American Bakers Association

Serving the Baking Industry Since 1897

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 03N-0076; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements (68 Federal Register 41507 (July 11, 2003)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The ABA and its members share FDA's goal of providing consumers with accurate, truthful and nonmisleading information about the trans fat content in food products.

Given the very complex and evolving scientific, product formulation, and consumer behavior issues surrounding trans fats, however, ABA considers rulemaking on this subject to be premature at this time because the public health outcomes simply cannot be determined. Rather, ABA believes that the best approach would be through agency guidance that is flexible and allows antideception principles to be derived through specific instances. Further, ABA believes that a cautionary footnote regarding trans and/or saturated fat is neither appropriate nor justifiable as a means to communicate meaningful information about trans fat to consumers.

I. New or Amended Nutrient Content Claims Regulations are Unsupportable At This Time

ABA believes that the current state of the evidence concerning the science, consumer behavior, and product formulation concerning trans fats is simply not sufficiently developed to constitute an appropriate basis for establishing qualifying criteria for trans fat nutrient content claims, or for establishing qualifying, disclosure, or

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disqualifying levels for trans fat in existing nutrient content claims and other health messages.

A. The Current Scientific and Consumer Behavior Evidence Cannot Support the Establishment of Regulatory Criteria for Nutrient Content Claims

FDA's general authority for regulating food labeling is derived from two provisions of the Federal Food, Drug and Cosmetic Act (FDCA). Section 403(a)(1) provides that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) states that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling. Moreover, FDA's authority to regulate commercial speech such as food labeling is bounded by the dictates of the First Amendment, which requires the government to demonstrate through evidence that any restrictions placed on the freedom of speech are carefully crafted to remedy a genuine harm that is established from evidence and that would otherwise occur without the speech restriction. In the absence of genuine evidence that the manufacturer's choice of expression is harmful, and that the government's speech restriction will alleviate the specific harm to a material degree. The current state of the evidence on consumer understanding of trans fat labeling and consequent consumption behavior is not sufficiently developed or appropriately focused to support specific categorical restrictions on trans fat claims at this time.

As an initial matter, the scientific evidence relating to trans fats has not been conclusively established. The evidence has not yet evolved to support a daily value for trans fats, and the comparative biological impact of consumption of trans and saturated fat has not been fully characterized. In the absence of sound scientific criteria, FDA's actions in setting the bounds of trans fat claims would be arbitrary and capricious.

Moreover, without a solid scientific basis for claims relating to trans fats, it is impossible to characterize the likely effects of such claims on consumer behavior, and in turn determine whether such behavior is justified or is the product of misleading label statements. Until the science evolves to supply the evidence considered to be "material" as relates to trans fat claims, FDA cannot determine what information has been unlawfully omitted or mischaracterized to render a claim misleading under the FDCA. Further, FDA would have no basis for meeting its First Amendment burden of demonstrating that its labeling requirements were carefully crafted to remedy real consumer deception.

B. Regulations Should Not Be Established Without an Understanding of Their Anticipated Public Health Outcomes

1. Consumer Behavior

As discussed above, it is impossible at this time to anticipate the consumer behavior that would flow from label claims concerning trans fats. More significantly, the

incomplete scientific picture precludes any policy determination as to how consumer behavior should be shaped in order to best promote the public health. Before embarking upon a regulatory endeavor, FDA should clearly define the public health outcomes it aims to accomplish, that is, FDA should characterize the concrete harms that it alleges to exist currently, and establish the efficacy of its approach in alleviating the alleged harm, as required under the First Amendment. Establishing the efficacy of regulations to serve public health outcomes as a matter of actual fact is essential for the agency to proceed in this complex area. Because of the challenging formulation issues involved and the interchangeability of the fat sources that contain trans fat versus saturated fat, ABA believes that there is a substantial risk that issuing regulations that cannot be fully supported by appropriate evidence and outcomes assessment would lead to unintended and serious adverse public health consequences. Adopting a "first do no harm" public health policy ethic in this area not only is essential for public health, but is fitting in view of the agency's obligations under the Administrative Procedure Act and the First Amendment. Because the current state of the scientific evidence supplies FDA no basis for establishing its desired public health outcome, any regulatory action concerning claims about trans fats would be unjustified and unsupportable at this time.

2. Product Formulation

FDA should consider how its labeling policies shape the business behavior and economic incentives in the food industry as well as the implications for consumer behavior. As a general policy matter, ABA believes that trans fat food labeling policy must be developed in a way that accounts for the real world formulation options food manufacturers have, and provides appropriate incentives for better choices within these options. FDA must recognize that in the manufacture of the bakery products that contribute most to trans fat consumption, it is rarely an option to reformulate a food using a fat source that is either naturally trans free (e.g., liquid vegetable oils), or is a specially formulated trans free partially hydrogenated fat of the kind seen in the margarine category. Saturated fats are the functional alternative to trans fats, and investigational trans free solid fats that do not increase saturates currently do not appear to be feasible.

Given these facts, a case-by-case approach to claims relating to trans fats, rather than a rigid one-size-fits-all regulation, is the approach that will most substantially advance the public health. For example, with regard to "reduced" saturated fat or trans fat claims, such claims should be allowed where the "reduced" product is a healthful alternative to the reference food, and should not be subject to arbitrary gram limits on trans or saturated fat that might have no meaning in the particular instance. Such an approach would encourage the reformulation of products to a healthier composition even if those products could not feasibly be reduced to within certain fixed limits.

C. FDA Can Shape Meaningful, Truthful and Nonmisleading Claims Through Guidance

Because of the highly complex and evolving issues surrounding trans fat labeling, ABA believes that a regulatory approach cannot possibly address the potential range of deception issues that might arise. Rather, ABA considers the best approach to be through agency guidance. Guidance would allow for appropriate flexibility in evaluating claims relating to trans fat, and would allow antideception principles to emerge from cases over time. Further, this approach is more consistent with the First Amendment's requirement that restrictions on speech be justified by evidence of concrete harm than by a prospective rulemaking approach that cannot be founded upon evidence at this time.

FDA has successfully employed a such a flexible approach in its January 2001 "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." Rather than prescribing express criteria for these claims, FDA relied upon general antideception principles, emphasizing the need to place the claims in proper perspective so that they would not be misleading, and requiring the proponents of a claim to have adequate substantiation. While the guidance allows a case-by-case approach to such claims, it also sets forth examples of statements that might be used, which effectively set forth "safe harbor" options for labeling.

Federal Trade Commission (FTC) guidances also operate similarly on antideception principles. For example, the FTC's "Dietary Supplements: An Advertising Guide for Industry" and that agency's Environmental Marketing Guides, or "Green Guides," are grounded in a case-by-case approach to substantiation that considers each claim in the context of actual consumer understanding and looks to evidence of genuine harm flowing from the claim. Further, these FTC guidances also present options intended to provide a "safe harbor" for marketers who want certainty about how to make certain claims, although these "safe harbor" examples do not represent the only permissible iterations of such claims.

The FDA Genetic Engineering guidance and FTC guidances provide examples of how FDA should proceed with respect to claims concerning trans fats. FDA could set forth the general antideception considerations applicable to claims relating to trans fats, and could also establish certain "safe harbor" claims along the lines of the criteria proposed by ABA for specific nutrient content claims in its April 14, 2000 comments on FDA's initial trans fat labeling proposal, a copy of which is attached. For example, ABA proposed that "trans fat free" claims should be permitted for any food containing up to 0.5 grams of trans fat/RACC, provided that saturated fat levels do not exceed 2 grams/RACC. The trans fat component of this claim is consistent with FDA's trans fat disclosure requirements. The saturated fat limit is derived from FDA's conclusion that foods containing up to 2 grams of saturated fat could be labeled "cholesterol free" without rendering the cholesterol claim misleading to consumers, for

the agency apparently concluded that this saturated fat limit would confine the cholesterol claims to beneficial food choices. Thus, guidance that establishes "safe harbor" claims would provide meaningful information to manufacturers wishing to make substantiated label claims while retaining a flexible approach that is governed by antideception principles rather than by prescriptive requirements that may not have relevance in a particular case.

Given the substantial scientific, manufacturing, and consumer behavior uncertainties surrounding trans fat labeling, a guidance approach rather than rigid regulation can further the public policy goal of ensuring that accurate, truthful and nonmisleading nutrition information reaches consumers in a manner that is meaningful and can shape ideal public health outcomes.

II. ABA Strongly Opposes a Cautionary Footnote

ABA previously expressed its strong opposition to the cautionary trans fat footnote proposed by FDA on November 15, 2002. *See* ABA's December 16, 2002 comments, a copy of which is attached. ABA continues to oppose the imposition of a cautionary footnote, whether it refers to trans fat alone or saturated fat as well, on the same grounds as expressed in its 2002 comments. In brief, ABA wishes again to call FDA's attention to the following serious concerns about such a footnote:

- A cautionary footnote promotes consumer confusion in making sound nutrition choices, by exaggerating the relative importance of avoiding trans fat in the context of concrete food choices presented. This take-away message if false and misleading, and does not square with the anti-deception standards FDA would apply to voluntary label statements manufacturers may choose to make in food labeling.

- Given the widespread presence of trans fat in the food supply, consumer compliance with such a cautionary footnote at this time "would require extraordinary changes in dietary intake patterns that might introduce other undesirable health effects and unknown health risks," -- a concern expressed by FDA in its November 2002 proposed rule.

- FDA has not established its authority to implement the footnote in conformance with First Amendment standards, which apply to regulations compelling speech as well as those that ban speech. *International Dairy Foods Association v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996) (ruling that mandatory labeling operating as "the functional equivalent of a warning" failed to satisfy First Amendment standards). The choice of what information to convey on the food label belongs to the manufacturer unless and until the government demonstrates, through concrete evidence of genuine harm, that the speech is misleading and that the compelled speech is carefully tailored to directly advance a substantial government

interest. A cautionary footnote along the lines proposed cannot satisfy these constitutional requirements.

- Similarly, a manufacturer's food label should not be burdened by what are essentially dietary guidance claims or nutrition education. FDA has many alternative channels available for dissemination of this type of health information, such as consumer education and awareness programs or government vehicles such as the website nutrition.gov, which operates as a repository of government-endorsed health and nutrition information.

- A cautionary footnote is actually a disincentive to food manufacturers to reformulate products to lower trans levels given that the footnote would still be required if there were any measurable amount of trans within the reformulated product (i.e., a reformulated product with a 50% trans decrease from 4 grams to 2 grams per serving).

Accordingly, a cautionary footnote appears to serve no legitimate or meaningful function, while impermissibly burdening the First Amendment rights of food manufacturers and providing a disincentive to formulation of products in a manner that would promote the public health.

ABA appreciates this opportunity to comment on this proposal, which is of great interest to the wholesale baking industry. The Association is hopeful that the concerns outlined above regarding claims relating to trans fat and a cautionary footnote will be useful to FDA as the Agency moves to establish its policy on these issues. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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