June 25, 2003

25 7:30 a.m.
6-24-03, ~~10:00am~~

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No.]

Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer research to consider nutrient content and health claims and possible footnote or disclosure statements

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to solicit information and data that potentially could be used to establish new nutrient content **claims about *trans* fat, to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and, in addition, as disclosure and disqualifying criteria** ~~or health claims about *trans* fat, and to revise existing nutrient content and health claims limits on saturated fat~~ to help consumers make heart-healthy food choices. The agency is also requesting comments on whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from

comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices. Elsewhere in this issue of the **Federal Register**, FDA is amending its regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line under the line for the declaration of saturated fatty acids.

DATES: Submit written or electronic comments by [insert date 3 months after publication in the Federal Register], 2003.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20830. Submit electronic comments to *http: www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301-436-2373..

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 17, 1999 (64 FR 62746) (the November 1999 proposal), FDA (we) proposed, among other things, to (1) amend our regulations on nutrition labeling to require that the amount of *trans* fatty acids (*trans* fats) present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fatty acids (saturated fats) with a footnote indicating the amount of *trans* fat in a serving of the product when the product contains 0.5 or more grams (g) per (/) serving, (2) establish a nutrient content claim for "*trans* fat free," and (3) revise existing nutrient content and health claims that have limits on levels of saturated fat to include a criterion for *trans* fat. In that proposal, FDA concluded that dietary *trans* fats, like saturated fats, have adverse effects on blood cholesterol measures that are predictive of coronary heart disease (CHD) risk (64 FR 62746 at 62754).

Comments received in response to the November 1999 proposal were very diverse. Many comments strongly opposed the inclusion of *trans* fat as part of the amount and %DV for saturated fat (see "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (the *trans* fat final regulation) found elsewhere in this issue of the **Federal Register**) and supported the declaration of *trans* fat on a separate line immediately under that for saturated fat. Comments relating to claims were equally diverse and indicated strongly opposing views. Comments objecting to proposed definitions for nutrient content claims were based on scientific, legal, and economic arguments with some comments stating that the agency was acting in advance of scientific justification. Moreover, comments encouraged the agency to wait for the soon-to-be published report on macronutrients by the Institute of Medicine

of the National Academy of Sciences (IOM/NAS) before finalizing the proposal. The comments explained that the IOM was expected to review the available science on *trans* fat and might establish a Dietary Reference Intake (DRI) level from which FDA could establish a Daily Reference Value (DRV) that would assist it in providing other information on the nutrition label, such as a %DV for *trans* fat.

In September of 2002, the IOM/NAS issued the report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) and found that, similar to saturated fatty acids, there is "a positive linear trend" between *trans* fatty acid intake and total and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of coronary heart disease (Ref. 1). Although the IOM/NAS macronutrient report recommended that the intake of *trans* fat be as low as possible while maintaining a nutritionally balanced diet, it did not provide a DRI for *trans* fat or information that the agency needs to establish a DRV for nutrition labeling purposes.

Dietary guidance for the general population similar to that in the IOM/NAS macronutrient report was included in the Dietary Guidelines for Americans (2000, 5th edition) (Ref. 2), which recommended cutting back on saturated and *trans* fats when reducing total fat intake. Moreover, the National Cholesterol Education Program's Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults recommended that individuals at high risk for CHD keep their intake of *trans* fatty acids low (Ref. 3).

In light of recommendations in the IOM/NAS macronutrient report, the agency published in the **Federal Register** of November 15, 2002 (67 FR 69171) a notice reopening the comment period of the November 1999 proposal (November 2002 reopening of the comment period) to

solicit comments on a proposed footnote statement that would be used in place of a %DV for *trans* fat on the nutrition label. In that document, the agency recognized the importance of providing information on the *trans* fat content of foods on food labels and set forth its thinking that the proposed footnote statement would provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. Thus, in the absence of a basis on which to establish a DV, the agency proposed to require an asterisk (or other symbol) in the %DV column for *trans* fat when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box and the statement that "Intake of *trans* fat should be as low as possible." The agency asked for comments on the proposed footnote statement.

A few comments to the November 2002 reopening of the comment period supported the proposed footnote statement, "Intake of *trans* fat should be as low as possible," with or without some modification to the statement. However, the majority of comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (gram/serving) label declaration of *trans* fat on a separate line below saturated fat with no %DV. A more thorough review of the comments can be seen in comment 17 of the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**.

The dominant concern, from both industry and consumers, was that the footnote would create a goal of achieving a "0" *trans* fat intake level so that the market (that is, manufacturer reformulations and consumer preferences) would be driven toward products that were devoid of *trans* fat, regardless of the level of saturated fat. One comment submitted two national on-line surveys that, in fact, showed that the proposed footnote statement led consumers to identify foods with much higher levels of saturated fat but no *trans* fat as "more healthful" than those

containing lesser amounts of saturated fat and *trans* fat combined (see comment 17 in the *trans* fat final regulation found elsewhere in this issue of the **Federal Register**).

Another concern expressed in comments was that the proposed footnote statement was inconsistent with the IOM/NAS report (Ref. 1) and other dietary guidelines. The comments argued that the footnote statement implies that intake of *trans* fat should be zero, in other words, a *de facto* DV of "zero;" whereas the IOM/NAS macronutrient report states that the intake of *trans* fats is unavoidable in ordinary diets. Moreover, the report states that any attempt to eliminate them from the American diet would require significant changes in dietary intake patterns that may result in unknown and unquantifiable health risks. The IOM recommendation was that intake of *trans* fat should be as low as possible "while consuming a nutritionally adequate diet." The comments noted that the IOM/NAS macronutrient report makes similar recommendations for saturated fat and cholesterol, which also have adverse effects on LDL-C.

Thus, the comments expressed the belief that the proposed footnote statement could mislead consumers into selecting foods with more saturated fat in an effort to avoid foods containing *trans* fat. Virtually all comments conveyed that *trans* fat and saturated fat (and perhaps cholesterol) need to be viewed in tandem – not one at the expense of the other(s).

Comments were also concerned about the absence of consumer studies to determine how the proposed footnote would be perceived. As noted above, industry comments perceived it as a warning label for consumers to avoid *trans* fat-containing foods at all costs, resulting in an increased intake of saturated fat and negating years of government health messages to limit saturated fat intake. Comments also indicated concerns about an additional footnote adding clutter to the label and thereby discouraging consumers from reading it. The comments strongly

supported consumer research on the proposed and other possible footnote statements to determine consumers' understanding of *trans* fat in light of such statements and how *trans* fat may be perceived relative to other cholesterol-raising lipids in a food, as well as how consumers would react to the footnote.

In the *trans* fat final regulation, found elsewhere in this issue of the **Federal Register**, we amend regulations on nutrition labeling to require that *trans* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids but without a %DV or the proposed nutrient content claims or footnote statement. In that document, we concurred with the comments that support consumer testing to ensure that any claim or footnote statement about *trans* fat, alone or in combination with other nutrients, such as saturated fat and cholesterol, provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. However, we ~~We~~ concluded~~, therefore,~~ that based on information and arguments presented in the comments, it is premature to establish new or revised definitions for nutrient content claims or require the use of the proposed footnote statement in the nutrition label. Instead, we decided to issue this ANPRM and solicit comment and consumer research on: (1) an appropriate basis for establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims and current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids as well as disclosure and disqualifying levels; (2) whether such claims mislead consumers about the total fatty acid profile if levels of all cholesterol-raising lipids are not addressed, and if so, whether qualifiers or disclosure statements would remedy this problem; (3) the use of a footnote, (4) the language that may be appropriate

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for use in a footnote, and (5) the impact of nutrient content or health claims or a footnote or disclosure statement on consumers' food selections.

II. Agency Request for Information

A. Nutrient Content Claims, Health Claims, Disclosure and Disqualifying Levels

FDA has a mandate to provide nutrition information on food labels to assist consumers in maintaining healthy dietary practices. As explained in the *trans* fat final regulation, published elsewhere in this issue of the *Federal Register*, although the science now supports a relationship between *trans* fat intake and risk of CHD, the agency believes that the current level of scientific evidence does not **provide the type of quantitative information that the agency would need to** ~~does not~~ support the establishment of a DRV for *trans* fat ~~at this time~~. **In 1993, when the agency established a DRV for saturated fat (58 FR 2206, January 6, 1993), it based the DRV on quantitative guidelines set forth by the National Academy of Science's 1989 report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 4) and a report from the National Cholesterol Education Program (National Heart, Lung, and Blood Institute of the National Institute of Health) (Ref. 5) that stated that saturated fatty acids should provide less than 10 percent of total calories. The agency derived a DRV of 20 grams for saturated fat (rounded) as the amount of saturated fat that would provide approximately 10 percent of the reference caloric intake (i.e., 2000 Calories/day) (55 FR 29476 at 29483; July 19, 1990). There is no such quantitative recommendation at this time for *trans* fat, either as an absolute amount or as a percentage of caloric intake. The**

IOM/NAS report recommended keeping trans fat intake as low as possible while recognizing that *trans* fatty acids are unavoidable in ordinary, non-vegan diets and that trying to eliminate *trans* fat from the diet entirely would require significant changes in eating patterns that may introduce undesirable effects. In the absence of a DRV for *trans* fat, ~~Thus,~~ the agency is providing for mandatory *trans* fat labeling, without a %DV, to provide consumers with information they need to help them make healthy food choices in the context of their total daily diet.

In addition to the information on the Nutrition Facts Panel, nutrient content and health claims are important tools for providing consumers with information about the level of one or more nutrients in a food product. Because the level of scientific evidence does not currently support the establishment of an appropriate reference value for daily consumption of *trans* fat, such as a Dietary Reference Intake (DRI) level, from which the agency could derive a DRV for *trans* fat, the agency decided, in the *trans* fat final regulation, to withdraw those provisions of the proposed *trans* fat rule pertaining to the establishment of a definition of "*trans* fat free," consideration of "reduced *trans* fat" and "reduced saturated fat and *trans* fat" claims and limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. However, the agency plans to continue to evaluate the emerging science and revisit the need for establishing nutrient content claims related to *trans* fat, and limits on *trans* fat in certain nutrient content claims, health claims, and disclosure and disqualifying levels through a new rulemaking once the scientific evidence has evolved to a point at which the agency believes the scientific evidence would support such a rulemaking.

The agency is concerned about ensuring that consumers obtain the best possible information related to *trans* fat and other cholesterol-raising lipids on the food label. Therefore, we are interested in receiving information from scientific bodies concerning recommended or upper intake levels of *trans* fat. We are also requesting interested persons to submit, as part of their comments on this ANPRM, scientific information and data, including consumer research data and analyses of risk inherent in selecting specific levels of *trans* fat, that would assist the agency in establishing qualifying criteria for *trans* fat in *trans* fat nutrient content claims, current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol raising fats, and, in addition, as disclosure and disqualifying levels. Alternatively, in the absence of evidence to support the establishment of such qualifying criteria, the agency is interested in receiving about any available data to support the usefulness of or need for a disclosure statement, in conjunction with nutrient content or health claims, concerning levels of saturated fat, *trans* fat, or cholesterol in a food or in the diet or a message about the role of such cholesterol-raising lipids in increasing the risk of CHD .

The agency is also interested in comments on the impact on consumers' shopping choices of a qualifying criterion for *trans* fat in saturated fat, cholesterol, lean and extra lean nutrient content claims and in health claims that contain a message about cholesterol-raising fats. What kinds of products would consumers buy more or less of because of such claims and a *trans* fat criterion?

B. Footnote Statements

We are asking interested persons and those with expertise in consumer research to submit, as part of their comments on the ANPRM, information and consumer research data on any of the following footnote statements:

- Intake of ~~saturated fat and~~ *trans* fat should be kept low while maintaining a nutritionally adequate diet,
- Intake of saturated fat and *trans* fat should be kept low while maintaining a nutritionally adequate diet,
- Intake of saturated fat, *trans* fat, and cholesterol should be kept low while maintaining a nutritionally adequate diet,
- As part of a nutritionally balanced diet, intake of saturated fat, *trans* fat, and cholesterol should be kept low,
- Healthy diets start with diets low in saturated fat, *trans* fat, and cholesterol.
- Nutritionally adequate diets include diets low in saturated fat, *trans* fat, and cholesterol.

Other footnote statements may also be considered.

In particular, we want information about whether a footnote about *trans* fat, alone or in combination with saturated fat and cholesterol, would be helpful to consumers and what kinds of footnote statements are likely to be helpful to consumers to achieve the goal of conveying information about *trans* fat and/or other cholesterol-raising lipids 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." (Section 2(b) of Public Law 101-535). Such information might consist of tests of the ability of various footnotes to assist consumers in making product choices or to draw correct inferences about product characteristics. It might also

be useful to know how different footnote statements are comprehended by consumers: whether they are seen as credible, whether they are understood as statements of dietary guidance or as product warning statements or whether they are seen as confusing. As always, we will take into account the adequacy of the sample, sample size, response rates, study design and the representativeness of the products and product comparisons used in the study when we evaluate and/or design a study.

We intend to conduct consumer research of this kind in the near future.

C. Specific Questions to be Considered

Comments are also requested on the following questions:

- How will nutrient content or health claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, change, if at all, the way consumers are likely to respond to the required declaration of the amount of saturated and *trans* fats in the Nutrition Facts Panel?
- Will a claim or a footnote or disclosure statement have an impact on consumers' shopping choices, and, if so, what kinds of products will consumers buy more of and less of?
- Is there any other information, beside claims or a footnote or disclosure statement, that FDA should consider requiring be included in labeling that would be more helpful to consumers with respect to cholesterol-raising lipids in maintaining a healthy diet and in getting accurate and reliable nutrition information, or that would help consumers make better use of the information about cholesterol-raising lipids on the label?

- Since the amount of *trans* fat will be listed in the Nutrition Facts panel right below the amount and %DV of saturated fat, what additional effect will claims or a footnote or disclosure statement about *trans* fat, either alone or in combination with saturated fat and cholesterol, have on the line of products that manufacturers choose to make?
- What kinds of existing products will manufacturers reformulate because of claims or a footnote or disclosure statement?
- What kinds of new products will manufacturers develop because of claims or a footnote or disclosure statement?
- What kinds of products will manufacturers stop producing because of claims or a footnote or disclosure statement?
- What First Amendment issues, if any, would be raised by establishing qualifying criteria for *trans* fat in *trans* fat claims and other nutrient content or health claims with existing criteria for saturated fat and by requiring a footnote or disclosure statement?
- How will manufacturers weigh the consumer concerns about both saturated and *trans* fats with the functional properties of those fats in the food. For example, if, as some manufacturers have claimed, functional considerations may sometimes cause *trans* fat to be replaced with equal or greater amounts of saturated fat, then how will consumers react to such an inappropriate substitution where a product that will list fewer grams of *trans* fat, but will list more grams of saturated fat and report a higher %DV for saturated fat? At what ratio of substitution of saturated fat for *trans* fat would it not be advantageous to a manufacturer to make such a substitution, even with a claim or footnote or disclosure statement? What steps could FDA take to discourage such unhealthful reformulation and encourage healthful

reformulation?

- In order to comply with the Small Business Regulatory Enforcement Fairness Act of 1996, what options for regulatory relief should we consider giving to small businesses?

III. References

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal government holidays.

1. IOM/NAS, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids," National Academy Press, Washington, DC, pp. S1-S17, 8-1 to 8-97, and 11-1 to 11-48, 2002 (Internet address: http://www.nap.edu/books/0309085373/html/).

2. U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Nutrition and Your Health: Dietary Guidelines for Americans*. 5th ed. Washington DC; Home and Garden Bulletin No. 232, 2000 (Internet address: www.health.gov).

3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Chapter II. "Rationale for Intervention" and Chapter V "Adopting Healthful Lifestyle Habits to Lower LDL Cholesterol and Reduce CHD Risk," 2001. (internet address:

http://www.NHLBI.nih.gov/guidelines/cholesterol/index.htm).

4. Committee on Diet and Health, Food and Nutrition Board, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," Chapter 28, Washington, DC, National Academy Press, 1989.

5. Population Panel, National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, "Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, Executive Summary" Bethesda, MD, NIH Publication No. 90-3047, November 1990.

IV. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this document by **[Insert date 3 months after publication in the Federal Register]**. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch reading room between 9 a.m. and 4 p.m., Monday through Friday.

This ANPRM is issued under sections 201, 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, and 371) and under the authority of the Commissioner of Food and Drugs.

Dated:

Signed:.