April 15, 2004

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

Re: Docket No. 2003N-0076; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Reopening of Comment Period (69 Federal Register 9559 (March 1, 2004))

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 non-misleading information about the *trans* fat content in food products and welcome this opportunity to comment further on several aspects of nutrition labeling for *trans* fatty acid as detailed below.

FDA Should Retain the July 2003 Requirements for Label Format

In summary, ABA strongly believes that FDA should maintain the nutrition facts label format and requirements as described in the final rule issued July 11, 2003 – calling for a separate line declaration with no footnote or DV. The addition of *trans* fat as a mandatory nutrient on a separate line maintains the appearance of the nutrition information that consumers are familiar with. The separate line quantitative declaration of *trans* fat allows consumers to compare that information and make purchase decisions based on *trans* fat content if that is important to their individual dietary needs. There is no justification for mandating additional label requirements at this time.

In its July 2003 final rule, FDA stated that the scientific evidence was not sufficient to support the establishment of a DV for *trans*. The 2003 IOM/NAS report on guiding principles for nutrition labeling provided no change in scientific evidence that was considered with the July 2003 final rule.

Comments on the IOM/NAS Recommendations

The IOM/NAS 2003 guidelines report provides a guideline for establishing a DV for *trans* fat and new DVs for saturated fat and cholesterol, and recommends combining the DVs for *trans* and saturated fats on the label. The DV approach prescribed in that report deviates from a scientific evidence approach as it includes a recommendation for menu modeling, along with use of food composition data (which is limited for *trans* fat at this time) and data from dietary surveys (which may be even more limited with respect to *trans* fat at this time). Menu modeling can conceivably be designed to achieve any arbitrary DV in a targeted range, although the science base for that methodology is questionable at best. This unique and complicated approach would undoubtedly necessitate significant staff resources for FDA staff and would require substantial public involvement. (It should be noted that this approach was also suggested for saturated fat and cholesterol.)

The IOM/NAS Dietary Reference Intake (DRI) 2002 Macronutrient Report did not establish an estimated average requirement, an adequate intake or an acceptable macronutrient distribution range for *trans* fat. Therefore, no DRI values can be readily used as the basis for a *trans* fat daily value.

The IOM/NAS 2003 guidelines report recommends that saturated fat and *trans* fat amounts be listed on separate lines, but one numerical value for the percent DV be included in the nutrition facts panel for these two nutrients. This format would create a cholesterol-raising fat category on the nutrition facts label. We believe that such an approach is unwarranted, and FDA should not pursue a combined DV.

Nutrition science is complex and scientific understanding of nutrition is constantly evolving over time. Distinct chemical definitions in labeling are not subject to changes in knowledge about the physiological effects of specific nutrients. A cholesterol-raising fat category, as implied by IOM/NAS, introduces the concept of a label based on physiological indicators, rather than the traditional chemical definitions. Even if one assumes that such a change in labeling parameters is justified, then ABA asks what justification is there for applying it to only a single physiological indicator?

On April 17, 2000, the Staff of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission (FTC) commented that separate saturated and *trans* fat categories will limit the nutrition facts panel to objective, accurate information; help promote consumer confidence in its reliability; and accommodate future scientific developments. They also noted that distinct fat categories would help to ensure that scientific debate over the relative effects of *trans* fats and other fatty acids takes place outside the context of the nutrition facts panel. ABA agrees with that comment.

Consideration of Other Government Policy Development– FDA Healthy Lifestyle Initiatives – Nutrition Facts Panel Review and HHS/USDA Dietary Guidelines for Americans 2005 / Food Guide Pyramid 2005

Based on FDA's recent announcement of the establishment of a Healthy Lifestyle Initiative which included the Agency's intent to review both the Nutrition Facts Panel as well as serving sizes, and the ongoing HHS/USDA Dietary Guidelines Advisory Committee discussions on *trans* in the diet as part of their policy review for the updates that are to be released in January 2005, ABA strongly believes that it would be unwise to proceed at this time with interim *trans* labeling changes in a piecemeal fashion.

Additionally, DVs for many of the nutrients will likely be changing as a result of recent IOM/NAS recommendations in the 2002 macronutrient report. These updates should be considered in one rule-making procedure so as to not erode consumer confidence in the label as a result of piecemeal changes. Not only would gradual labeling changes be confusing to consumers, that approach would also be burdensome and impose significant costs to the food industry. Such an approach would result in a series of sporadic, uncoordinated changes to food packaging and nutrition labeling over the next several years. A systematic, well developed plan with one major, uniform labeling compliance date would be beneficial to the Agency, consumers and industry alike.

Consideration of Consumer Understanding of Percent Daily Value (%DV) Concept

As part of its plan, FDA should additionally review consumers' understanding of the daily value (DV) concept and whether it is used and effectively understood by consumers to gain the nutritional information they seek when making food choices. Current data reveals that use of the percent DV listing in the nutrition facts panel is questionable at best. The majority of consumers who use the nutrition facts panel, in food purchase decisions, use quantitative amount declarations. A Year 2000 study by Lisa Levy and co-workers, cited in the IOM/NAS 2003 Guidance Report (page 2-15), indicates that the majority of test subjects could not define %DV and did not find it useful for assessing the fat content of a product or how to use it to appropriately select a diet low in fat. Additionally, FDA's own research in the "Calories Count" Report of the Working Group on Obesity (2004) finds that "(V)ery few participants reported using the %DV column on the Nutrition Facts Panel. Either they did not understand the meaning of %DV, or they thought that it was not relevant to them since they did not consume a 2000 calorie diet."

Further, there is no legal mandate for DV's for all nutrients to be listed in the nutrition facts panel. The Nutrition Labeling and Education Act (NLEA) (21 U.S.C. §343) does mandate that FDA devise a label format to serve two purposes: 1) to allow product to product comparisons, and 2) to allow consumers to make judgments about how a single product fits into the diet. However, it does not require use of the percent DV format. Certainly, there is no mandate for adoption of a DV without a scientific basis. There are other nutrients, for example sugars, for which FDA has not adopted a DV.

However, if the Agency chooses to proceed, it should develop a clear, comprehensive educational plan on DV before advancing this concept to the public. It would be premature for the Agency to adopt a DV for *trans* fat without key educational components being in place; without that foundation, ABA would question the public health benefit to such a labeling change.

ABA Continues to Strongly Opposes a Cautionary Footnote

ABA previously expressed its strong opposition to the cautionary *trans* fat footnote proposed by FDA. (*See* ABA's December 16, 2002 comments and October 9, 2003 comments, a copy of both 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 and 2003 comments. The nutrition facts panel should provide factual nutrient content information to consumers. Broader dietary guidance should be provided through off-label activities of public and private health and nutrition education programs. ABA continues to strongly advocate off additional label nutrition education efforts and has made this comment to the Agency before regarding a variety of nutrition labeling issues including its October 9, 2003 comments on *trans* fat. In brief, ABA wishes again to call FDA's attention to the following serious concerns about such a footnote:

- 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.

- 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 www.nutrition.gov, which operates as a repository of government-endorsed health and nutrition information.

New Cost Impact Analysis Needed

As ABA noted in its December 16, 2002 comments (Docket No. 94P-0036) that are attached, FDA's preliminary economic impact analysis from the original 1999 *trans*

fat labeling proposal grossly understated the cost to industry to make nutrition labeling changes for *trans* fat. Given the currently mandated labeling changes that become effective January 1, 2006 and the possibility of expanded and even more complicated changes in the future, ABA continues to strongly urge a new cost impact analysis - it is essential.

Further, it should be noted that baking companies have already invested significant resources and have already started modifying their packaging and labels to accommodate the July 11, 2003 final rule which must be implemented by January 1, 2006. If further label changes are made with respect to *trans* fat labeling, these additional labeling additions/changes for %DV and perhaps a footnote, would require bakers to recreate much of the work done to date, in some cases, doubling costs for packaging changes and virtually making it impossible for the industry to comply by a January 1, 2006 uniform compliance date.

ABA recognizes the significant concern as regards to coronary heart disease in the nation today and we recognize that blood cholesterol levels are a significant factor in considering risks for heart disease; however, we are unaware of studies indicating that current heart disease rates are a direct result of the presence of *trans* fat in diets.

For example, the web-site of the Centers for Disease Control includes a summary of data accomplishments from the National Health and Nutrition Examination Surveys (NHANES) at http://www.cdc.gov/nchs/about/major/nhanes/DataAccomp.htm. That summary states as follows regarding cholesterol levels: "Today, people routinely keep an eye on their cholesterol. When NHANES started testing, one-third of adults had high cholesterol. Today fewer than 1 in 5 adults has high cholesterol." Similar information is available in statistics published by the American Heart Association and the American Stroke Association (2004 Update).

In the timeframe in which NHANES started testing, many food products were developed using partially hydrogenated vegetable oils in place of higher saturated fat alternatives. NHANES data do not parallel this change and, thus, do not justify the need to single cholesterol-raising fats out in labeling. This is information it relevant to a new cost impact analysis.

Reformulation Technology

Recent discussions by the HHS/USDA Dietary Guidelines Advisory Committee (DGAC) at their March 29 meeting regarding *trans* in foods, specifically baked goods, and the possibility of reformulation in the future have prompted ABA to remind FDA that reformulation for some foods to remove *trans* is easier than for others. Unfortunately, many baked goods require a solid fat, either in the form of saturated fat or *trans* fat, because of the melting point, structure and shelf life requirements. While technology in this area is evolving, the alternatives that have been developed at present are limited.

Further, the Agency should remember that *trans* was formulated for use in bakery products and many other food products in the 1970's to replace palm oil, lard and butter

with what was thought to be healthier vegetable oil sources. While bakers are optimistic that technology developments will provide cost effective, healthier alternatives in the future, such alternatives are severely limited at present. In fact, many of the alternatives may lead to either a one-for-one replacement of saturated fat for *trans* fat, or even a greater amount of saturated fat added than the quantitative reduction in *trans* fat. ABA believes that industry will be able to develop viable alternatives and to reformulate in many cases.

FDA should also recognize the fact that there is a very low level of naturally occurring *trans* in flour (.5g trans in wheat flour and 1.0g trans in whole wheat flour per 100 grams); this fact has not been taken into consideration of policy making to date. In some cases this will limit the ability of bakers to remove all trans fat when suitable substitutes are available for partially hydrogenated oils.

Relationship of *Trans* Fat to Certain Nutrient Content Claims

ABA believes that truthful claims should be allowed and should be fashioned in a form that will provide meaningful, non-misleading information to consumers and encourage manufacturers to reformulate products to achieve such claims where that is possible. ABA believes the following claims should be allowed as stated below:

- "*Trans* Fat Free" - Should require less than 0.5 grams of *trans* fat and no more than 1.0 grams of saturated fat. If the term "*trans* fat free" is declared and the product contains a partially hydrogenated ingredient, the manufacturer must use an asterisk in the ingredient statement to inform consumers that the partially hydrogenated ingredient contributes an insignificant amount of *trans* fat. This allows for voluntary use of an asterisk in the ingredient statement to explain that a partially hydrogenated ingredient contributes an insignificant amount of *trans* fat, even if a manufacturer chooses not to make a *trans* fat free claim.

- "Saturated Fat Free" – Should require less than 0.5 grams of saturated fat and no more than 1.0 grams of *trans* fat. This slight increase in the amount of *trans* fat over the current rule would provide flexibility that would encourage manufacturers to reformulate products.

- "Reduced Trans Fat" and "Reduced Saturated Fat" – Should require a reduction of at least 25%. The reduction should also be at least 0.5 g for the reduction to be nutritionally significant, since 0.5 g is the smallest change that would be reflected on the nutrition panel.

- "No Cholesterol" – Should require less than 2.0 mg of cholesterol. This claim should have the additional requirement of no more than two grams combined of saturated fat and *trans* fat.

Additionally, ABA believes that criteria for any *trans* fat claims must allow the use of healthier oils which would include the use of some saturated fat at greater amounts than the "free" level. For example, olive oil contains approximately 11% saturated fat. Overly rigid claims criteria would disallow a trans free claim on this healthy oil.

ABA appreciates this opportunity to comment on the reopening of this advanced notice of proposed rulemaking, which is of great interest to the wholesale baking industry. The Association is hopeful that the concerns outlined above regarding a variety of issues relating to fat will be useful to the Agency as it moves forward to establish further policy. 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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Enclosures