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December 16, 2002

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

**Re: Docket No. 94P-0036; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period; 67 Fed. Reg. 69171 (Nov. 15, 2002)**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates this opportunity to offer comments concerning the Food and Drug Administration (FDA) proposal to require that the statement "Intake of *trans* fat should be as low as possible" be provided each time that *trans* fat is listed in the Nutrition Facts box. AFFI supports FDA's efforts to provide meaningful guidance to consumers regarding healthy dietary practices. We are concerned, however, that the proposed statement will not accomplish this goal. Indeed, AFFI believes that the proposed statement will mislead and confuse consumers because the concept that underlies the statement is too complex to convey effectively within the confines of nutrition labeling. AFFI strongly recommends that, in lieu of the proposed statement, FDA support educational efforts to assist consumers in fully understanding current dietary guidelines for *trans* fat consumption.

AFFI is the national trade association representing frozen food manufacturers and their marketers and suppliers. AFFI's more than 500 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. As food industry leaders, AFFI members have a strong interest in nutrition labeling regulatory and policy issues.

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AFFI understands that the agency is proposing to require an asterisk (or other symbol) in the percent daily value column for *trans* fat when it is declared. This asterisk or symbol would be linked to a similar symbol at the bottom of the Nutrition Facts box that would be followed by the statement, “Intake of *trans* fat should be as low as possible.” AFFI further understands that this information is intended to assist consumers in using the quantitative *trans* fat information to help maintain healthy dietary practices. FDA states that the source of the statement is the recent National Academy of Sciences/Institute of Medicine (NAS/IOM) report, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (National Academy Press 2002) (the “macronutrient report”).

The NAS/IOM macronutrient report recommends that *trans* fat consumption be minimized to the amount of *trans* fat that is incidental to a nutritionally adequate diet.<sup>1</sup> The NAS/IOM explains that it would be unrealistic—and indeed, potentially undesirable—for consumers to attempt to take the extreme steps that would be necessary to eliminate *trans* fat entirely:

Because *trans* fatty acids are unavoidable in ordinary, non-vegan diets, consuming 0% of energy would require significant changes in patterns of dietary intake. Such adjustments may introduce undesirable effects (e.g., elimination of commercially prepared foods, dairy products, and meats that contain *trans* fatty acids, may result in inadequate intakes of protein and certain micronutrients) and unknown and unquantifiable health risks. Nevertheless, it is recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.<sup>1</sup>

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<sup>1</sup> NAS/IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (National Academy Press 2002), at 8-2.

<sup>1</sup> *Id.* (emphasis added).

The statement proposed by FDA, “Intake of *trans* fat should be as low as possible,” takes these NAS/IOM recommendations out of context. Because it is theoretically “possible” to eliminate *trans* fat, AFFI believes that consumers will interpret the proposed statement to advocate an intake of zero grams of *trans* fat per day, which oversimplifies and misrepresents the advice provided in the macronutrient report. In response, some consumers may go to extreme lengths to avoid *trans* fat, which, as the NAS/IOM noted, could lead to adverse nutritional consequences. Alternatively, confusion caused by the statement may lead other consumers to disregard or place less emphasis upon the important information provided in nutrition labeling.

The proposed statement is also of concern because it is a new element in the Nutrition Facts box that apparently has not been subject to any type of consumer testing to evaluate its effect on consumer understanding and comprehension. The Nutrition Labeling and Education Act of 1990 (NLEA) required FDA to ensure that nutrition labeling is “conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.”<sup>1</sup> In designing the original Nutrition Facts box, FDA considered extensive consumer research and related data to ensure that nutrition information would provide meaningful guidance to consumers.

Particularly troubling, the proposed footnote is a descriptive statement that constitutes a departure from the numeric reference values (e.g., %DV declarations) traditionally used by FDA. A descriptive reference of the type that FDA has proposed is unprecedented and its novelty may well lead consumers to believe that *trans* fat is to be emphasized over all other nutrients, including saturated fat and cholesterol. The agency is urged to refrain from adopting a precedent-setting labeling format of this type until (1) the Food and Nutrition Board issues its recommendations concerning use of the dietary reference intakes (DRIs) in food labeling, and (2) any proposed format is fully tested with consumers to ensure it does in fact enhance consumer understanding of the desired information.

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<sup>1</sup> NLEA § 2(b)(1)(A).

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AFFI also requests that the agency consider that, in the 1999 *trans* fat proposal, the agency's economic analysis was based upon a rule that would require new labels only for foods that contain *trans* fatty acids at levels that equal or exceed 0.5 grams per serving. As described in the November 15, 2002, proposal, however, FDA's intent is to require new labels, in a substantially revised format, across the board. In light of this departure from the original proposal, the agency should perform a new economic impact analysis.

In summary, the proposed statement appears to be an untested measure that AFFI believes will result in consumer confusion. AFFI appreciates that some education will be required to assist consumers in fully understanding the amount of *trans* fat consumption that may be incidental to a nutritionally adequate diet. We believe, however, that it is simply infeasible to convey such a nuanced message within the confines of the current Nutrition Facts box or elsewhere in food labeling. The agency is urged to withdraw the proposed statement and to instead pledge to undertake or support consumer education efforts that can more effectively convey current dietary guidelines for *trans* fat consumption.

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AFFI is committed to the development of food labeling policy that enhances consumer understanding of current recommendations for healthful dietary practices. AFFI looks forward to working with the agency on the *trans* fat and other labeling issues and would be pleased to discuss with CFSAN any of the points made in these comments.

Sincerely,



Leslie G. Sarasin, CAE  
President and  
Chief Executive Officer