology" definitions or other criteria that would fail to distinguish common nano-sized components of food for which safety is well established. For example, in the context of the agency's participation in the interagency National Nanotechnology Initiative (NNI), FDA has recognized the NNI definition of "nanotechnology" for scientific purposes, but has refrained from adopting the NNI definition for regulatory purposes under the FD&C Act.[6] While the NNI definition may have value in purely scientific contexts, the definition is overly broad and thus inadequate to distinguish such naturally occurring nano-sized food components, including certain food proteins, polysaccharides, and lipids,[7] from the materials produced by emerging nanotechnologies of regulatory interest here. For this reason, the NNI definition and other comparable "nanotechnology" definitions would provide an unworkable basis, without more clarity, for defining the conditions in which nanotechnology materials should be regarded as novel for safety evaluation purposes and thus subject to the proposed pre-market notification system.

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food/feed supply;" and urging that the government "move beyond the current voluntary system and make pre-market notifications and early food safety evaluations mandatory").

[6] NNI has established a scientific definition, which considers an activity to be "nanotechnology" if it involves all of the following elements: (1) research and technology development at the atomic, molecular, or macromolecular levels, in the length scale of approximately 1-100 nanometer range; (2) creating and using structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size; and (3) ability to control or manipulate on the atomic scale. Lux Research, Inc. offers a more succinct definition of nanotechnology: "The purposeful engineering of matter of scales of less than 100 nanometers (nm) to achieve size-dependent properties and functions." *The Nanotech Report 4th Edition*. New York, NY: Lux Research, Inc., 2006, p. 1.

[7] Information Statement, Institute of Food Science & Technology Trust Fund, February 2006 at 4.

5. Labeling Guidance for Novel Food Uses of Nanotechnology Materials

The Associations urge FDA to issue guidance to assist manufacturers in the development of labeling claims for food, food packaging, and other food contact materials produced from novel applications of nanotechnology materials. Existing FDA labeling policies applicable to foods derived from biotechnology provide useful guidance for the development of comparable nanotechnology labeling policies. Consistent with FDA's food biotechnology labeling policies,[8] FDA labeling policies for foods produced with nanotechnology should be well grounded in the anti-deception standards established by FD&C Act sections 403(a) and 201(n).[9] FDA is urged to issue guidance concerning the substantiation of claims related to foods produced with nanotechnology materials, which is consistent with the "competent and reliable scientific evidence standard" developed under the Federal Trade Commission Act[10]

The Associations would again like to commend the agency for holding the recent public meeting. The Associations will be submitting more detailed comments on this important issue pending further analysis of key topics identified above. Thank you for the opportunity to comment on this important issue.

Sincerely,

Craig Henry, Ph.D.
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Chief Operating Officer
Scientific and Regulatory Affairs
Food Products Association

Mary Sophos
Senior Vice President,
Chief Government Affairs Officer
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[8] Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, January 2001, available at: http://www.cfsan.fda.gov/~dms/biolabgu.html.

[9] Section 403(a) of the Act provides that a food is misbranded "if its labeling is false or misleading in any particular," and Section 201(n) specifies that labeling can be misleading through the failure to reveal "material" information. Section 201(n) provides that information may be "material" either "with respect to consequences which may result from the use of the article," or "in light of representations [made or suggested]."

[10] *See, e.g.*, FTC Enforcement Policy Statement on Food Advertising, May 1994; available at: http://www.ftc.gov/bcp/policystmt/ad-food.htm.