



DEC 19 2003

Ms. Diana E. Kelly
838 Flin Way
Sunnyvale, CA 94067

Re: Docket No. 2003P-0289/CP1

Dear Ms. Kelly,

This letter is in response to your citizen petition, dated June 2, 2003, requesting that the Food and Drug Administration (FDA) outlaw and completely prohibit the use of hydrogenated and partially hydrogenated fats and other known sources of *trans* fatty acids as intentional ingredients in the preparation, manufacture and processing of food products intended for human consumption. In support of your petition, you cite the National Academy of Sciences/Institute of Medicine (NAS/IOM) report entitled, "Letter Report on Dietary References Intakes for *Trans* Fatty Acids," which you state concludes that "there is a positive linear trend between *trans* fatty acid intake and total and LDL cholesterol concentration, and therefore increased risk of CHD [coronary heart disease], thus suggesting a Tolerable Upper Intake Level (UL) of zero." You further state that the reason that you want FDA to take the requested action is "[b]ecause the Institute of Medicine has determined that there is no safe level of *trans* fatty acids." Finally, you assert that food containing *trans* fatty acids are in a multitude of different food products that can have a cumulative detrimental health effect when consumed over time, that labeling for *trans* fatty acids is totally inadequate, and that there are natural oils and fats available that can substitute for these artificial fats. You emphasize that *trans* fatty acids are not nutrients and eliminating them is necessary to protect the public health, especially the health of children. You provide no data or information, other than a reference to the NAS/IOM report, in support of your petition. We received one comment to the docket on this petition; however, the comment was not relevant to the petition.

In accordance with 21 CFR 10.30(e)(3), this letter is to advise you that FDA is denying, without prejudice, your petition. An explanation of the decision follows. Please note that there may be deficiencies in your petition, other than those discussed, that the agency did not need to reach in making its decision.

While the NAS/IOM recent report on *trans* fatty acids and its summary statement about a linear trend between *trans* fatty acid intake and risk of CHD suggests a Tolerable Upper Intake Level (UL) of zero, the NAS/IOM report also states,

"Because *trans* fatty acids are unavoidable in ordinary diets, achieving such a UL would require extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods, such

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as 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 may be introduced by any extreme adjustments in dietary pattern. For these reasons, no UL is proposed. Nevertheless, it is recommended that *trans* fatty acids consumption be as low as possible while consuming a nutritionally adequate diet." [NAS/IOM report, page 14]

Thus, contrary to what you rely on as the basis to support your petition (i.e., that the IOM determined that there is no safe level of *trans* fat), the NAS/IOM, in its report, has not determined that there is no safe level of *trans* fatty acids. Rather, the NAS/IOM recommends that *trans* fatty acids consumption be "as low as possible while consuming a nutritionally adequate diet." [NAS/IOM report, page 14] In fact, the NAS/IOM expressed concern about the elimination of *trans* fatty acids in the diet due to the extraordinary changes in patterns of dietary intake that would be required and due to the unknown and unquantifiable health risks that may ensue from such extreme adjustments in dietary pattern. [NAS/IOM report, page 14] Therefore, the NAS/IOM report fails to support your assertion that there is no safe level of *trans* fatty acids and fails to support your request that the agency should prohibit the use of hydrogenated and partially hydrogenated fats and other known sources of *trans* fatty acids as intentional ingredients in the preparation, manufacture and processing of food products intended for human consumption. Moreover, you provide no additional data or information in your petition to support such assertion or request.

Further, you state that "labeling for *trans* fatty acids is totally inadequate" and assert that *trans* fatty acids are not a nutrient. You provide no data or information in your petition to support these statements. FDA recently published a final rule entitled "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" on July 11, 2003 (68 FR 41433) (copy enclosed) requiring manufacturers to list *trans* fatty acids on the Nutrition Facts panel of conventional foods and some dietary supplements on a separate line, immediately under the line for saturated fats. We believe this new labeling requirement will better assist consumers in lowering their intake of *trans* fatty acids, as well as saturated fats and cholesterol, which in turn will hopefully reduce the risk of CHD. While scientific reports have confirmed the relationship between *trans* fatty acids and an increased risk of CHD, none has provided a reference value for *trans* fatty acids or any other information that FDA believes is sufficient to establish a Daily Value (DV). Therefore, the % Daily Value (% DV) column in the Nutrition Facts panel will be left blank as it now is when monounsaturated and polyunsaturated fats are listed. If FDA determines in the future that the science is sufficient to support the establishment of a reference value for *trans* fatty acids, FDA will seek to establish a DV at that time.

FDA also issued on July 11, 2003, an advanced notice of proposed rulemaking (ANPRM) entitled "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements" (68 FR 41507) (copy enclosed). This ANPRM may lead to more information that could assist consumers in lowering their intakes of cholesterol raising fats in the diet.

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Finally, you state that "there is no reason not to prohibit the use of hydrogenated and partially hydrogenated fats and oils since there are natural oils and fats available that can substitute for these artificial fats." The mere fact that there are substitute ingredients that may be able to replace *trans* fatty acids in the preparation, manufacture, and processing of food products for human consumption, is not, by itself, a sufficient basis on which the agency can rely to support the prohibition of the use of *trans* fatty acids as a food ingredient. The agency does not prohibit the use of food ingredients that are not natural, simply because there are natural food ingredients that could be used instead.

In summary, while we appreciate your interest in the use and labeling of *trans* fatty acids, you have not provided any data or information in your petition that provides support for your requested action. Therefore, for the reasons discussed above, FDA is denying your petition without prejudice.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John M. Taylor, III", with a long horizontal flourish extending to the right.

John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Enclosures: (2)



Federal Register

Friday,
July 11, 2003

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101
Food Labeling; Trans Fatty Acids in
Nutrition Labeling; Consumer Research to
Consider Nutrient Content and Health
Claims and Possible Footnote or
Disclosure Statements; Final Rule and
Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P-0036]

RIN 0910-AB66

Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (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 immediately under the line for the declaration of saturated fatty acids. This action responds, in part, to a citizen petition from the Center for Science in the Public Interest (CSPI). This rule is intended to provide information to assist consumers in maintaining healthy dietary practices. Those sections of the proposed rule pertaining to the definition of nutrient content claims for the "free" level of *trans* fatty acids and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels are being withdrawn. Further, the agency is withdrawing the proposed requirement to include a footnote stating: "Intake of *trans* fat should be as low as possible." Issues related to the possible use of a footnote statement in conjunction with the *trans* fat label declaration or in the context of certain nutrient content and health claims that contain messages about cholesterol-raising fats in the diet are now the subject of an advance notice of proposed rulemaking (ANPRM) which is published elsewhere in this issue of the **Federal Register**.

DATES: This rule is effective January 1, 2006.

FOR FURTHER INFORMATION CONTACT: Julie Schrimpf, Center for Food Safety and Applied Nutrition (HFS-832), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2373.

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I. Background

A. Nutrition Labeling

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101-535) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide, among other things, that certain nutrients and food components be included in nutrition labeling. Section 403(q)(2)(A) and (q)(2)(B) (21 U.S.C. 343(q)(2)(A) and (q)(2)(B)) of the act state that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) can, by regulation, add or delete nutrients included in the food label or labeling if he or she finds such action

necessary to assist consumers in maintaining healthy dietary practices.

In response to these provisions, in the **Federal Register** of November 27, 1991 (56 FR 60366), FDA published a proposed rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." In that document, the agency proposed to require that foods bear nutrition labeling listing certain nutrients and the amount of those nutrients in a serving of the food. Given the scientific knowledge about *trans* fatty acids at the time, FDA did not propose to require that *trans* fatty acids be listed. However, FDA requested comments on whether the listing of *trans* fatty acids should be voluntary (56 FR 60366 at 60371). (Note: throughout this preamble, FDA has used the term "*trans* fatty acids" and "*trans* fat" interchangeably; likewise, for the terms "saturated fatty acids," and "saturated fat").

In the **Federal Register** of January 6, 1993 (58 FR 2079), FDA issued a final rule implementing the 1990 amendments entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" that prescribes how nutrition labeling is to be provided on foods that are regulated by the agency. In that document, the agency required the declaration of total fat and saturated fat in the nutrition label, with the declaration of both monounsaturated fat and polyunsaturated fat (both defined as the *cis* isomers only) required, when claims are made about fatty acids and cholesterol. Based on its review of the comments, the agency stated that it was premature to include *trans* fatty acids in nutrition labeling because of a lack of agreement on the dietary implications of *trans* fatty acid intake. However, the agency acknowledged that it might be necessary to revisit the labeling of *trans* fatty acids in the future (58 FR 2079 at 2090-2092).

FDA received a citizen petition, dated February 14, 1994, from CSPI (docket number 94P-0036/CP1) stating that an increasing body of evidence suggests that dietary *trans* fatty acids raise blood cholesterol levels, thereby increasing the risk of coronary heart disease (CHD). The petitioner argued that the 1993 final rules implementing the 1990 amendments do not adequately reflect the effect of dietary *trans* fatty acids on CHD and that label values for saturated fat underestimate the total amount of "heart-unhealthy" fats because *trans* fatty acids are not declared. CSPI requested that FDA amend the definition of saturated fat in

§ 101.9(c)(2)(i) (21 CFR 101.9(c)(2)(i)) to include *trans* fatty acids so that the declaration of saturated fat on the nutrition label would provide consumers with complete information on all "heart-unhealthy" fatty acids. In addition, the petitioner requested that all saturated fat claims in § 101.62(c) (21 CFR 101.62(c)), the saturated fat threshold on all cholesterol claims in § 101.62(d), the claims for "lean" and "extra lean" in § 101.62(e), and disqualification and disclosure levels for health and nutrient content claims be amended to reflect the combined levels of saturated and *trans* fatty acids. Further, CSPI requested that FDA: (1) Limit "vegetable oil" claims (e.g., "made with vegetable oil") to foods that are low in both saturated and *trans* fatty acids, and (2) require that "partially hydrogenated" fat be listed on food labels as "partially saturated."

On July 13, 1998, CSPI amended its petition in a way that would maintain the definition of saturated fat in § 101.9(c)(2)(i), yet provide consumers with information on the *trans* fatty acid content of the food. Specifically, CSPI suggested that FDA either: (1) Disclose the sum of *trans* and saturated fats next to the term "saturated fat*" with an asterisk at the bottom of the label that states "contains ___ grams of *trans* fat," or (2) disclose the sum of *trans* and saturated fats next to the term "saturated + *trans* fat" when *trans* fat was present.

In response to CSPI's petition, FDA issued a proposed rule in the **Federal Register** of November 17, 1999 (64 FR 62746), entitled "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims" (hereinafter identified as "the November 1999 proposal"). In that document, FDA proposed to amend its nutrition labeling regulations to require that the amount of *trans* fatty acids in a food, including dietary supplements, be included in the amount and percent Daily Value (%DV) declared for saturated fatty acids, with a footnote indicating the amount of *trans* fatty acids in a serving of the product, when the product contains 0.5 or more grams (g) *trans* fatty acids per serving. FDA reviewed recent research that showed that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum low-density lipoprotein cholesterol (LDL-C), a major risk factor for CHD. The proposed rule was issued to assist consumers in maintaining healthy dietary practices (64 FR 62746 at 62754).

B. Nutrient Content and Health Claims

In the **Federal Register** of November 27, 1991 (56 FR 60478), FDA also published a proposed rule entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food." Although the agency proposed definitions for fat, fatty acid, and cholesterol nutrient content claims, it did not propose a definition for the nutrient content claim "saturated fat free." However, the comments in response to that proposal recommended that FDA define the claim "saturated fat free."

In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA issued a final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food," (hereinafter the "nutrient content claims final rule"). In that rule, the agency stated that it did not set a *trans* fat criterion for most claims because the evidence suggesting that *trans* fatty acids raise serum cholesterol was inconclusive at that time (58 FR 2302 at 2332 and 2340). However, FDA did set a *trans* fat criterion for the "saturated fat free" claim stating that "because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a 'saturated fat free' claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of *trans* fatty acids to bear a 'saturated fat free' claim" (58 FR 2302 at 2332). The *trans* fat criterion for the claim "saturated fat free" was set at a level not to exceed 1 percent of total fat in the food (58 FR 2302 at 2419). The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acids below that level were not reliable (58 FR 2302 at 2332). This action was taken under the authority of section 403(r)(2)(A)(vi) of the act, which prohibits a claim if it is misleading in light of the level of another nutrient in the food.

Some comments that FDA received after publication of the nutrient content claims final rule objected to the 1 percent criterion for *trans* fatty acids in the definition of "saturated fat free." One comment pointed out that a cookie containing 1.5 g of total fat would be allowed to have only 0.015 g of *trans* fatty acids, an amount that could not be

accurately measured. In response to these comments, in the **Federal Register** of August 18, 1993 (58 FR 44020 at 44032), the agency amended the definition of "saturated fat free" to require that a food contain less than 0.5 g of *trans* fatty acids in addition to less than 0.5 g of saturated fat per reference amount customarily consumed (hereinafter referred to as "reference amount") and per labeled serving to be eligible to bear the claim.

In the November 1999 proposal, FDA concluded that dietary *trans* fatty acids have adverse effects on blood cholesterol measures that are predictive of CHD risk (64 FR 62746 at 62754). Consequently, to avoid misleading claims, the agency proposed that the amount of *trans* fatty acids be limited wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. In the November 1999 proposal, the agency did not propose to take action requested by CSPI to amend § 101.65(c)(3) (21 CFR 101.65(c)(3)) to state that "made with vegetable oil" is an implied claim that the product is low in saturated fat and *trans* fats combined (64 FR 62746 at 62762) because the agency proposed to amend nutrient content claims for saturated fat to include a *trans* fatty acid criterion. The agency stated that the proposed amendments to nutrient content claims and the requirements for implied nutrient content claims in § 101.65(c)(3) adequately addressed the petitioner's request.

In addition, in the November 1999 proposal, FDA requested comment on whether "*trans* fat free" claims would help consumers maintain healthy dietary practices and whether they would provide incentive to the food industry to reduce the amount of *trans* fat in the food supply (64 FR 62746 at 62759). FDA proposed a definition for the *trans* fat free claim. FDA concluded that there was no basis for defining "low *trans* fat" without quantitative recommendations for daily intake of *trans* fat. Further, FDA did not define a "reduced *trans* fat" claim because it was concerned that a reduced *trans* fat claim would detract from educational messages that emphasize lower intakes of saturated fat. Persons who believed that a "reduced *trans* fat" claim would be useful were advised to submit a petition under § 101.69 (21 CFR 101.69).

In the November 1999 proposal, FDA proposed to deny CSPI's request that the agency require that "partially hydrogenated" fat be listed as "partially saturated" fat (64 FR 62746 at 62762). Among other reasons, the agency stated that "hydrogenated" and "partially

hydrogenated" are not intended to describe the nutritional properties of the fat or oil. It explained that the purpose of the ingredient statement is to identify the ingredients in a food by listing the common or usual names of each ingredient (64 FR 62746 at 62762–62763).

Comments to the November 1999 proposal requested that the final rule define the nutrient content claim "reduced *trans* fat." Other comments suggested a "reduced saturated fat" claim that would be defined as a reduction of saturated and *trans* fats combined. The agency considered these comments and determined that all interested parties should have an opportunity to comment on whether the final rule should define claims that address reduced levels of *trans* fat. Therefore, FDA reopened the comment period for the November 1999 proposal on December 5, 2000, for a period of 45 days (65 FR 75887) stating that it would consider only comments that addressed "reduced *trans* fat" and "reduced saturated and *trans* fat" claims.

Subsequent to FDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) (Ref. 140) and found, similar to the effect of saturated fat, "a positive linear trend" between *trans* fatty acid intake and total and LDL-C concentrations, and therefore increased risk of CHD. Because *trans* fats are unavoidable in ordinary diets, the IOM/NAS report recommended that "*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Likewise, the conclusions in two other scientific reports, which became available subsequent to the November 1999 proposal, i.e., the Dietary Guidelines for Americans, 2000 (Ref. 88) and guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89), were similar with recommendations to limit *trans* fat intake in the diet. Although the IOM/NAS report (Ref. 140) underscored the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasized that consumers need to limit *trans* fat in their diets, it did not provide a Dietary Reference Intake (DRI) value for *trans* fat or information that FDA believes is sufficient to support the agency's establishing a Daily Reference Value (DRV) or other information on the label, such as a %DV, for *trans* fat.

In response to the recommendations of the new scientific reports to limit the intake of *trans* fat and to provide consumers with label information that may better assist them in understanding the quantitative declaration of *trans* fat in the context of a total daily diet, FDA reopened the comment period of the November 1999 proposal for a period of 30 days (67 FR 69171, November 15, 2002). In that document 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 that is followed by the statement "Intake of *trans* fat should be as low as possible." The agency stated that the statement is taken from the IOM/NAS macronutrient report and is consistent with the dietary guidance in the other recent scientific reports identified in that document (67 FR 69171 at 69172).

In the November 15, 2002, **Federal Register** document to reopen the comment period the agency also stated that it would consider the exercise of its enforcement discretion for those manufacturers who wanted to begin labeling the *trans* fat content of food products prior to publication of the final rule (67 FR 69171 at 69172). The agency cautioned manufacturers that the *trans* fat final rule may differ from what was being proposed in the November 15, 2002, document to reopen the comment period and that manufacturers would then be required to change their labels to conform to the final rule.

C. Comments

FDA received over 1,650 letters in response to the November 1999 proposal, over 45 letters in response to the December 5, 2000, notice reopening the comment period, and over 25 letters in response to the November 15, 2002, proposal and notice to reopen the comment period. Each of these letters contained one or more comments. Responses were received from industry, trade associations, consumers, consumer advocacy organizations, academia, health care professionals, professional societies, city and State governments, other Federal agencies, and other countries. Some of the comments supported the proposal generally or supported aspects of the proposal. Other comments objected to specific provisions and requested revisions. Some comments requested that the proposal be withdrawn or repropose. A few comments addressed issues outside the scope of the proposal and will not be discussed here. On September 18, 2001, the Office of Information and Regulatory Affairs

(OIRA), Office of Management and Budget, sent to the Secretary of the Health and Human Services (the Secretary) a letter requesting that the Secretary and FDA consider giving greater priority to the November 1999 proposal (Ref. 156) in light of the growing body of scientific evidence suggesting that consumption of *trans* fatty acids in foods increases the consumer's risk of developing CHD. The estimated public health benefits from increased consumer awareness of *trans* fat content in foods that were described in FDA's preliminary Regulatory Impact Analysis in the November 1999 proposal, and the subsequent evidence found in more recent studies, strongly support the interests of the Government to lower the incidence of and economic burden of CHD in the United States. This final rule summarizes the relevant comments that were received in response to the November 1999 proposal and provides the agency's conclusions regarding the labeling of *trans* fat on the Nutrition Facts panel.

A summary of the relevant comments that pertain to nutrition labeling of *trans* fat, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. Highlights of the Final Rule

In this final rule and given the current state of scientific knowledge, FDA is requiring the mandatory declaration in the nutrition label of the amount of *trans* fatty acids present in foods, including dietary supplements. The declaration of this nutrient must be on a separate line immediately under the declaration for saturated fat but it will not include a %DV that is required for some of the other mandatory nutrients, such as saturated fat. In addition, the agency is withdrawing those sections of the proposed rule pertaining to the definition of nutrient content claims for "free" and for "reduced" levels of *trans* fatty acids, and limits on the amounts of *trans* fatty acids, wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a footnote stating: "Intake of *trans* fat should be as low as possible."

The action the agency is taking in this final rule is based on its evaluation of comments received in response to the November 1999 proposal, the reopening of the comment period on November 15, 2002, and on scientific evidence that shows that consumption of *trans* fatty acids increases LDL-C, a primary risk factor for CHD. The scientific evidence includes current authoritative reports,

such as Dietary Guidelines 2000 (Ref. 87), that recommend that Americans cut back on *trans* fats when reducing fat intake. The agency concludes that the declaration of this nutrient on a separate line, will help consumers understand that *trans* fat is chemically distinct from saturated fat and will assist them in maintaining healthy dietary practices. The agency intends to promote consumer awareness and understanding of the health effects of *trans* fat as part of an educational program. FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research that potentially could be used to establish new nutrient content claims about *trans* fat, to establish qualifying criteria for *trans* fat in certain nutrient content claims and health claims, and to establish disclosure and disqualifying criteria for *trans* fat. In addition, the ANPRM is soliciting comment 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 consumer's understanding about cholesterol-raising lipids.

III. Legal Authority

General Comments

FDA received a number of comments from trade associations and others in industry asserting that FDA did not meet its burden under the first amendment in proposing to mandate nutrition labeling of *trans* fat. Further, the comments asserted that FDA did not meet its first amendment burden for establishing restrictions on specific claims by virtue of how FDA defined nutrient content claims or established disqualifying and disclosure levels, including the effects that those actions would have on restricting certain health claims on food. In addition, comments raised questions about whether the agency's proposed action was consistent with the Administrative Procedure Act (APA) and whether the agency was acting consistent with its authority under the act.

As stated in section VI of this document, FDA is withdrawing those sections of the rule pertaining to the definition for nutrient content claims that were proposed, and to limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels. Further, the agency is withdrawing the proposed requirement to include a

footnote stating "Intake of *trans* fat should be as low as possible." The agency provides an overview of comments received on these withdrawn sections in section VI of this document, and therefore, is not addressing those comments here. Thus, the agency is addressing only those comments that pertain to legal issues about the agency's action to require mandatory *trans* fat labeling.

A. Statutory Authority

Several comments question whether the agency's proposed requirement for mandatory *trans* fat labeling would prevent consumer deception or would assist consumers in maintaining healthy dietary practices. The comments suggest that the data do not support mandatory *trans* fat labeling, unless the label contains a nutrient content or health claim related to fat or cholesterol or unless polyunsaturated fat or monounsaturated fat is voluntarily declared on the label. Specifically, the comments assert that mandatory *trans* fat labeling in the absence of claims, or statements about other fats, would not assist consumers in following healthy dietary practices or would not prevent consumer deception.

A few comments suggest that there was no basis for concluding any health benefit can be expected from disclosure of *trans* fat levels on foods when present in amounts that have not been clinically shown to have a material impact on human health or disclosure on foods with a trivial contribution of fat.

Another comment argues that the agency could only require mandatory labeling of *trans* fat under the statute where the absence of such labeling constitutes the omission of a material fact under section 201(n) of the act (21 U.S.C. 321(n)), such as when nutrient content claims are made about cholesterol or fatty acids, or when polyunsaturated and monounsaturated fats are voluntarily listed. A related comment suggests that *trans* fat labeling would be appropriate where the declaration of "total fat" and "saturated fat," that did not explicitly include *trans* fat, were established as misleading under section 201(n) of the act (without *trans* fat listed). The comment seems to suggest that the declaration of "total fat" and "saturated fat" in that situation would be misleading if the actual nutrition contribution from *trans* fat that such products make to the diet was greater in comparison to other products. In addition, one comment suggests that mandatory nutrition labeling of *trans* fat can only be "material" where there is sufficient *trans* fat present in the food to significantly impact the overall fatty

acid contribution that the food makes to the diet, such that only having total fat and saturated fat on the label would misrepresent the nutritional value of the product in a material way.

FDA believes it has adequate authority to adopt this rule. FDA's authority under the act to require *trans* fat labeling includes sections 201(n), 403(a)(1) and (q), and 701(a) of the act (21 U.S.C. 371(a)). FDA has authority under section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA can require labeling of certain facts that are material in light of representations made in the labeling or with respect to consequences which may result from the use of the article in order for a product not to be misbranded under sections 201(n) and 403(a) of the act. Further, under section 403(q)(2)(A) of the act, the Secretary (and FDA, by delegation) may require that information relating to a nutrient be in the labeling of food for the purpose of "providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices."

The agency believes that the data in the record supports mandatory *trans* fat labeling to ensure that consumers are not misled and are adequately informed about the product's attributes. Accordingly, FDA believes that mandatory *trans* fat labeling is necessary for foods not to be misbranded under section 403(a) of the act. The absence of information about the content of *trans* fat in foods that are subject to mandatory labeling would constitute an omission of a material fact under section 201(n) of the act.

Under the act, the agency has the mandate to ensure that labeling provides truthful and nonmisleading information to consumers. Thus, the law provides the agency with authority to require specific label statements when needed for reasons other than to ensure the safe use of food. Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act amplifies what is meant by "misleading" in section 403(a)(1) of the act. Section 201(n) of the act states that, in determining whether labeling is misleading, the agency shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of such representations made or suggested in the labeling or material with respect to consequences which may result from use of the article to which the labeling relates under the conditions of use prescribed in the labeling or under such

conditions of use as are customary or usual (see § 1.21 (21 CFR 1.21)). Thus, the omission of certain material facts from the label or labeling of a food causes the product to be misbranded within the meaning of 21 U.S.C. 343(a)(1) and 321(n).

In general, the agency believes the concept of "material fact" is one that must be applied on a case-by-case basis. The agency has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product. For example, although protein products intended for use in weight reduction are not inherently unsafe, FDA requires a warning statement for such products that states, in part, that very low calorie protein diets may cause serious illness or death. Another example of required information is the use of the term "milk derivative" following the ingredient declaration of sodium caseinate when used in a product labeled "non dairy" (21 CFR 101.4(d)).¹

Consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know—and the agency believes is material information that the reasonable consumer should know—the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow consumers to calculate the *trans* fat content by finding the difference between the sum total of all the mandatory fats listed on the label and

the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat is still a "material fact" for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers "to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet" (section 2(b)(1)(A) of Public Law 101-535). Further, foods in which *trans* fat has replaced saturated fat would appear to be heart healthy based on the saturated fat grams listed on the nutrition facts panel, when, in fact, such foods may not be heart healthy due to the large contribution of *trans* fat to the total fat content. Consumers would be misled without having *trans* fat information available on the label. Thus, for the reasons set forth previously, FDA concludes that it is acting within its statutory authority under the act to require *trans* fat labeling.

Moreover, Congress provided the agency with the express authority to add to the list of nutrients on the label under section 403(q)(2)(A) of the act. As stated in section V.A of this document, section 403(q)(2)(A) gives FDA the authority to require that information on additional nutrients be included in nutrition labels if FDA determines that providing such information will assist consumers to maintain healthy dietary practices. Section IV of this document provides ample evidence of the heart unhealthy effects from consumption of *trans* fat over a range of intakes, information the agency believes is material information that the reasonable consumer should know. When scientific evidence supports such labeling, the agency has discretion to determine whether to require the addition of a particular nutrient to the label of food products. Thus, the agency is well within its statutory authority for requiring mandatory labeling of *trans* fat and is not limited to requiring such information only when certain claims are made or only when other fats are listed on the label.

Further, the agency disagrees with the comments that assert that mandatory *trans* fat labeling would not assist consumers to maintain healthy dietary practices, unless the label also carries a nutrient content or health claim or

information about other fats. The agency also disagrees with comments suggesting that there is no basis for concluding any health benefit can be expected from disclosure of *trans* fat if foods contain a trivial amount of *trans* fat or if *trans* fat is not present in amounts that have not been clinically shown to adversely affect human health.

The agency is exercising the discretion that Congress gave it in the 1990 amendments to include *trans* fat as a mandatory nutrient in food labeling, based on the state of the scientific evidence on the increased LDL-C levels from intake of *trans* fat (see section IV of this document). The scheme that Congress established would require all mandatory nutrients be listed on the food label, including those that the agency determines are necessary under section 403(q)(2)(A) of the act. Congress wanted one uniform statutory scheme for food labeling and discussed the importance of maintaining consistency in the format and content of the food label to "help all consumers to better understand and improve their eating habits by providing uniform information in a coherent and understandable format." (136 Cong. Rec. S 16607 at 16609 (statement of Senator Metzenbaum)). The statute does not require other mandatory nutrients to be listed, for example, saturated fat, only when monounsaturated and polyunsaturated fat are voluntarily listed. Mandatory nutrients are listed for each food that bears a nutrition facts panel. Food that bears a nutrition label must contain certain required nutrients as part of that label to not be misbranded.

Further, section 403(q)(2)(A) provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. Consumers would have information on the amount of *trans* fat in a product, along with other information about the amount of saturated fat and cholesterol. Consumers could use information about all three fats, not just saturated fat and

¹ FDA's regulation regarding the failure to reveal material facts (§ 1.21) states that "affirmative disclosure of material facts * * * may be required, among other appropriate regulatory procedures, by * * * regulations in this chapter promulgated pursuant to section 701(a) of the act; or direct court enforcement action (emphasis added)." Thus, establishing a requirement for mandatory *trans* fat labeling is consistent with § 1.21.

cholesterol, to incorporate nutrition education information about recommended contributions for all three fats to the diet when making healthier food choices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and there is a new and strong consensus among the scientific community for reducing *trans* fat intake. Thus, the agency believes it is within the bounds of its statutory authority under section 403(q)(2)(A) of the act to require the listing of *trans* fat on the food label, which listing is not dependent on the presence of claims or other voluntary fat information.

B. The First Amendment

Several general comments were received asserting that the agency's action to mandate labeling is subject to review under the first amendment. The comments assert that mandatory labeling of *trans* fat is commercial speech, and thus, such speech is entitled to the full range of first amendment protections as all commercial speech (citing to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)). The comments further assert that "compelled speech" is entitled to the same protections as speech "bans," (citing to *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 477 U.S. 557 at 566 (1980)). One comment explained that the court in *Pearson* emphasized that the first amendment does not allow FDA to restrict truthful, nonmisleading information as a "paternalistic" means of directing consumer food choices (164 F.3d at 656 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350 at 377(1977) ("[W]e view as dubious any justification that is based on the benefits of public ignorance.")); 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J. joined by Kennedy, J., and Ginsburg, J.) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.")). The comment further cited several cases for the proposition that the government cannot compel speech when disclosures are not necessary to materially alleviate real consumer harm (citing to *IDFA v. Amestoy*, 92 F.3d 67, 73 (2nd Cir. 1996); *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136 (1994); and *Edenfield v. Fane*, 507 U.S. 761 (1993)). Another comment suggests that the agency needed to consider the limitations imposed by the first amendment to avoid unjustified burdens and costs on food labeling where there is no genuine

public health benefit from a rule that does not materially alleviate a genuine harm of potential consumer deception.

Some comments assert that FDA's proposal to mandate *trans* fat labeling does not remedy a concrete harm as required by the first amendment. One comment suggests that a *trans* fat labeling rule could be supported if carefully crafted to remedy consumer deception but not where risk of consumer deception cannot be established as a genuine harm. Other comments state that FDA did not tailor its approach to labeling and would be requiring mandatory labeling of *trans* fat for foods containing as little as 0.5 g *trans* fat, which would not alleviate a genuine harm. The comment seems to further suggest that including *trans* fat in the total fat content on the label would be sufficiently tailored to alleviate a genuine harm. Another comment states that there is mere speculation in the record that providing information on *trans* fat would assist consumers to maintain healthy dietary practices, and thus, is not narrowly tailored to materially alleviate a genuine harm.

A few comments state that treating *trans* fats the same as saturated fat on labeling would be the same as proposing to require false information on labels. Such an outcome, the comments state, would be indefensible on Constitutional grounds. One comment states that mandatory declaration of *trans* fat can only be justified under constitutional provisions when the absence of such declaration would constitute an omission of a material fact.

FDA believes that this regulation is consistent with the first amendment. As noted previously, the failure to disclose the amount of *trans* fat in a product is an omission of material fact. When a manufacturer makes explicit or implicit health claims, the failure to provide *trans* fat information is likely to mislead the consumer. Moreover, the reasonable consumer would expect that the information on the label would give them the most important nutrition information relative to the healthfulness of a product. Yet the omission of *trans* fat runs counter to that expectation, impeding rational consumer choice. As the agency has explained earlier, consumers need information about *trans* fat on all foods, not just those that contain a certain threshold level of *trans* fat, to reduce overall intake of *trans* fat in the diet. Consumers can use that information to compare products and make selections that can reduce their risk of CHD.

Accordingly, FDA believes that this final rule passes muster under the four-

part test in *Central Hudson* primarily because, as discussed previously, requiring the factual information on the amount of *trans* fat in labeling ensures that the label is not false or misleading. Under the first prong of *Central Hudson*, commercial speech must be related to lawful activity and not be misleading. Speech that is false or misleading is not protected and may be prohibited (*Central Hudson*, 447 U.S. 557 at 563-564).²

Given this determination, arguably the agency need not address the other three parts of the *Central Hudson* test at all. Nonetheless, and particularly in light of FDA's showing that such information is important to ensuring that consumers are adequately informed about the products they are buying, the proposed requirement satisfies the next three prongs. Turning to the second prong, the asserted governmental interest must be substantial. FDA's interest is clearly substantial, for at least two reasons. As noted previously, the FDA has a substantial interest in protecting and promoting public health and in preventing consumer deception by ensuring the accuracy and completeness of *trans* fat information in labeling. (See *Pearson*, 164 F.3d at 656.) The food labeling regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, and not misleading. (58 Fed. Reg. 2478, 2526 (1993)). Consumers have a first amendment interest in obtaining information on which to base a decision, particularly one that has health consequences, regarding whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." (*National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978)).

Moreover, FDA has a substantial governmental interest in assisting consumers to maintain healthy dietary practices. Such interest is consistent with the purpose of section 403(q)(2)(A) of the act; to provide information to consumers on nutrients (*trans* fat content of food) when such information is of public health importance. The government is not confined to asserting a substantial government interest in preventing consumer deception for a regulation before that regulation can sustain a first amendment review (*Rubin v. Coors Brewing Co.*, 514 U.S.476, 484-

² The agency does not need to address the comments that asserted that proposing to treat *trans* fat the same as saturated fat in the November 1999 proposal would be the same as requiring false labeling. Since the agency is requiring separate line labeling in this final rule, those comments are moot.

85 (1995) (finding that the protection of the health, safety, and welfare of citizens is a substantial government interest). In fact, FDA's interest in this rule includes an interest in ensuring consumers have information they need to help them maintain healthy dietary practices by providing factual information to consumers on food labels so that they can reduce CHD risk.

Under the third prong of *Central Hudson*, the regulation must directly advance the government's interest asserted (*Central Hudson* 447 U.S. 557 at 566). Requiring mandatory *trans* fat labeling on food products directly advances the government interest. As stated in section V.A of this document, analyses of survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. The most frequently reported label use and the one that increased the most following the implementation of the 1990 amendments was to see how high the food was in nutrients such as fat. Mandatory *trans* fat labeling would help consumers maintain healthy dietary practices because it would provide needed information about the amount of *trans* fat in a given product so that consumers could plan a daily diet in a way that would reduce their intake of *trans* fat. Further, as stated in section V.A of this document, consumers need to be able to see the *trans* fat content of all foods subject to mandatory labeling so that they can compare the relative contribution of *trans* fat from each and make purchasing decisions accordingly.

Finally, under the fourth prong of *Central Hudson*, the regulation must be no more extensive than necessary to serve the government interest (*Central Hudson* 447 U.S. 557 at 566). That is the case here. Given, as stated in section V.A, that consumers need to understand the relative contribution of *trans* fat from all foods subject to mandatory labeling to make choices among products that will reduce their intake of *trans* fat, there are not "numerous and obvious less-burdensome alternatives" (*Cincinnati v. Discovery Network*, 507 U.S. 410, 418 n.13 (1993)) than the requirement imposed here. Imparting truthful, factual, noncontroversial information about the presence or absence and amount of *trans* fat in food products on the label will provide consumers with information to help them to reduce their risk of CHD. Thus, the agency's action to require factual information be imparted to consumers about *trans* fat content of foods by requiring such information in labeling is sufficiently narrowly tailored to meet the fourth prong of *Central Hudson*. The

"government is not required to employ the least restrictive means conceivable" rather it is required to have "'a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served'" (*Greater New Orleans Broadcasting Ass'n, Inc. v. U.S.*, 527 U.S. 173 at 177 (citing *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989))). Requiring disclosure of *trans* fat content would assist consumers to maintain healthy dietary practices, provide complete, factual information on a food label to help them to reduce *trans* fat intake and thereby reduce their risk of CHD. Further, it would prevent them from being misled by providing information on *trans* fat that can help them make product comparisons and choose products that are heart healthy.

The agency disagrees with the suggestion that narrow tailoring under the fourth prong of *Central Hudson* requires that *trans* fat content be included in the figure for total fat content. Such an approach would not provide consumers with labeling information on the amount of *trans* fat in a product. To provide consumers with a way to calculate the amount of *trans* fat in a product, all other fats (including monounsaturated and polyunsaturated fats) would be required to be on the label. The comment provided no basis for why monounsaturated fat and polyunsaturated fat should be made mandatory, why it would make sense for consumers to have to calculate the value for *trans* fat content from each label under the statutory scheme in section 403(q)(2)(A) of the act, and why such an approach would be less burdensome under the fourth prong of *Central Hudson* to support its assertion.

Moreover, there is a substantial argument that the agency need not satisfy the *Central Hudson* test because that test applies to prohibitions on speech, and not compelled commercial speech, which is at issue here. Although consumer curiosity alone is an insufficient interest to compel factual speech (*International Dairy Foods Ass'n v. Amestoy*, 92 F. 3d 67, 74 (2nd Cir. 1996)), the government can compel manufacturers to disclose information that "bears on a reasonable concern for human health or safety or some other sufficiently substantial government concern." *Id.* FDA's rule to require mandatory *trans* fat labeling is one that would require manufacturers to disclose such information.

Further, the U.S. Court of Appeals for the second circuit upheld a regulation

compelling speech where the goal of the statute was to reduce the amount of mercury released into the environment: a goal that was "inextricably intertwined with the goal of increasing consumer awareness of the presence of mercury in a variety of products" (*National Electrical Manufacturer's Ass'n v. Sorrell*, 272 F. 3d 104, 115 (2d Cir. 2001)). FDA is providing information that will assist consumers to maintain healthy dietary practices and prevent consumers from being misled if incomplete nutrition information on *trans* fat were provided on the food label, i.e., information that did not include the presence or amount of *trans* fat in foods. Similar to the goal the State of Vermont has in increasing awareness of consumers to prevent the harmful consequences of mercury containing products entering the environment, FDA wants to prevent the harmful consequences (increased risk of CHD) to consumers from *trans* fats. Thus, the agency's action to require *trans* fat labeling in this rule comports with similar actions in other compelled commercial speech cases which have been upheld under the first amendment.

For all of the foregoing reasons, the agency believes it has complied with its burdens under the first amendment to support mandatory disclosure of the amount of *trans* fat in food labeling. The information that FDA is requiring in food labeling for *trans* fat, i.e., the amount of *trans* fat listed in grams or an optional footnote stating "Not a significant source of *trans* fat" if zero grams are present, is purely factual information. FDA's action to compel *trans* fat labeling does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by word or act their faith therein." Rather, it simply provides for factual and uncontroversial information that can be supported if such labeling is reasonably related to FDA's government interests (*Zauderer*, 471 U.S. at 650-51 (distinguishing between the level of review necessary under the first amendment where factual and uncontroversial information is required and recognizing that the constitutionally protected interest in not providing such information is minimal); see also *Glickman v. Wileman Brothers & Elliott, Inc.*, 521 U.S. 457, 472 (1997) (distinguishing compelled financial contributions that promote speech to encourage consumer purchases from speech in which the content of the message focuses on political or ideological differences). FDA's interests in requiring mandatory *trans* fat labeling

is to protect the public health by providing consumers with information that will assist them in maintaining healthy dietary practices and by preventing misleading labeling by providing factual, truthful, and noncontroversial information.

Providing information to consumers about the *trans* fat content of foods on food labeling is reasonably related to the agency's interest of assisting consumers to maintain healthy dietary practices. As explained in section IV of this document, there is a relationship between the level of *trans* fat in the diet and risk of CHD. To reduce this risk, consumers need information about the level of *trans* fat in food products. The agency has evidence that consumers refer to product labels when purchasing food products and use labels to determine how much fat is in a product (Ref. 96). Thus, by requiring that *trans* fat information be on a food label, the agency will be assisting consumers in making food purchasing decisions that can result in a reduction in *trans* fat intake so that they can reduce their risk of CHD. Moreover, because the presence or absence of *trans* fat is a material fact under section 201(n) of the act, as explained earlier, mandatory labeling that provides information about the presence or absence of *trans* fat, and if present, at what levels, is a reasonable means for imparting full, factual information to consumers so that they will not be misled in purchasing decisions because they have no information about *trans* fat content and may not even be able to calculate it based on information on other fats on the label.

The agency has carefully considered the limitations imposed by the first amendment to avoid unjustified burdens and costs of food labeling where there is no genuine public health benefit from the rule that does not alleviate a harm of potential consumer deception. The agency did carefully calculate the costs and benefits of food labeling (see section IX of this document) and determined that the scope of mandatory *trans* fat labeling was in proportion to the government interest served. *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (stating that a regulation "should indicate that its proponent 'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition" (quoting *Fox*, 492 U.S. at 480)). Moreover, the agency has documented that there is a public health benefit to the final rule. To the extent that those who commented "believe that their money is not being well spent, 'does not mean

that they have first amendment complaint.'" *Glickman*, 521 U.S. at 472.

Administrative Procedure Act

One comment asserts that FDA must adopt regulations that are supported by the rulemaking record and that are not otherwise arbitrary and capricious in light of the statutory limitations on the agency's authority. This comment and another assert that the data do not support a basis for treating *trans* fat and saturated fat the same either chemically or for purposes of one's health, and that therefore, FDA is proposing to require food labels that provide false information. One comment said that to equate *trans* fat and saturated fat on the existing body of evidence would be arbitrary and capricious in violation of the APA. Another comment asserts that FDA did not account for legal and policy considerations that are necessary to construct an appropriate *trans* fat regulatory framework and thus, does not have a rulemaking record that satisfies the agency's burden of proof under the APA. The comment seemed to relate deficiencies in the record necessary to satisfy first amendment requirements to a failure to satisfy APA requirements. One comment asserts that the rulemaking record for FDA's proposal does not support the expansive scope of the mandatory *trans* fat labeling proposal, and therefore, fails to satisfy the requirements of the APA. The comment states that the body of scientific evidence did not establish a genuine "harm" from *trans* fat consumed at ordinary intake levels from foods that would be subject to the mandatory labeling requirements.

To the extent that comments were raising concerns about the agency going to a final rule based on including *trans* fat in the amount and % DV for saturated fat and that doing so would be the same as requiring false information on labels, those comments are now moot since the agency is requiring a separate line for labeling *trans* fat. FDA disagrees with the comment that suggests that FDA did not account for legal and policy considerations necessary to construct an appropriate *trans* fat regulatory framework, and that the rulemaking record does not support the scope of this rule. As stated previously, the agency is using the statutory framework that Congress provided in section 403(q)(2)(A) of the act to require mandatory *trans* fat labeling. Further, the agency has explained its rationale, based on the science, for why it believes that it is necessary for consumers to have information on the *trans* fat content of foods to maintain healthy dietary practices. To the extent that the

comments assert that the body of scientific evidence did not establish a "harm" from *trans* fat consumed at ordinary intake levels from foods, and thus, would preclude the agency from requiring mandatory *trans* fat labeling under the APA, the agency disagrees. The science supports adverse health effects from consumption of *trans* fat among a range of intakes that includes intakes at average intake levels among the U.S. population (see section IV of this document). That said, mandating the disclosure of this information does not require FDA to find that *trans* fatty acids actually cause CHD. In mandating the disclosure of this information, FDA need not meet the standard of proof required to establish causation in a private tort action (*Glatetter v. Novartis Pharmaceutical Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)).

"The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50 percent) is required since the law believes it is unfair to require an individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it * * *."

In re "Agent Orange" Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y.) 1984), *aff'd* 818 F. 2d 145 (2d Cir. 1987). In making its decision, the agency follows "the preventive perspective that agencies adopt in order to reduce public exposure to harmful substances." *Glatetter*, 252 F. 3d at 991, quoting *Hollander v. Sandoz Pharmaceuticals Corp.*, 95 F. Supp. 2d 1230, 1234 n.9 (W.D. Okla. 2000). Accordingly, so long as we conclude that the consumer would reasonably expect this information to be disclosed and that it is scientifically justifiable to require its disclosure, we are justified in taking this action.

The agency has determined, based on this scientific evidence, that consumers need this information to maintain healthy dietary practices. Thus, the agency is not precluded under the APA, as the comment suggests, from issuing this final rule. In addition, the agency has discussed why it believes that this final rule comports with the first amendment, and thus, disagrees with the comment that suggests that because it did not meet its burdens under the first amendment, it did not satisfy the APA requirements.

IV. Review of the Science

A. Reviews by the Federal Government and the Institute of Medicine (IOM)/National Academy of Sciences (NAS)

In the November 1999 proposal, FDA reviewed reports published by the U.S. Federal government and the IOM/NAS. These reports, which were published between 1988 and 1995, showed that conclusions about the role of *trans* fat in raising LDL-C, the primary risk factor for CHD, and dietary recommendations were evolving as results from new studies became available (64 FR 62746 at 62749). For example, the 1988 Surgeon General's Report (Ref. 2) and the 1989 IOM/NAS Report (Ref. 4) found no adverse effects of *trans* fat. Later, the 1993 publication from the NCEP stated that "*trans* fatty acids raise LDL-C levels nearly as much as do cholesterol-raising saturated fatty acids" (Ref. 5). The fourth edition of Dietary Guidelines for Americans, a joint 1995 publication from the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA) stated that, "Partially hydrogenated vegetable oils, such as those used in many margarines and shortenings, contain a particular form of unsaturated fat known as *trans*-fatty acids that may raise blood cholesterol levels to a similar extent as saturated fat" (Ref. 6).

Subsequent to the November 1999 proposal, new expert panels have been convened to update, in light of new scientific evidence, the conclusions and recommendations in the reports discussed previously. FDA has reviewed these new reports to evaluate whether their updated conclusions reversed or significantly altered its earlier conclusions.

The Dietary Guidelines 2000 (Ref. 87) makes the following statements regarding *trans* fatty acids and food sources of *trans* fat:

Foods high in *trans* fatty acids tend to raise blood cholesterol. These foods include those high in partially hydrogenated vegetable oils, such as many hard margarines and shortenings. Foods with a high amount of these ingredients include some commercially fried foods and some bakery goods. (Ref. 87, p. 28);

Aim for a total fat intake of no more than 30 percent of calories, as recommended in previous editions of the Guidelines. If you need to reduce your fat intake to achieve this level, do so primarily by cutting back on saturated and *trans* fats. (Ref. 87, p. 30);

Limit use of solid fats, such as ... hard margarines, ... and partially hydrogenated shortenings. Use vegetable oil as a substitute. (Ref. 87, p. 30).

In the report describing the basis for its recommendations, the Advisory Committee on Dietary Guidelines 2000 (Ref. 88) suggested that information be

provided to help the reader of the Dietary Guidelines 2000 distinguish among the different kinds of fats—saturated, *trans*, and unsaturated. The advisory committee summarized the scientific evidence on *trans* fatty acids as follows:

Trans fatty acids are included because a definitive body of recent experimental evidence indicates that *trans* fatty acids raise the concentration of the most dangerous form of serum cholesterol (LDL-cholesterol).

The advisory committee further states: *Trans* fatty acids also tend to lower a protective form of serum cholesterol (HDL-cholesterol). Prospective epidemiological studies further note that higher intakes of *trans* fatty acids are associated with a higher incidence of coronary heart disease. (Ref. 88, p. 37).

Recent guidelines from the National Cholesterol Education Program (NCEP) (Ref. 89) provide an update to the 1993 NCEP report (Ref. 5). The 2001 NCEP report is an evidence-based report that extensively references the scientific literature. The expert panel concluded that:

Trans fatty acids raise serum LDL-cholesterol levels. Through this mechanism, higher intakes of *trans* fatty acids thus should increase risk for CHD. Prospective studies support an association between higher intakes of *trans* fatty acids and CHD risk. (Ref. 89, p. 15).

Based on the scientific evidence, the expert panel recommends that individuals at increased risk for CHD that:

Intakes of *trans* fatty acids should be kept low. The use of hard vegetable oil, soft margarine, and *trans*-free and *trans*-free margarine are encouraged instead of butter, stick margarine, and shortening. (Ref. 89, p. V-15).

Lastly, a recent report of the IOM/NAS found "a positive linear trend between *trans* fatty acid intake and LDL cholesterol concentration, and therefore increased risk of CHD" (Ref. 140). The report summarized that this would suggest a Tolerable Upper Intake Level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended "that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet."

In summary, the recently updated Dietary Guidelines (Ref. 87), NCEP (Ref. 89), and IOM/NAS (Ref. 140) reports, based on current scientific evidence, consistently find that *trans* fatty acids are associated with increased LDL-C levels and, therefore, that lower intakes of both saturated and *trans* fatty acids are important dietary factors in reducing

the risk of CHD in the general population and for those at increased risk for CHD. In addition, these new reports (Refs. 87, 89, and 140) either reversed previous scientific conclusions of no deleterious effects of *trans* fatty acids (Refs. 2 and 4), or strengthened previous scientific conclusions of an adverse effect of *trans* fat intakes on CHD risk (Refs. 5 and 6). Thus, based on the current body of scientific evidence, there is strong agreement among the expert panels that the available evidence is sufficiently compelling to conclude that *trans* fat intakes increase CHD risk. Accordingly, these expert panels recommended, in addition to their longstanding recommendations that Americans consume diets limited in saturated fat, that consumers also select food products that are low in *trans* fat. Although the expert panels' primary emphases remain on limiting intakes of saturated fat (which contributes on average about 11–12 percent of calories in U.S. diets), they also have recommended limiting intakes of *trans* fats (which contribute, on average, about 3 percent of calories in U.S. diets). These recommendations are made for the general population (Refs. 87 and 140) and people at increased risk for CHD (Ref. 89). The expert panels also recommended that:

Based on the scientific evidence, the expert panels recommend whether the conclusions regarding *trans* fat would be supported by pending scientific reviews. Some of these comments recommended that FDA not issue a final rule until after publication of Dietary Guidelines 2000. Other comments recommended waiting until the IOM/NAS completes work on a review of dietary reference values for macronutrients.

The Dietary Guidelines 2000 have been published (Refs. 87 and 88). While they do not mention *trans* fat in its broad guideline, "Choose a diet that is low in saturated fat and cholesterol and moderate in total fat," the recommendations from the Dietary Guidelines 2000 and the accompanying advisory committee review clearly state that foods high in *trans* fatty acids tend to raise blood LDL-C which increases the risk of CHD. Reductions in intakes of both saturated and *trans* fats are suggested for maintaining total fat to no more than 30 percent of calories. Substitutions of foods low in *trans* and saturated fatty acids (e.g., vegetable oils) for foods with higher levels of *trans* fatty acids (e.g., hard margarines, partially hydrogenated shortenings) are also recommended. Thus, in the Dietary Guidelines 2000, the recommendations to reduce *trans* fat intake are definitive,

not tentative. Additionally, the recommendations in the Dietary Guidelines 2000 are reinforced by similar findings and recommendations from other recent expert panels (Refs. 89 through 91, and 140), including those of the IOM/NAS report on macronutrients (Ref. 140), which has also been published. The IOM/NAS report recommends that “*trans* fat consumption be as low as possible while consuming a nutritionally adequate diet.”

(Comment 2) One comment suggested that *trans* fat is a healthier choice than saturated fat, quoting 1994 and 1998 statements that it attributed to the American Heart Association (AHA) recommending that margarine be used instead of butter and that *trans* fats displace saturated fats in the diet. The comment suggested that, if AHA or others in the scientific community recommend margarine be used instead of butter, this establishes that hydrogenated vegetable oils and *trans* fats are a healthier choice, at least in comparison to saturated fatty acids. Several other comments stated that *trans* fats displace saturated fats in the diet, but also stated that they are

not a healthier choice because they are not substituted for saturated fats. The comment also stated that the AHA provides a basis for concluding that *trans* fat has health benefits or is a healthier choice than saturated fats. The AHA guidelines (64 FR 62746 at 62752) (Ref. 91) recommend that intakes of foods with a high content of cholesterol-raising fatty acids (i.e., *trans* and saturated fats) be limited because both raise serum LDL-C levels, and consequently, increase CHD risk. Specifically, the AHA recommends limiting the intake of: (1) Foods rich in saturated fatty acids (e.g., full-fat dairy products, fatty meats, tropical oils), and (2) *trans*-fatty acids, the major contributor of which is hydrogenated fat (Ref. 91). Relative to *trans* fat, the 2000 AHA guidelines state that, “It has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol” (Ref. 91). Moreover, the AHA recommendations are consistent with the recommendations of the other scientific bodies described earlier in this document. All of these reports recommend substituting vegetable oils for animal fats; and, within the vegetable oil category, recommend selecting those products that are lower in or free of *trans* fat (e.g., liquid vegetable oils, soft margarines, and *trans*-free margarines) in place of more

hydrogenated oil products (e.g., stick margarines and shortenings). More recently, the IOM/NAS concluded that there is no evidence of health benefits associated with *trans* fat intakes, but that *trans* fat does increase LDL-C and, therefore, the risk of CHD (Ref. 140). Thus, the comment’s premise that the current recommendations of the AHA and other scientific bodies support the conclusion that *trans* fat is a healthful alternative to butter and animal fats is not consistent with, nor supported by, the full context and intent of recommendations by the AHA and other scientific bodies.

Those comments that said *trans* fat is a healthful alternative to saturated fat also are not consistent with the recommendations of the AHA and other scientific bodies. These expert bodies all concluded that both *trans* and saturated fatty acids increase the risk of CHD by increasing serum LDL-C levels and, therefore, they recommended limiting intakes of both *trans* and saturated fats.

It should be noted that recommendations to consume margarine instead of butter are based on the fact that the combined amount of

cholesterol-raising effects of both

R. Published Studies

The November 1999 proposal stated that *trans* fat increases the risk of CHD (64 FR 62746 at 62752). FDA reviewed the scientific evidence cited in the petition and recent human studies from its own literature search. In the November 1999 proposal, FDA summarized its review of the findings of intervention and observational studies on the relationship between intakes of *trans* fatty acids and CHD (64 FR 62746 at 62749–62754). FDA considered the findings from human studies to constitute evidence that is more directly relevant and persuasive than findings from animal studies. FDA gave greater weight to results from dietary intervention studies than to observational (epidemiological) studies because of an intervention study’s ability to provide evidence for a cause-effect relationship. FDA regarded results from observational studies as indirect evidence for a relationship between *trans* fatty acid intake and CHD risk. FDA also reviewed estimates of dietary intakes of *trans* fatty acids in the U.S. population (64 FR 62746 at 62752–62753).

In the November 1999 proposal, FDA evaluated results of 12 dietary

intervention studies (Refs. 7 through 15, 34, 36, and 82). FDA focused on the physiological measures of serum and plasma LDL-C concentrations to evaluate whether *trans* fatty acid intakes influence the risk of CHD because such measures are recognized as valid predictors of increased risk for CHD (Ref. 5). FDA concluded that controlled intervention studies, in different population groups in the United States and other countries, consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL-C (a major risk factor for CHD) compared with consumption of diets containing *cis*-monounsaturated or *cis*-polyunsaturated fat sources (64 FR 62746 at 62753). The agency also compiled reports of changes in serum total and high density lipoprotein cholesterol (HDL-C) and serum lipoproteins to present a more complete picture of serum lipid changes (64 FR 62746 at 62753).

In addition, FDA also reviewed nine publications that examined associations between *trans* fatty acids, serum lipids and CHD (64 FR 62746 at 62753). These publications describing

cross-sectional studies, including one and one publication describing a cross-sectional study (Ref. 23). FDA stated that these epidemiological

studies on the relationship between dietary *trans* fatty acids and risk of CHD must be interpreted cautiously because of the imprecision associated with the dietary collection methodologies used, the difficulty of eliminating confounding factors, and because no dose-response relationship has been demonstrated in the studies (64 FR 62746 at 62752). FDA also stated that despite these generally recognized deficiencies in the observational studies, the repeated and consistent findings from these studies show that consumption of *trans* fatty acids is associated with adverse effects on CHD risk in humans, which supports the findings from intervention studies (64 FR 62746 at 62752).

Thus, in the November 1999 proposal, FDA concluded that controlled intervention studies in different population groups in the United States and other countries consistently indicate that consumption of diets containing *trans* fatty acids, like diets containing saturated fats, results in increased serum LDL-C compared with consumption of diets containing *cis*-monounsaturated or *cis*-polyunsaturated

fat sources (64 FR 62746 at 62753). FDA also concluded that these findings are consonant with findings from observational studies among free-living persons in the United States and other countries (64 FR 62746 at 62753).

In the November 1999 proposal, FDA also summarized the results of estimates of dietary intake of *trans* fatty acids in the U.S. population (64 FR 62746 at 62752). FDA noted that estimates of mean consumption of *trans* fatty acids in the United States ranged from about 3 g/day to about 13 g/day. Based on national food disappearance data, estimated mean values for the daily per capita consumption of total *trans* fatty acids were variable: 12.8 g/day (Ref. 24), 10.2 g/day (Ref. 39), and 8.1 g/day (Ref. 25). Based on a nationally representative sample of the U.S. population, the estimated mean intake of *trans* fatty acids was 5.3 g/day (2.6 percent of calories) and the 90th percentile intake was 9.4 g/day for individuals 3 years of age and older in the U.S. population (Ref. 12). Estimates of mean *trans* fatty acids intake were 4.4 g/day for men and 3.6 g/day for women in one observational study in the United States (Ref. 19). In another study, the mean intakes of *trans* fatty acids were 3.1 g/day for men and 3.0 g/day for women in the lowest quintile and 6.7 g/day for men and 6.8 g/day for women in the highest quintile (Ref. 16). Another study reported intakes of 1.5 g/day and 5.3 g/day, respectively, for the lowest and highest quintiles of male health professionals (Ref. 19). For female nurses in the United States, mean energy-adjusted intakes of *trans* fatty acids were 2.4 and 5.7 g/day, respectively for the lowest and highest quintiles of *trans* fatty acid intakes (Ref. 21). FDA concluded that, overall, the estimates of mean *trans* fatty acids intakes are similar to intakes of *trans* fatty acids in the U.S. intervention studies (the selected intervention studies used in this comparison were those in which *trans* fatty acid contents were determined by chemical analysis of duplicate portions of the diets and for which statistically significant increases in serum LDL-C were reported compared to diets containing *cis*-polyunsaturated fatty acids (Refs. 13, 34, and 82) or *cis*-monounsaturated fatty acids (Ref. 12)). The intakes of *trans* fatty acids for which the increases in serum LDL-C were statistically significant in the intervention studies ranged from 7.6 g/day to 13 g/day (Refs. 12, 13, 34, and 82). FDA stated that these levels are very similar to the

estimated intakes of the many individuals in the United States whose *trans* fatty acid intake is greater than the mean of 5.3 g/day (64 FR 62746 at 62753).

Subsequent to the November 1999 proposal, additional studies on the topic of *trans* fatty acid intakes and CHD risk have been published (Refs. 98 through 102). FDA reviewed the findings from these new studies to evaluate whether they differ significantly from the findings of studies included in the proposed rule. In general, the results from these recently published intervention and prospective studies are consistent with the results from the studies included in the November 1999 proposal in that they also found that diets containing *trans* fat increased LDL-C, and therefore, CHD risk (Refs. 98 to 101) and that, in free-living populations, consumption of *trans* fat was associated with increased risk of heart attack and death from CHD (Ref. 102). In addition, a cross-sectional observational study has been published (Ref. 93). This study, which was the subject of several comments, suggests no relationship between current intakes of *trans* fat in European countries and CHD risk (Ref. 93). Comments on the November 15, 2002, proposal questioned the scientific evidence for establishing whether *trans* fatty acids adversely affect CHD risk by raising LDL-C levels. A number of comments found the evidence to be inconclusive regarding the need for labeling on foods. Other comments questioned whether there was sufficient evidence to warrant labeling of *trans* fat content. Several comments stated that the health impact of the intake levels reported in population-based surveys and observational studies was minimal.

A few comments to the November 15, 2002, proposal to reopen the *trans* fat comment period questioned the scientific validity of the IOM/NAS report based on the underlying science and regression equations relied upon. The comments argued that one of the articles relied upon (Ref. 83) was an opinion essay and was not peer-reviewed by the *New England Journal of Medicine* (NEJM) where it was published.

Based on an evaluation of the scientific evidence, FDA concludes that the scientific evidence is sufficient to require nutrition labeling of *trans* fat. In the November 1999 proposal, FDA systematically summarized and reviewed the available individual human studies (64 FR at 62749–62754 and 62798 to 62821). In re-examining this review in light of the comments,

FDA finds no basis to alter its earlier conclusion that, in general, there is consistency in finding adverse effects of *trans* fat on CHD risk. Controlled intervention studies in different population groups in the United States and other countries consistently indicated that consumption of diets containing *trans* fat results in elevations of LDL-C, and therefore, increased risk of CHD (Refs. 7 to 15, 34, 36, and 82). In addition, positive statistical associations are consistently reported in observational studies between estimated *trans* fat intake in free-living populations and incidence of CHD manifested as heart attack or death from CHD (Refs. 16 to 22, and 38) or increased risk of CHD as assessed by higher levels of LDL-C (Ref. 23) (64 FR 62751 to 62753). Thus, FDA continues to find that a large body of the most persuasive types of evidence (i.e., intervention trials and prospective cohort observations) consistently shows that *trans* fat intake adversely affects CHD risk under both controlled trial conditions and in free-living populations following their usual dietary patterns. This consistency was seen in studies that (1) had a high degree of control over several variables, (2) used a variety of methods to assess intakes and status of *trans* fatty acids, (3) had a wide range of *trans* fatty acids (less than (<) 1 percent to 7 percent of calories), (4) by different investigators and research groups, (5) with different methods and statistical considerations, and (6) within different total dietary contexts. This relationship was also consistently found in comparisons of high vs. low consumers of *trans* fats in free-living U.S. populations consuming their normal diets. Thus, whether controlled intervention trials or among free-living U.S. populations consuming their usual diets, the adverse effects of *trans* fat intakes on CHD risk were consistently observed.

Moreover, FDA's conclusions were consistent with those of independent Federal Government expert panels that published dietary recommendations for U.S. population groups subsequent to publication of the November 1999 proposal (Refs. 87 and 89 through 91) that were cited in the **Federal Register** to reopen the comment period on November 15, 2002. These expert panels, reviewing the same scientific evidence as FDA described in the proposed rule, and given their knowledge of U.S. dietary patterns, consistently concluded that *trans* fat intakes are associated with increased CHD risk and recommended that U.S.

consumers and those who need to lower their LDL-C level minimize their intakes of *trans* fat to reduce their risk of CHD. For example, the IOM/NAS noted "a positive linear trend between *trans* fatty acid intake and total and LDL-C concentrations, and therefore, increased risk of CHD, thus suggesting an upper limit of zero" (Ref. 90). However, they further stated that, because *trans* fatty acids are unavoidable in ordinary diets, a complete avoidance of these fats is not possible without extraordinary changes in patterns of dietary intake. Such extraordinary adjustments may introduce other undesirable effects (e.g., elimination of foods such as dairy products and meats that contain *trans* fatty acids may result in inadequate intakes of protein and certain micronutrients). For these reasons, the IOM/NAS recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet.

Comments about the scientific validity of an article used in the IOM/NAS report, FDA notes that the paper by Ascherio and coworkers (Ref. 83) is not

the cholesterol ratio used in the Ascherio et al. analysis to be a useful endpoint for purposes of the *trans* fatty acid rule-making. FDA's independent evaluation of the scientific evidence concluded that there is consistency in finding adverse effects of *trans* fat on risk of CHD. Therefore, even though the independent reviews of FDA and the other expert panels differed to some degree in how they used the available scientific evidence, the resultant consistency of the conclusions across these reviews provides strong credence to the finding that *trans* fatty acid consumption increases CHD risk via increases in LDL-C.

In summary, based on the consistent results across a number of the most persuasive types of study designs (i.e., intervention trials and prospective cohort studies) that were conducted using a range of test conditions and across different geographical regions and populations, the agency now agrees with the comments that stated that the available evidence for an adverse relationship between *trans* fat intakes and CHD risk is strong. FDA also finds the results from the large prospective cohort studies among free-living U.S. population groups to be persuasive

evidence that the *trans* fat intakes associated with U.S. dietary patterns can have a significant adverse effect on CHD risk for U.S. consumers. The scientific agreement for this relationship among the various expert groups and consensus among these expert groups in recommending that U.S. consumers limit their intakes of saturated and *trans* fats now provide further evidence of the strength of the science and the public health importance of lowering *trans* fat intakes for U.S. consumers. Therefore, the comments do not persuade FDA to change its position in the proposed rule that labeling of *trans* fatty acids is warranted based on: (1) The scientific evidence; and (2) the public health importance of the guidelines recommending that consumers limit their intakes of both of the LDL-C-raising fats: *trans* and saturated fats. Thus, FDA concludes that its tentative conclusion in the proposed rule that "under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased LDL-C levels, which increases the risk of CHD" (64 FR 62746 at 62754) is no longer tentative. FDA continues to find the overall weight of scientific evidence in

that a few observational studies by van de Vijver et al., "Association between *trans* fatty acid intake and cardiovascular risk factors in Europe:

no association between average total *trans* fat intake in Europe and LDL-C or HDL-C so that average *trans* fat intake in the United States is probably not detrimental to human health.

FDA disagrees with the comments. The *transFAIR* study had a cross-sectional design, measuring *trans* fatty acid intake and serum lipids in 327 men and 299 women, ages 50 to 65 years, in 8 European countries from approximately 1997 to 1999. The study reported no statistically significant association between total *trans* fat intake and serum LDL-C. The habitual intake of *trans* fat was estimated to be about 2 g/day (e.g., approximately 1 percent of calories).

FDA notes that cross-sectional designs, such as the one used by van de Vijver et al., are relatively weak designs for showing associations between diet and serum lipids (Ref. 93). As an observational study, they are generally considered to be less persuasive than intervention trials. Moreover, compared with other types of observational studies (e.g., prospective (cohort) observational studies and retrospective (case-control)

studies), they are considered particularly weak. Considering the weaknesses of the cross-sectional design used in the *transFAIR* study compared with the much larger body of evidence from more persuasive types of studies (i.e., intervention trials and prospective observational studies) that consistently demonstrate an adverse effect of *trans* fat intakes on LDL-C, FDA does not find the *transFAIR* study to be sufficiently compelling to override the overall weight of the scientific evidence reviewed in the November 1999 proposal or to override the independent conclusions of recent expert panels convened by the Federal Government (Refs. 87 and 89), the IOM/NAS (Ref. 90), and the AHA (Ref. 91).

For the reasons cited previously, FDA disagrees with the comments that a lack of association between *trans* fat intake and serum lipids in the European *transFAIR* study indicates that average *trans* fat intake in the United States

(Comment 5). Many comments emphasized the inadequacies in the assessment of intakes of *trans* fatty acids by the U.S. population and noted that

the small number of samples. Thus, the comment concluded that extrapolation of *trans* fatty acid content from a few

content of the foods that make up the diets of the U.S. population. This extrapolation results in intake estimate errors with unknown effects. Some comments assert that the data are an over-estimate of the U.S. population's *trans* fatty acid intake and other comments assert that the data are an under-estimate.

FDA agrees that estimates of dietary intakes of *trans* fat, as with all intake estimates based on participant reports and limitations in compositional data bases, are subject to multiple sources of error. In the November 1999 proposal, the agency reviewed intake estimates from three different types of data: (1) National food consumption survey, (2) national disappearance data, and (3) observational studies done in U.S. population groups. By examining results from multiple methods of estimating intakes, the agency was able to assess some, but not all, of the uncertainties in current intake estimates. In discussing these data, FDA noted the very limited composition data available for the *trans* fatty acid composition of foods and the difficulties in determining the accuracy

of reported *trans* intakes with current knowledge and methods (64 FR at 62752–62753).

In the November 1999 proposal, FDA reviewed an analysis that used the results of the 1989–1991 Continuing Survey of Food Intakes by Individuals (CSFII), a national food consumption survey of the U.S. population conducted by the USDA (Ref. 26). This study reported a mean *trans* fatty acid intake of 5.3 g/day (2.6 percent of calories) for persons 3 years and older. One way to evaluate the accuracy of survey intake estimates is to compare the reported caloric intakes to known requirements, or to levels from intervention trials that have been shown to maintain body weight for some period of time. The authors of this study stated that these reported caloric intakes were 20–40 percent below known physiologic requirements, suggesting significant under-reporting of intakes (Ref. 26). The reported caloric intakes in the CSFII were on average approximately 200 to 1,000 calories/day below levels required to maintain body weights for U.S. subjects in intervention trials (Ref. 26). Therefore, the estimates of intakes from the CSFII survey are likely

underestimated. The intake estimate considered in the November 1999 proposal was derived from estimates of *trans* fatty acids available in the U.S. food supply (Refs. 24, 25, and 26). USDA's Agricultural Research Service fats and oils production figures and food disappearance data for fats and oils. Three studies provided daily per capita estimates of *trans* fatty intakes of 12.8 g, 10.2 g, and 8.1 g. (Refs. 24, 39, and 25, respectively). Although all three estimates were "corrected" for losses due to waste in processing and use, per capita intake estimates based on disappearance data generally overestimate intakes (Ref. 4).

Finally, observational studies conducted in U.S. populations also can provide intake estimates. In the November 1999 proposal, FDA reviewed several observational studies, including several prospective cohort studies conducted in U.S. populations who were healthy at the time of enrollment (Refs. 19, 21, and 38). Estimates of daily *trans* intakes ranged from 1.3 to 3.2 percent of calories and from 1.5 to 6.4 g/day for adult participants in these studies. These ranges of intake estimates are somewhat lower than those in the CSFII survey so are therefore also likely underestimated. However, even with these relatively low intake estimates,

these studies found that among free-living adults, those adults consuming *trans* fatty acids at the highest quintiles of intake had increased relative risk of CHD as compared to adults consuming *trans* fatty acids at the lowest quintiles of intake.

In summary, the different types of studies, and different studies within a study type, estimated different intake levels for the U.S. population. The estimates from the food disappearance data are likely overestimated. The estimates from the observational studies and the national food consumption survey are likely underestimated. All estimates used the same compositional data base which, as noted above, has very limited data on the *trans* fat content of foods. Although we have no external "gold standard" against which to determine which estimate is most accurate, the available intake estimates suggest that average intakes of U.S. consumers probably fall within the range of 1.3 g to 12.8 g/day.

Because of the multiple sources of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention studies. The scientific and public health importance of *trans* fat labeling was based on the totality of the scientific evidence. In this evaluation, FDA weighted the results of the intervention studies most heavily. Intervention trials clearly demonstrated, in a cause and effect manner, an adverse effect of *trans* fat intakes on LDL-C levels, and therefore on CHD risk, across a broad range of intakes (less than 1 percent to 7 percent of calories), dietary patterns, and population groups. For the purposes of determining that the scientific evidence was sufficient to conclude that *trans* fat labeling was warranted from a public health perspective, FDA finds that the intervention and observational studies provided strong evidence of both a causal relationship between *trans* fat intake and risk of CHD and applicability to the general U.S. population. Therefore, FDA does not need to rely solely on dietary intake estimates to make this determination.

Because of the serious public health consequences of CHD in the U.S. population, prudent public health dictates that we help consumers control those risk factors which they can alter directly through their own behavior. Heart-healthy diets that limit the intakes of both saturated and *trans* fats can serve this purpose as is evidenced by

recommendations in the recent expert panel reports (Refs. 87, 89 through 91, and 140).

(Comment 6) Many comments addressed the issue of the relevance of intervention study intakes to usual conditions of use in the United States. Some comments expressed concern that FDA's conclusions relied on intervention studies in which the intakes of *trans* fatty acids were very high and not representative of U.S. intakes of about 5.3 g/day (3 percent of calories).

FDA disagrees with the comments that it relied heavily on intervention trials with high *trans* fat intake. A range of fatty acid intakes was included in the dietary intervention assessments. For example, the four U.S. research investigations with chemical analyses of the diets included a total of 15 study diets (Refs. 12, 13, 34, and 82). These studies included diets with little or no *trans* fat (e.g., 0.4 to 0.6 percent of calories), diets with moderate levels of *trans* fat (e.g., 3 to 4 percent of calories), as well as diets with a higher intake of *trans* fat (e.g., 6 to 7 percent of calories). FDA relied on the totality of the evidence, i.e., intervention studies that included the full range of *trans* fat intakes, to compare the effect of *trans* fat from observational studies that showed an adverse relationship between *trans* fat intakes and CHD risk among U.S. populations consuming their usual diets.

Thus, in the aggregate, the U.S. intervention studies included an assessment of the effect of a wide range of *trans* fatty acid levels that overlap the range of intake estimates for the U.S. population. As noted in FDA's response to Comment 5, the relevance of the findings from the intervention studies for the U.S. population are shown by the consistent findings of an adverse relationship between *trans* fat and CHD risk in the prospective studies of free-living U.S. population groups. Thus, the relevance of the *trans* intakes used in the intervention studies for the U.S. population was confirmed by the consistent findings in the prospective studies that showed an adverse association between *trans* intake and CHD risk among free-living U.S. population groups. The recommendations of recent expert panels that Americans limit their intakes of *trans* fat shows that a broad-based scientific agreement exists as to the public health merits of *trans* fat labeling for the U.S. population within the context of current dietary intakes.

(Comment 7) Other comments suggested that the study populations were not representative of the U.S. population. For example, one comment said that the intervention studies included individuals at high risk with serum cholesterol levels greater than (>) 320 milligrams (mg)/deciliter (dL) or LDL-C > 130 mg/dL. Another comment stated that the agency failed to reflect that relative risk will depend on the base risk of the population used for comparisons with the U.S. general population.

FDA disagrees with these comments. Of the 512 subjects included in the dietary intervention studies cited in the November 1999 proposal, 48 percent of the dietary intervention population had an LDL-C level of 100 to 120 mg/dL that is categorized as near or above optimal level according to the NCEP lipid classification scheme (Ref. 89). Thirty-eight percent had an LDL-C of 130 to 159 mg/dL, categorized as borderline high, and 14 percent had a LDL-C level greater than or equal to (≥) 160 mg/dL, categorized as high. Only 5 percent of the participants had a low HDL-C level, < 40 mg/dL, and another 7 percent had a high HDL-C level, ≥ 60 mg/dL. Most participants had a normal HDL-C level in the range of 40 to 59 mg/dL. The study population was representative of the U.S. general population, including individuals at high risk, e.g., men < 45 years of age and women < 55 years of age. The study populations were described as participants who had normal heart, kidney and liver function, and were not taking medications that affect lipid levels. Many participants had near or optimal LDL-C levels and most had HDL-C levels that were neither high nor low by the NCEP criteria. The data that FDA relied on included a dietary intervention population that is representative of the U.S. general population.

(Comment 8) Some comments suggested that the test products were not representative of available commercial products in the U.S. marketplace. One comment suggested that several studies were designed to study the effects of different food oil sources and not designed to specifically study the effect of *trans* fat on blood lipid levels.

FDA disagrees with these comments. In general, the test products used in studies done by U.S. research groups were either commercially available products or were produced specifically for a study by U.S. manufacturers using oil sources commonly used in the U.S. market (Refs. 12 through 15, 34, and 82). However, regardless of whether studies used products typical of those

commercially available in other countries, products commercially available in the United States, or products developed specifically for the study at hand, results were generally consistent across all these studies and consistent with the larger body of evidence that included studies done in Europe and with European oils. That is, there was consistency across studies in finding that higher intakes of *trans* fat resulted in increased levels of LDL-C and, therefore, in increased risk of CHD. Moreover, the observational studies in U.S. populations, where participants were consuming products commercially available in the U.S. marketplace, also consistently showed that higher intakes of *trans* fat were associated with adverse effects on CHD risk (Refs. 19, 21, and 38).

FDA also recognizes that the intervention studies were designed with a variety of objectives in mind. Some were designed to compare two different sources of hydrogenated oils (e.g., Refs. 9, 14, 15, and 36). Many were designed to compare the effects of different types of fatty acids by varying the source oils to achieve the desired fatty acid types and levels (e.g., Refs. 7, 8, 10, 11, 12, 13, 15, 16, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94). The study designs were not designed to evaluate the effect of *trans* fat on blood lipid levels of interest. Due to these differences in objectives and study design, the general consistency across studies in finding that *trans* intakes are adversely related to CHD risk has been found that the relationship is likely real and not simply an artifact of a particular type of study design (Ref. 94).

Thus, most of the intervention trials provide enough information about test products, study population, and study diets to evaluate their relevance to the U.S. general population. The wide range of *trans* fatty acid intakes, products, and population characteristics in these studies overlaps with those found for U.S. consumers in the general population. Important, however, is that there is remarkable consistency across the intervention studies, regardless of population, products and diets used, in finding that higher intakes of *trans* fatty acids are associated with increased levels of serum LDL-C, a major risk factor for CHD. Thus, the available intervention studies show consistent results across a broad range of use conditions and population characteristics. FDA, therefore, disagrees with comments that suggest that the test products used in intervention studies are not applicable to the U.S. marketplace, or the study designs are not applicable to evaluating

the relationship of *trans* fat to CHD risk in the U.S. population.

(Comment 9) Many comments questioned whether the scientific evidence shows that the physiological effects of *trans* fat on CHD risk are equivalent to, greater than, or less than those of saturated fat on a gram-for-gram basis. Some comments noted that the intervention studies show that the increase in LDL-C levels associated with *trans* fat is greater than that from unsaturated fats but less than that from saturated fat. Some comments noted that in the review of science for the November 1999 proposal, FDA concluded that the available studies do not provide a definitive answer to the question of whether *trans* fatty acids have an effect on LDL-C and CHD risk equivalent to saturated fats on a gram-for-gram basis, but in the preliminary regulatory impact analysis, FDA estimated that the effects of saturated and *trans* fatty acids on LDL-C levels are about equivalent.

FDA notes that the intervention studies demonstrate that the net physiologic effect of a particular fatty acid or category of fatty acids is dependent upon the composition of both the intervention diet and the population being studied. The study designs to assess the effect of a defined quantity of *trans* fatty acids (provided by food sources of hydrogenated oil) on levels of serum or plasma lipids used in these designs controlled the variation in the ranges of protein, fat, cholesterol, and carbohydrate with particular attention given to the fatty acids. The effect of *trans* fat study diets were compared by replacement with food sources of: (1) *Cis*-unsaturated fatty acids, (2) monounsaturated (oleic) fatty acids, and (3) saturated fatty acids. As FDA stated in the November 1999 proposal (64 FR 62745 at 62750), the intervention study data showed the following: (1) *Trans* fatty acids increased LDL-C in comparison with *cis*-polyunsaturated fatty acids (Refs. 8, 13, 15, and 82); (2) *trans* fatty acids increased LDL-C levels in comparison with *cis*-monounsaturated fatty acids (Refs. 7, 11 and 12); and (3) *trans* fatty acids increased LDL-C, or there was no significant difference, in comparison with saturated fatty acids (Refs. 7 through 12). Based on these results, FDA concluded in the science review section of the November 1999 proposal that the available studies do not provide a definitive answer to the question of whether *trans* fatty acids have an effect on LDL-C and CHD risk equivalent to

saturated fats on a gram-for-gram basis. However, FDA also stated that the studies that compared a saturated fat diet with a diet in which some of the saturated fat was replaced with *trans* fat showed that *trans* fat, like saturated fat, increases LDL-C.

For purposes of its regulatory impact analysis in the proposal, FDA needed a basis for quantifying its estimates of the compliance costs and benefits associated with given changes in *trans* fat intakes and the associated changes in CHD risk. The available evidence always presents some uncertainty for these types of analyses, as there is with other inputs into regulatory decisions. Given these caveats, FDA, in order to develop the tools required for a quantitative evaluation of benefits and costs, reviewed a meta analysis of five intervention trials that included six levels of *trans* fat intakes (Refs. 62 and 69). Using multiple regression to statistically control for differences in other fatty acids between *trans*-enriched diets and reference diets, the authors projected linear increases in LDL-C as a function of level of increasing *trans* fat intake. According to the regression equations, each additional percent of energy from *trans* fat, when substituted for saturated fat, increased LDL-C by 1.5 mg/dL. This relationship was then used as the basis for estimating the benefits and costs of the proposed rule and not for purposes of establishing whether there is a gram-for-gram relationship between *trans* and saturated fatty acids on LDL-C levels and CHD risk. FDA notes that, in rulemaking to implement the 1990 amendments, the agency also found it necessary to use coefficients derived from regression equations to estimate the benefits and costs of various regulations (56 FR 60856, November 27, 1991; 58 FR 2927, January 6, 1993). In one such analysis, FDA used the equation of Hegsted and Keys to predict how changes in total serum cholesterol would be affected by projected changes in saturated fat intake (56 FR 60856 at 60869, November 27, 1991). Because the Hegsted and Keys equations did not include coefficients for *trans* fat or information on components of total cholesterol (e.g., LDL-C), FDA found it necessary to find regression equations that included *trans* fat intakes and LDL-C levels. The equations of Katan et al. and Zock et al. (Refs. 62 and 69), together with the equations of Mensink and Katan (Ref. 65), which summarized the results of 27 clinical trials, were available to meet this need for a quantitative basis on which to estimate

the benefits and costs of the proposed rule.

In estimating the benefits and costs, FDA also recognized that the type of macronutrient substituted for *trans* fat in the diet would affect the magnitude and nature of the changes in LDL-C in response to decreases in *trans* fatty acid intakes. Thus, FDA also estimated how the benefits and costs would be altered if saturated fat, *cis*-polyunsaturated fat or carbohydrate, rather than *cis*-monounsaturated fat, were used to replace some of the *trans* fat in the diet. In this analysis an intermediate step in the calculation showed that when saturated fat was substituted for *cis*-monounsaturated fat, LDL-C was raised by 1.52 mg/dL, an amount similar to that found when *trans* fat was substituted for *cis*-monounsaturated fat (1.50 mg/dL).

Regardless of whether FDA reviewed the effects of saturated fat and *trans* fat on LDL-C and CHD risk for the science section or the regulatory impact section, the conclusion about those effects is the same. That is, both *trans* fatty acids and saturated fatty acids raise LDL-C levels, a major risk factor for CHD risk. Consumers need to minimize their intakes of both types of fatty acids without a relative increase in the intake of saturated fat. The results are consistent with those reached independently by expert panels (Refs. 87, 89, 90 and 91).

(Comment 10) Many comments addressed the issue of the potential adverse effects of *trans* fat on HDL-C levels. Some comments suggested that *trans* fat has more adverse health effects than saturated fat because *trans* fat, in addition to raising LDL-C, also lowers HDL-C, the so-called "good" cholesterol, whereas saturated fat raises HDL-C. Some comments noted that *trans* fat raises the LDL/HDL ratio approximately twice as much as saturated fat. Other comments stated that, in the prospective studies, the risk of CHD associated with *trans* fat intake was much greater than the risk associated with saturated fat, and much greater than would be predicted based on the effect on serum lipids. In contrast, one comment stated that it is premature to conclude that *trans* fat intake lowers HDL-C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL-C.

Based on the recommendations of the 1993 NCEP Expert Panel (Ref. 5), in the November 1999 proposal, FDA concluded that an examination of the effects of *trans* fatty acids on serum LDL-C would provide the strongest

evidence, and should be the primary criterion, to evaluate whether *trans* fatty acids influence CHD risk. In the November 1999 proposal, FDA tentatively concluded that the available evidence demonstrated that under conditions of use in the United States, consumption of *trans* fatty acids contributes to increased serum LDL-C levels, which increases the risk of CHD. The evidence for this relationship alone was sufficient for the agency to tentatively conclude that addressing *trans* fatty acids in nutrition labeling is important to public health.

FDA's review of the intervention trials showed that HDL-C decreased when *trans* fats replaced saturated fats. Further, Federal Government advisory groups (Refs. 88 through 90, and 140) and an advisory group of health professionals (Ref. 91) have stated that substitution of *trans* fat for saturated fat lowers HDL-C.

To date, lowered HDL-C levels have been shown to be a useful predictor of heart disease risk because of its correlation with CHD risk. However, it is not known whether lowering HDL-C is related to CHD risk in a cause and effect manner. Until this relationship is confirmed by appropriate study designs, the use of HDL-C as a criterion to evaluate the benefits and costs of the rule is subject to the uncertainty surrounding this use. For example, FDA notes that the NCEP 2001 Report (Ref. 89) makes several statements that both recognize and qualify the relationship between *trans* fatty acids, HDL-C, and CHD risk. While the NCEP Report states that a low HDL-C level is strongly and inversely associated with risk for CHD, the NCEP Report also states that, because of the association of low HDL levels with other atherogenic factors, a low HDL-C is not as strongly independent in its prediction as suggested by usual multivariate analysis.

Therefore, while FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL-C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored (64 FR 62746 at 62798 to 62821). For this reason, FDA included information on the effects of *trans* fatty acids on HDL-C levels when reviewing the available human studies in the science review section. Additionally, because of the possibility of an adverse effect on HDL-C levels from *trans* fat intake and a correlation between such an effect with CHD risk, the possible impact on HDL-C levels from *trans* fat

intake was used in the regulatory impact section as one of several possible approaches for determining cost benefit ratios of *trans* fat labeling. The agency would have been remiss in evaluating the full range of possible cost/benefit relationships if it had failed to include this potential adverse effect from *trans* fatty acid intakes to CHD risk in these analyses.

The question of interpretation of LDL/HDL ratios is more difficult. For example, concurrent small changes in both LDL-C and HDL-C could result in a similar LDL/HDL ratio as would concurrent large changes in both LDL-C and HDL-C assuming the changes are in the same direction. Or, large changes in HDL-C with moderate changes in LDL-C could give similar LDL/HDL ratios as would moderate changes in HDL and small changes in LDL. However, it is likely that the magnitude of the change in the individual blood cholesterol levels is as, or more, important than is a change in the ratio of the two. Thus, interpretation of the LDL/HDL ratio is unclear and until there is evidence by which its meaning can be more precisely defined, use of this ratio requires considerable caution. However, even with these caveats, the data on the health benefits and costs of decreasing levels of LDL-C and increasing levels of HDL-C lead to the conclusion is the same: *trans* fat intakes increase CHD risk.

(Comment 11) A number of comments emphasized that, in addition to HDL-C, *trans* fat has other adverse effects that may contribute to CHD risk but saturated fat does not. The comments mentioned that *trans* fat has adverse effects on various CHD risk factors including serum lipoprotein(a), serum triglycerides, insulin resistance and diabetes risk. These comments also stated that *trans* fat has adverse effects on aspects of lipid metabolism that may cause increased CHD risk, such as interference with metabolism of omega-3 fatty acids, interference with enzymes such as delta-6-desaturase, promotion of essential fatty acid insufficiency, and increase in free radical formation. Several of the comments argued that some of these CHD risk factors represent additional biological mechanisms related to *trans* fat that could account for the amount of CHD risk observed in prospective studies beyond that explained by changes in LDL-C and HDL-C.

Some comments stated that *trans* fat may have adverse effects on other health conditions, besides CHD. One of these comments requested that, in order to provide the full picture of health issues involved with *trans* fats, FDA review

trans fat effects on cancer, obesity, immunity, reproduction, development, and diabetes when publishing the final rule. Another comment characterized *trans* fatty acids as being atypical fatty acids with an insidious nature in disrupting lipid metabolism. Some comments identified potential adverse effects of *trans* fat on lowered birth weights and decreased visual acuity in infants exposed to high levels of *trans* fatty acids in utero or via breast milk. The comments suggested that FDA advise pregnant and lactating women to limit their *trans* fat intake.

FDA recognizes that the relationship of biomarkers, other than LDL-C, and to a lesser degree, HDL-C, with CHD risk is less well established and difficult to interpret. Moreover, at this time, the findings suggesting effects of *trans* fat on non-heart disease risks are preliminary. Therefore, FDA finds that its focus on LDL-C provides a sufficient basis for concluding that the labeling of *trans* fat levels in food products is warranted.

V. Nutrition Labeling of *Trans* Fats

In the November 1999 proposal, FDA proposed that when *trans* fats are present in a food, including dietary supplements, the label for a combined saturated fat must include the combined quantitative amount by weight of both saturated and *trans* fats. Further, FDA proposed that when 0.5 or more grams per serving of *trans* fats are present, the declaration be followed by a symbol that refers to a footnote at the bottom of the nutrition label stating the number of grams of *trans* fat present in a serving of the product, i.e., "Includes ___ g *trans* fat." The agency also had discussed, in addition to the one proposed, several other options for declaring *trans* fat in the Nutrition Facts panel. These included: (1) Declaring the combined amount of both saturated fat and *trans* fat as "Saturated fat" without identifying the amount of *trans* fat, (2) declaring the combined amount of both saturated fat and *trans* fat as "Saturated + *trans* fats" without identifying the amount of *trans* fat, (3) declaring the combined amount of both saturated fat and *trans* fat as "Saturated + *trans* fats" with an explanatory footnote stating the amount of each fat separately, and (4) declaring the amount of *trans* fat as a separate line item under saturated fat. The agency proposed that with all of these options the term "*trans* fatty acids" and "*trans* fat" could be used interchangeably.

A. Voluntary v. Mandatory Declaration of *Trans* Fatty Acids in Nutrition Labeling

(Comment 12) The majority of the comments supported the November 1999 proposal, which required the mandatory declaration of *trans* fat in nutrition labeling when it is present in a food, including dietary supplements. An overwhelming majority of comments supporting the mandatory declaration of *trans* fat did so because of public health concerns. Some comments stated that the scientific evidence clearly demonstrates that consumption of *trans* fat contributes to increased LDL-C and, hence, increased risk of CHD. Several comments noted that consumers are increasingly aware of the relationship between dietary fat and chronic disease, especially CHD, and look to the nutrition label for information about "heart-unhealthy" fat. A few comments noted that another benefit of mandatory labeling of *trans* fat is that it may provide an incentive to manufacturers to reduce the *trans* fat content of their foods.

A few comments stated that mandatory labeling of *trans* fat was not warranted because the scientific data linking *trans* fat to CHD is weak and because the average intake of *trans* fat, estimated at 2.1 percent of energy in the proposal, is minimal. Other comments also opposed mandatory labeling stating that the effect of *trans* fat on LDL-C or CHD risk was not sufficient to establish public health risk at ordinary levels of intake.

Some comments stated that, although mandatory labeling of *trans* fat was not warranted, a requirement for label declaration of *trans* fat could be justified in certain circumstances. Several of these comments stated that required label declaration of *trans* fat was justified if it was needed to prevent the label from being misleading because of the level of *trans* fat in light of other information on the label about total fat or fatty acids. Several comments that opposed mandatory declaration of *trans* fat suggested that, in order to prevent consumer deception, *trans* fat declaration should be required when nutrient content claims or health claims are made about fatty acids or dietary cholesterol or when there is label declaration of monounsaturated and polyunsaturated fats. One comment stated that there is no evidence that *trans* fat declaration would assist consumers in following healthy dietary practices unless certain claims are made or unless monounsaturated and polyunsaturated fats are declared on the label. One comment stated that the

amount of *trans* fat is "material" only when *trans* fat is present at greater than 1 g per serving because it would then significantly impact the overall fatty acid contribution to the diet. Another comment stated that *trans* fat declaration should be required only when *trans* fat is present at greater than 2 g per serving because that threshold would capture the food categories that contribute the vast majority of *trans* fat to the diet but would exclude products that contain only a trivial amount of *trans* fat. This comment stated that mandatory *trans* fat labeling of products with 2 g *trans* fat or less per serving would have a significant labeling burden although the foods make little overall contribution to *trans* fat in a mixed diet and have not been shown to have any public health impact. Another comment suggested that, if no claims are made, *trans* fat declaration should be voluntary if *trans* fat is present at 0.5 g or less per serving. One comment suggested that, if there are no claims about fatty acids or cholesterol, *trans* fat declaration should not be required when the food is "low" in total fat. The comment stated that a food "low" in total fat conforms with dietary recommendations; that no material improvement in food choices can be made from knowledge of the specific *trans* fat level in a "low fat" food; and that the level of *trans* fat in a "low fat" food is not enough to have any adverse impact on public health.

One comment stated that *trans* fat declaration should be optional because consumers prefer simplicity and clarity in nutrition labeling and consumers are unlikely to benefit from added verbiage about a nutrient that is not familiar to them. One comment suggested that *trans* fat declaration should be voluntary, but should be required under the same conditions that declaration of monounsaturated and polyunsaturated fat is required. The comment stated that *trans* fat declaration would then be required when fatty acid or cholesterol claims are made, and this would be the case for important food sources of *trans* fat, such as margarines, which often make such claims. According to the comment, although not all foods would choose or be required to disclose *trans* fat, the foods that are predicted to reformulate and that generate the expected health benefits of *trans* fat labeling would do so. After the initial disclosure of *trans* fat by these foods, additional foods would disclose *trans* fat due to competitive pressure (described by the comment as "the unfolding principle") The comment

facilitation of information flow, rather than mandatory disclosure, are the best ways to achieve *trans* fat disclosure.

FDA disagrees with comments opposed to mandatory declaration of *trans* fat. The 1990 amendments mandated nutrition labeling on most foods to provide consumers with information about specified nutrients that would help them maintain healthy dietary practices, as well as to create an incentive to food companies to improve the nutritional qualities of their products. Section 403(a) requires that food be adequately labeled and that material facts about a food's characteristics be disclosed to consumers. Section 403(q)(2)(A) of the act gives the Secretary (as delegated to FDA in § 5.10 (21 CFR 5.10)) the authority to require that information on additional nutrients be included in nutrition labels, if the Secretary determines that providing such information will assist consumers to maintain healthy dietary practices. In the legislative history of the 1990 amendments, Congress noted that "Scientific evidence has clearly linked dietary habits to good health. For this reason, it is important for FDA to provide consumers with better information about the foods they eat." (Ref. 141). As described in section IV of this document, scientific studies have demonstrated consistently that consumption of *trans* fat increases LDL-C, a major risk factor for CHD.

New studies and recent expert reports (Refs. 87, 90, 95, and 140) have been published and confirm the relationship between *trans* fat intake and risk of CHD. These studies' reports corroborate the agency's earlier finding in the proposed rule that information on *trans* fat on the nutrition label will assist consumers to maintain healthy dietary practices. Dietary Guidelines 2000 cautions consumers that foods high in *trans* fatty acids tend to raise blood cholesterol and gives examples of food sources of *trans* fat (Ref. 87). The Guidelines advise Americans who need to reduce fat intake to "do so primarily by cutting back on saturated and *trans* fats" (Ref. 87). Likewise, the Executive Summary of the NCEP 2001 report urges primary prevention of CHD in the United States through lifestyle changes (Ref. 95). The NCEP's Therapeutic Lifestyle Changes Diet recommends that those who wish to lower their LDL-C level reduce their intake of saturated fat and keep consumption of *trans* fat low (Ref. 89). Similarly, the IOM/NAS report recommends "that *trans* fat consumption be as low as possible while consuming a nutritionally

persons interested in following these recommendations and maintaining optimal LDL-C levels must be able to determine levels of both saturated and *trans* fats in individual food products. This information provides consumers with the ability to maintain healthy dietary practices. Information on saturated fat content is already available in Nutrition Facts panels on food labels. The practical way to inform consumers of the level of *trans* fat in individual food products is for the information also to be included in the Nutrition Facts panel.

Government and industry surveys consistently find that a majority of American consumers report looking at the nutrition label the first time they purchase a food product (e.g., about 75 percent according to FDA surveys (Ref. 96) and 51 percent according to a 1997 industry survey (Ref. 97). According to the FDA surveys, the most frequently reported label use and the one which increased most following the implementation of the 1990 amendments was "to see how high or low the food is in things like calories, salt, vitamins, fat, etc." (70 percent in 1995, up 12 percent from 1994) (Ref. 96, table 16.1).

These survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect and want to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled about a food's basic characteristics.

Therefore, FDA, as delegated by the Secretary, has concluded that *trans* fat is a material fact which cannot be omitted from the label. In addition, information on the *trans* fat content of food will assist consumers in maintaining healthy dietary practices. As such, FDA is acting in accordance with section 403(a) and (q)(2)(A) of the act to require that information on *trans* fat content be included in nutrition labeling. Including *trans* fat as a mandatory component of nutrition labeling will allow consumers to choose foods that will reduce their intake of *trans* fat, along with saturated fat, within the recommended intake level for total fat in a manner that is consistent with the most recent dietary

FDA disagrees with the comments that stated that mandatory labeling of *trans* fat is not warranted because average *trans* fat intake is minimal or because *trans* fat consumption is not a matter of public health risk at ordinary levels of intake. As described in section IV of this document, subjects in intervention studies showing that *trans* fat intake raises LDL-C levels had a wide range of *trans* fat intake levels, including levels that overlap the range of intake estimates for the U.S. population. The findings from intervention studies are supported by findings of a positive association between *trans* fat intake and increased CHD risk in the prospective observational studies, among free-living subjects consuming ordinary diets. Taken together, these studies demonstrate that *trans* fat consumption in the United States is a matter of public health concern at ordinary levels of intake.

FDA disagrees with the comments that suggested that the nutrition label would not be misleading if grams of *trans* fat were not listed, except where claims about fatty acids or cholesterol were made, monounsaturated fats and polyunsaturated fats were declared, or where *trans* fats were present at less than 2 g, 1 g or 0.5 g per serving. The agency believes that the absence of information of the amount of *trans* fat in a product, when labeling of *trans* fat as a mandatory nutrient is required, even where *trans* fat is present at less than 0.5 g, would be misleading. The presence or absence of *trans* fat in a product is a material fact as to the consequences that may result from the use of the product. Consumers need to know when a product contains less than 0.5 g *trans* fat just as much as they need to know when a product contains 1, 2, or more grams of *trans* fat in order to understand how each product impacts their overall dietary intake of *trans* fat. Such need is not based solely on the presence or absence of claims, levels of other fats, or declaration of other fats on the label. Consumers need to understand how each product contributes to their overall intake of *trans* fat in order to maintain healthy dietary practices which call for reducing *trans* fat intake as low as possible while consuming a nutritionally adequate diet. Consumption of several foods, each with 0.5 to 1 g *trans* fat per serving, over the course of a day may result in a significant overall *trans* fat intake for the day. The association between the intake of *trans* fat over a range of intakes and the risk of CHD are discussed in

low levels of *trans* fats may have significant impacts on increased CHD risk. There are important public health reasons for excluding foods high in *trans* fat intake and for including foods lower in *trans* fat intake. Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act.

Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, is consistent with statutory directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of other information on the label. FDA also disagrees with the comments that stated that *trans* fat declaration would assist consumers in maintaining healthy dietary practices only under certain circumstances, such as when certain claims are made, when monounsaturated and polyunsaturated fats are declared on the label, when *trans* fat is present at greater than 0.5 g, 1 or 2 g per serving or when the food is not "low" in total fat (i.e., more than 3 g fat/reference amount). As described previously, consumers need information on both saturated and *trans* fats in individual food products so that they can follow current dietary recommendations and maintain optimal LDL levels. It is the provision of *trans* fat information on foods consumed throughout the day that can assist consumers in maintaining healthy dietary practices, and the usefulness of this information is not limited to foods with certain nutritional characteristics. In addition, the consumption of several foods with 0.5 or 1 g of *trans* fat per day that may provide a total of 8 g of *trans* fat to the diet would be expected to have the same effect on LDL-C levels as consumption of one food with 8 g *trans* fat. Requiring *trans* fat to be declared only when present at a specified level

directives for nutrition labeling in section 403(q)(1) of the act, where amounts of nutrients of public health significance are required to be listed, regardless of the amount present.

Similarly, tying mandatory declaration of *trans* fat to the declaration of monounsaturated and polyunsaturated fats overlooks the difference in health effects of these fatty acids and the basic premise of section 403(q) of the act that requires the listing of nutrient information necessary to assist consumers in maintaining healthy dietary practices. Unlike information on *trans* fat, FDA has not determined that information on monounsaturated and polyunsaturated fat is necessary to assist consumers in maintaining healthy dietary practices. Accordingly, the declaration of those fatty acids is not mandatory. Rather, unless claims are made about fatty acids or cholesterol, the agency provides that their listing is voluntary (§ 101.9(c)(2)(ii), (c)(2)(iii), and (c)(3)), consistent with the authority in section 2(b)(1)(C) of the 1990 amendments that stipulates that regulations shall "permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section * * *"

Regarding the comment that consumers prefer simplicity and clarity in labels, FDA does not agree that providing a listing of the amount of *trans* fat on a label is not simple or clear nor did the comment provide any rationale for its assertion. Further, FDA does not agree that *trans* fat listing on a label would be "added verbiage" about an unfamiliar nutrient that likely will not benefit consumers. The comment presented no information to support its assertion. The addition of *trans* fat as a mandatory nutrient on a separate line will not significantly change the appearance of the nutrition information that consumers are already familiar with. Having consistent information about *trans* fat present on all food labels will facilitate consumer education efforts about *trans* fat, as discussed later in this document (see Comment 28).

FDA is not persuaded by the comment that it is not necessary to make *trans* fat labeling mandatory because, after an initial disclosure of *trans* fat by certain foods, additional foods would disclose *trans* fat due to competitive pressure (unfolding principle). Although some disclosure of *trans* fat under competitive pressure might occur, the overall extent of such voluntary disclosure is not

were enacted, provision of nutrition labeling information was voluntary except in certain circumstances. At the time when nutrition labeling was voluntary, many foods did not provide nutrition labeling, demonstrating that the disclosure suggested by the "unfolding principle" was incomplete. To remedy this situation, Congress enacted the 1990 amendments, mandating that nutrients of public health significance be declared on food labels under section 403(q) of the act.

As mentioned earlier, section 403(q)(2)(A) of the act provides for the inclusion of an additional nutrient(s) if the Secretary (as delegated to FDA in § 5.10) determines that it should be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. FDA is not asserting, as its basis for mandatory *trans* fat nutrition labeling, a rationale that is different from that which Congress declared by statute for such mandatory labeling. Lacking any congressional direction to do otherwise, the agency considers it implicit that any such added nutrients would be listed in a similar manner to those specified in section 403(q)(1) of the act. Accordingly, the agency is amending § 101.9 *Nutrition Labeling of Food*, to add *trans* fat as a mandatory component of nutrition labeling on all foods in accordance with section 403(q)(2)(A) of the act.

B. Format, Including Percent of Daily Value (% DV), for Nutrition Labeling of Trans Fat

FDA received many comments regarding the proposed option for nutrition labeling of *trans* fatty acids and other options discussed in the preamble. In addition, comments were received suggesting that *trans* fat be listed in conjunction with the listing of total fat.

The agency did not receive comments supporting either of the two options that would declare only the combined amount of saturated fat and *trans* fat rather than the individual amounts present. In light of the lack of support for these two options and the fact that these options do not allow consumers to determine the individual amounts of saturated fat and *trans* fat, the agency is not considering them further.

FDA also received a few comments that supported the proposed footnote statement "Intake of *trans* fat should be as low as possible" or a modification of it. However, the overwhelming majority of comments opposed the use of the

1. Proposed Option

(Comment 13) Many comments supported the proposed option of having the amount of *trans* fat included in the amount declared for "Saturated Fat" and in the calculation of the corresponding % DV with a footnote stating "Includes ___ g *trans* fat" when the food contains *trans* fat. Comments stated that combining both saturated and *trans* fat in the declaration of saturated fat maintains a consistent public health message and provides consumers with a less confusing means to identify "heart-unhealthy" fats in one place on the label. Comments suggested that, to assist consumers, *trans* fat should be included with saturated fat because saturated and *trans* fats have similar physiological and functional properties and because there is no DV for *trans* fat. Comments suggested that combining saturated and *trans* fats will decrease the likelihood that consumers would look only at the declared level for *trans* fat and choose a food because it has little or no *trans* fat, even though it contains a high amount of saturated fat. Furthermore, the comments suggested that combining *trans* with saturated fats would create an incentive for manufacturers to decrease "heart-unhealthy" fats in foods.

Comments supporting inclusion of *trans* fat in the calculation of the % DV for saturated fat stated that such action is reasonable for purposes of consumer information. One of these comments argued that *trans* fats are already included in recommendations to limit total fat to 30 percent of calories, a number that should not be increased, and are excluded from definitions of unsaturated fats for labeling purposes (i.e., § 101.9(c)(2)(ii) and (c)(2)(iii)). This comment acknowledged that including *trans* fat would in effect lower the reference value for saturated fat. The comment argued that this would help Americans reduce their risk of heart disease, quoting from the IOM/NAS report "Diet and Health" which states that "saturated fatty acid intake [should] be maintained at less than 10 percent of total calories by individuals," but that "further reduction, to 8 or 7 percent of calories or lower, would confer greater health benefits." The comment said that including *trans* fat in the % DV would help Americans follow this advice.

However, many comments opposed this option of including *trans* fat with saturated fat, arguing that including *trans* fat with saturated fat is scientifically inaccurate and misleading because *trans* and saturated fats are chemically, functionally, and

pointed out that chemically *trans* fats are unsaturated fatty acids that contain one or more double bonds in a *trans* configuration while saturated fats do not contain double bonds. Moreover, comments stated that *trans* fatty acids do not have the same functional characteristics as saturated fats because their melting and crystallization kinetics are quite different. Comments also pointed out that *trans* fat is physiologically distinct from saturated fat, stating that *trans* fat decreases HDL-C levels and that saturated fat does not. In addition, there were comments suggesting that *trans* fat adversely affects other factors that contribute to CHD, such as lipoprotein(a), and may cause adverse effects unrelated to CHD. For these reasons, the comments were adamant that *trans* fat should not be treated as though it is "bioequivalent" to saturated fat and, consequently, the listing of *trans* fat should be disassociated from the listing of saturated fat.

In addition, several comments objected to combining both *trans* and saturated fats on the grounds that it is inconsistent with FDA's regulatory precedent of classifying nutrients based on their chemical definition or structure, rather than their physiological effect. Specifically, the comments cited FDA's decision when implementing the 1990 amendments to establish a chemical definition for saturated fat rather than a physiological definition (58 FR 2079 at 2089).

A few comments expressed concern that by including *trans* fat with saturated fat, FDA is creating a category of "bad" or "cholesterol-raising" fat that is inconsistent with the current nutrition label, which provides consumers with information about the nutrient profile of a product rather than providing information about perceived health effects. Other comments stated that FDA's proposal to combine *trans* fat and saturated fat may mislead consumers, albeit misleading them for their own good, by causing them to misclassify *trans* fats as saturated fats or causing them to assume that the DV for saturated fat has been reduced (the effect of combining the quantitative amounts of *trans* and saturated fats and determining the % DV using the established DV for saturated fat). Further, several comments stated that adding *trans* fat to the amount of saturated fat declared may mislead and confuse consumers by leading them to incorrectly conclude that the amount of saturated fat has increased.

Other comments stated that, because of the magnitude of CHD risk in the

labeled more prominently than proposed in the November 1999 proposal. These comments argued that listing the amount of *trans* fat in a footnote is more confusing and implies that it is unimportant. In addition, comments stated that footnotes, which can use smaller type size, are more difficult to read. One comment stated that it was not surprising that consumers were unfamiliar with the term since it was not allowed to appear on Nutrition Facts labels. This comment suggested that consumer knowledge about *trans* fat would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in food labeling.

Other comments objected to including *trans* fats when calculating the % DV for saturated fat stating that the effects of *trans* fat on LDL-C have not been proven to equal the effects of saturated fat on LDL-C, so they should not be held to the same standard. These comments argued that including *trans* fat in the calculation of % DV assumes that *trans* fat is equivalent to saturated fat on a gram-for-gram basis, whereas the agency admitted in the proposal that available studies do not allow for such a conclusion. The comments stated that no authoritative bodies have recommended that *trans* fat be considered as a part of the dietary recommendation for saturated fat. Also, they stated that including *trans* fat, in effect, lowers the DRV for saturated fat and there is no new data on saturated fat that supports this action, i.e., that there is no basis for concluding that saturated fats are now sufficiently worse than previously believed to justify an apparent reduction in recommended intakes. One comment also argued that if the declaration of % DV changed on a product as a result of including *trans* fat with saturated fat, consumers may incorrectly assume a change has been made which made the product less healthy when, in fact, no such change had occurred.

One comment said that FDA should not include *trans* fat in the calculation of % DV unless the DRV for saturated fat is increased to 22 g since the agency had actually rounded down the DRV for saturated fat from 22.2 g (equivalent to 10 percent of calories from a 2,000 calorie diet) to 20 g when implementing the 1990 amendments (see 58 FR 2206 at 2219). Another comment objected to the idea of increasing the DRV for saturated fat because products that do not contain *trans* fat would appear healthier (i.e., have a lower % DV) even though the amount of saturated fat in

Based on comments received, FDA is persuaded that there are inherent weaknesses and inconsistencies in its proposed option. Therefore, the agency has reconsidered its proposal to include *trans* fats in the declaration of saturated fat with a footnote indicating the amount of *trans* fat. The agency acknowledges that declaring the amount of saturated fat and *trans* fat together, even with the proposed footnote, could lead some consumers to believe that the two types of fatty acids are chemically and physiologically the same. Clearly, *trans* fats contain double bonds and thus, are chemically distinct from saturated fat. Likewise, although both saturated and *trans* fats do raise LDL-C levels, physiologic distinctions between the two types of fatty acids do exist as discussed previously in Comments 10 and 11. While findings on some of these distinctions are preliminary, they do not support the position which the agency took in the November 1999 proposal that the two fatty acids should be declared as one combined entity because of similar physiological effects.

The agency re-evaluated its position, noted in the final rules implementing the 1990 amendments, that there is insufficient knowledge about the physiological effects of particular fatty acids to use anything other than a chemical definition for saturated fats (58 FR 2079 at 2089). In that rulemaking, FDA reconsidered its regulatory position in place since 1973 (38 FR 2132 at 2134, January 19, 1973) of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL-C and determined that a chemical definition was a more appropriate approach. The agency stated that a chemical definition avoids much of the controversy regarding blood cholesterol effects of short to medium and certain very long chain fatty acids because the definition is not subject to changes in knowledge about the physiological effects of a particular fatty acid. In addition, the agency stated that a chemical definition approach to labeling fatty acids avoids the uncertainty about physiological effects other than those related to CHD (58 FR 2079 at 2089). Based on its re-review of the position noted in the final rules implementing the 1990 amendments, the comments received on proposed rule opposing a contrary position, and current science on *trans* fat, the agency is persuaded that it would be important to approach *trans* fat labeling on the basis of using a chemical definition and not based on physiological effects.

it is necessary to disassociate saturated and *trans* fats on the nutrition label so that consumers do not misinterpret the declaration of saturated fat by thinking that *trans* fats are included in that definition.

The agency also acknowledges the concerns expressed in comments about the prominence given to the information on *trans* fat. Current food labeling regulations do allow for a smaller type size for footnotes (§ 101.9(d)(1)(iii)) and limit the declaration of amounts in footnotes to statements saying that the food is not a significant source of specified nutrients (e.g., § 101.9(c)(3)). Consequently, consumers may overlook quantitative information on *trans* fat content placed there.

In the November 1999 proposal, FDA expressed concern that consumers may not yet know what *trans* fats are or know about their impact on health (64 FR 62746 at 62755). The agency agrees with the comment that suggested that consumer knowledge would improve as more dietary recommendations are made for limiting *trans* fats and as they are listed in nutrition labeling. In addition, the agency notes that media attention to *trans* fat has been widespread since publication of the November 1999 proposal. For example, public awareness about *trans* fats was increased as reports of the IOM/NAS report on *trans* fatty acids were issued (Ref. 140), as consumer and health groups issue press releases and reports about *trans* fats (Refs. 147 and 148), as food manufacturers add information about the *trans* fat content of products to labels, and as industry announcements are made about the *trans* fat content of packaged and restaurant foods (Refs. 149 and 150). In addition, the agency is planning a consumer education program discussed later in Comment 28 to further heighten consumers' knowledge of what *trans* fats are and their impact on health. Thus, the agency no longer believes that its prior reasoning, i.e., that *trans* fat would need to be included in the declaration of saturated fats in order for consumers to understand that *trans* fats are heart unhealthy is necessarily true. Consumers should be more aware of *trans* fat based on the public exposure to information on *trans* fat over the past years and FDA efforts before the rule becomes effective.

In the November 1999 proposal, FDA tentatively concluded that, in the absence of dietary recommendations for *trans* fats, it was reasonable to include *trans* fats in the % DV for saturated fat (46 FR 62746 at 62756). Consequently, FDA proposed that the % DV be

saturated fat and *trans* fat in a food and dividing by the DRV for saturated fat (20 g). In effect, this is equivalent to having a combined DRV for saturated and *trans* fat of 20 g. FDA agrees with the comments that suggest that this approach is problematic in that by displacing the DV for saturated fat with *trans* fat, the DV, in essence, is lowered for saturated fat. However, the DV for saturated fat has not changed. Therefore, it would be scientifically more accurate to keep the DV for saturated fat intact, without displacing it with *trans* fat. This approach would be consistent with the recent IOM/NAS macronutrient report (Ref. 140) that does not treat saturated and *trans* fats together. FDA concludes that there is an insufficient scientific basis at this time for combining the declared amounts of *trans* and saturated fats and calculating the % DV. Additionally, FDA is persuaded by the arguments discussed previously that point to the differences between saturated fat and *trans* fat that it is inappropriate to do so.

Accordingly, the agency concludes that other options that disassociate *trans* fat from the listing of saturated fat would be preferable to the proposed option. The other options identified in the proposal and those suggested in comments are discussed later.

2. Option to List Saturated and *Trans* Fat on Same Line

(Comment 14) Several comments preferred the option identified in the November 1999 proposal that would list "Saturated + *trans* fat" with the amount in grams and the % DV based on the combined value, and the individual amounts of both saturated and *trans* fats in a footnote. One comment suggested that the footnote declare the specific amount of *trans* fat only, while another suggested that the individual amounts be listed in separate lines immediately below the combined amount rather than in a footnote. These comments stated that this type of declaration shows that: (1) There are two different fatty acid categories, thereby maintaining the chemical definitions of *trans* fat and saturated fat and indicating equal importance to health; (2) gives them equal prominence with poly- and monounsaturated fats; (3) suggests to consumers that *trans* fats have similar cholesterol-raising properties as saturated fats; and (4) provides an easy method for comparing the "heart-unhealthy" fat content of foods. The comments also argued that this type of declaration indicates the combined total amount of saturated and *trans* fats, a number that would stay constant when

for each other, and it was therefore clearer to declare the sum of both.

Alternatively, a few comments recommended declaring the individual amounts for saturated fat and *trans* fat on one line in the nutrition label, i.e., "Saturated fat __g + *trans* fat __g." These comments pointed out that declaring saturated and *trans* fats in this way would be consistent with the chemical definitions for each type of fatty acid and would help consumers see that *trans* fats are different from saturated fats. The comments argued that research may elucidate new properties or biological effects of both saturated and *trans* fatty acids, warranting this distinction between them. From a consumer perspective, one of the comments also argued that, if FDA begins to mandate the placement of nutrient content information in locations other than the current nutrient list, consumers may become increasingly confused about where on the food label to locate information that they need.

Two comments urged the agency to harmonize its *trans* fat labeling policy internationally, noting that this format, i.e., "Saturated fat __g + *trans* fat __g," was proposed by Canada in June 2001, for use in mandatory nutrition labeling in that country (Ref. 103).

Other comments did not favor listing saturated and *trans* fats on the same line as "Saturated + *trans* fat" for the same reasons expressed in opposition to the proposed option, namely because *trans* and saturated fats are chemically different, because they have different effects on HDL-C, and because, according to preliminary data, *trans* fat may have effects on non-heart disease risks that saturated fats are not reported to have. In addition to concerns about the chemical and physiological differences between *trans* and saturated fats, some comments expressed opposition to labeling the two on the same line because public health and scientific organizations that are instrumental in establishing daily reference intake values have not yet established a DV for *trans* fat. Many other comments objected to having saturated and *trans* fats on one line, in any manner, if it resulted in *trans* fat being included in the calculation of the % DV for saturated fat. Specific arguments against including *trans* fat when calculating the % DV for saturated fat are discussed in the preceding comment.

The agency is not persuaded by comments supporting this option. While this option does indicate more clearly than the proposed rule that saturated

categories of fat, it would still necessitate a displacement of the % DV for saturated fat by *trans* fat and would not disassociate the two fats in terms of potential physiologic effects. Based on the reasons set forth in response to Comment 13, we believe that it would be scientifically more accurate to not displace the % DV for saturated fat with *trans* fat. In addition, this option would not be consistent with our rationale, as explained in the response to Comment 13, for why a chemical definition approach to labeling is preferred. Such an approach avoids the uncertainty about physiological effects now or in the future. While the two fatty acids do both lead to increased LDL-C, advisory groups (as noted in comment 10 of this document) have stated that substitution of *trans* fat for saturated fat lowers HDL-C. Low levels of HDL-C can be a predictor of CHD. While evidence concerning the differing effects of saturated fat and *trans* fat on other disease risk factors is preliminary, FDA is convinced by comments that it is preferable to disassociate the two fatty acids and maintain a chemical definition approach to labeling. Accordingly, the agency finds this option unacceptable.

Those comments stating that saturated and *trans* fat are substituted for each other recognized that the two types of fats have some functional similarities. However, comments were not unanimous in stating that the combined total amount of saturated and *trans* fats would stay constant when one of the two fatty acids was raised or lowered. Some comments indicated that *trans* fats could be reduced significantly with a smaller concomitant increase in saturated fat. In addition, FDA points out that the intent of this rulemaking is not to make such substitutions easier from a labeling perspective but to encourage the reduction of both types of fats to assist consumers in maintaining healthy dietary practices.

FDA recognizes that Canada has issued final rules on nutrition labeling that declare saturated fat and *trans* fat on one line. However, FDA has determined, based on comments to this final rule, that such declaration would not be an appropriate approach for the agency at this time. Such an option would not account for the chemical and physiological differences between saturated and *trans* fat, and thus, would be inconsistent with the agency's past approach to labeling that is based on chemical differences. Further, there are additional differences between Canada's new nutrition labeling rule and existing U.S. regulations, under § 101.9, that will

After further review and discussion, the United States and Canada can consider the possibility of mutual recognition of nutrition labels.

3. Option to Include *Trans* Fat as a Part of Total Fat

(Comment 15) Several comments recommended a new option that would place an asterisk (or other symbol) after the declaration of total fat (i.e., "Total Fat*") that references a footnote stating the number of grams of *trans* fat included in the total fat declaration (e.g., "*Includes ___g *trans* fat"). A few comments proposed an alternative to this option that would declare *trans* fat in a parenthetical statement on the same line with "total fat" (i.e., "Total Fat ___g (includes ___g *trans* fat)").

Some of these comments suggested that declaring *trans* fat as a part of total fat alleviates many of the concerns voiced about the proposed option. The comments stated that this option discloses the amount of *trans* fat in scientifically accurate terms and is consistent with current regulations that include the quantity of *trans* fat within the amount declared for total fat. A comment said that this option should be used until a DRV is established for *trans* fat. Another comment suggested that the DRV for total fat should be increased to accommodate *trans* fat. Other comments stated that current dietary guidelines recommend monitoring both total fat and saturated fat intake, especially for consumers concerned about their heart health, and that the AHA recommends focusing on the total amount of fat consumed to address concerns about *trans* fat consumption.

The comments stated that placing the asterisk beside "total fat" has advantages for consumers. At least one comment stated that this type of listing may be more readily seen by consumers since it gives greater prominence to the *trans* fat information. Other comments stated that including *trans* fat as a part of total fat avoids the confusion that consumers would experience with FDA's proposed option when amounts declared for saturated fat would appear to have increased.

The agency disagrees with those comments suggesting that concerns about *trans* fat consumption can be addressed by focusing on the total amount of fat consumed. FDA agrees that *trans* fats are chemically a component of total fat; however, that is also true for saturated, polyunsaturated, and monounsaturated fatty acids that are listed as subcomponents of total fat in many food labels. Therefore, the agency does not agree that *trans* fatty

total fat until there is an established DRV for *trans* fatty acids, particularly since DRVs also have not been established for poly- or monounsaturated fatty acids. The agency also points out that the current DRV for total fat includes all fatty acids, so does not need to be increased to accommodate *trans* fatty acids.

Further, placing an asterisk after "Total Fat" on the label with a footnote stating the grams of *trans* fat, or a statement of the grams of *trans* fat beside the total fat on the label likely would lead to the same types of objections that were raised when that approach was considered for saturated fat. Moreover, previous comments in comment 13 raised concerns about consumers overlooking quantitative information in a footnote. Further, comments raised concern about not maintaining the chemical distinction for individual fatty acids, as has been the past agency practice. Placing *trans* fat on the same line of total fat may raise questions about how *trans* fat is to fit within the % DV for total fat. The agency is not persuaded by any the comments that the problems with this option would be any different than those with the option to label *trans* fat on the same line as saturated fat. Thus, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

Moreover, while total fat in the diet is important, the composition of that total fat intake is at least equally, if not more, important. Recent recommendations from the Dietary Guidelines 2000 (Ref. 87) and the Dietary Guidelines Advisory Committee (Ref. 88) have emphasized reducing intake of both saturated and *trans* fats while placing less emphasis on reducing total fat intake. For example, while the 1995 edition of the Dietary Guidelines recommended that Americans choose a diet "low" in fat and saturated fat (Ref. 6), the 2000 edition now recommends "moderate" total fat (Ref. 87) with guidance that consumers needing to reduce their total fat intake do so by cutting back on saturated and *trans* fats. Similarly, the 2000 AHA Guidelines specifically recommend limiting "intake of foods with high content of cholesterol-raising fatty acids" (i.e., saturated and *trans* fatty acids) rather than total fat (Ref. 91). The 2001 NCEP report increased the recommendation for individuals with elevated LDL-C for total fat intake from 30 to 35 percent of calories provided that saturated and *trans* fats be kept low

The comments suggesting that *trans* fat information would have greater prominence and be more readily seen when related to total fat rather than saturated fat did not provide any data to support this position. While doing so would move *trans* fat up one line in the Nutrition Facts label, FDA has no basis to conclude that this would make it more prominent to consumers.

The agency acknowledges that the options of using an asterisk next to total fat with a footnote listing *trans* fat or listing *trans* fat parenthetically next to total fat would avoid any possible confusion experienced by consumers as a result of the proposed option if levels of saturated fat appeared to have increased when, instead, amounts of *trans* fat were added to the amount of saturated fat. However, other options, such as the option of declaring *trans* fat on a separate line would also avoid the possibility of such confusion and, at the same time, would more clearly identify *trans* fat as a separate subcomponent of total fat, in a manner similar to the other subcomponents, i.e., saturated, poly- and monounsaturated fats.

For the reasons noted previously, the agency is not persuaded that the nutrition label should identify levels of *trans* fat in the total fat declaration through the addition of a footnote or parenthetical listing.

4. Option to Include a Separate Line for *Trans* Fats

(Comment 16) Many comments recommended that *trans* fat content be declared on a separate line on the Nutrition Facts panel because of the problems ascribed to the proposed option. In general, these comments stated that there is no scientific evidence to support FDA's proposal to combine saturated and *trans* fatty acids because both of these fatty acids have different chemical structures and physiological effects. They asserted that a separate line on the nutrition label for *trans* fats would fully inform consumers about the kind of fats that are in the foods they select and consume. These comments urged the agency to list *trans* fat in the same way as other subcomponents of total fat, i.e., saturated and poly- and monounsaturated fats. They stated that doing so would clarify the chemical differences between the fatty acids, including saturated fatty acids, and would be easier for consumers to understand since it eliminates the need for a footnote. Comments also noted that adding a separate line for *trans* fat would be consistent with FDA's regulatory precedent, which was

nutrition labeling regulations, of classifying nutrients based on their chemical definition or structure, rather than their physiological effect (58 FR 2079 at 2089). Moreover, the comments argued that listing *trans* fat on a separate line now would avoid having to do it later if future scientific research shows that the effects of *trans* fat consumption are significantly different from the effects of saturated fat consumption.

Several comments argued that by providing a separate line for *trans* fat, consumers can be educated more easily about the health effects of *trans* fatty acids. These comments disagreed with FDA's position in its November 1999 proposal that *trans* fat should be combined with saturated fat because consumers lack knowledge about *trans* fat information and do not understand the term *trans* fat. Also, some comments stated that FDA's rationale for not listing *trans* fat more prominently (i.e., that consumers are not familiar with the term "*trans* fat") is not justified since consumers do not generally know much about mono- or polyunsaturated fats yet quantitative information may be provided for them in nutrition labeling and must be provided when claims are made about fatty acids or cholesterol. A few comments also stated that creating a separate line for *trans* fat establishes a basis for current and future consumer education about the health risks and benefits of a variety of fatty acids that affect LDL-C and HDL-C levels.

A few comments in favor of a separate line for *trans* fat in nutrition labeling specifically addressed the need to establish a DRV for *trans* fat. One comment stated that FDA could establish a DRV for *trans* fat based on international recommendations for *trans* fat consumption. Another comment indicated that a DRV for *trans* fat could be established at a level equal to or below the average daily intake of *trans* fat. One other comment stated that the only basis for establishing a daily value would be the amount of naturally-occurring *trans* fat in ruminant (dairy) products since they have not been shown to be associated with increased risk of CHD; otherwise, the DRV for *trans* fats formed through partial hydrogenation should be zero. However, the majority of those commenting stated that scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat because no public health or scientific organization has proposed guidelines for dietary intake levels of *trans* fat at this time. Some of these comments said that *trans* fat should be treated in a manner consistent with poly- and monounsaturated fats, i.e.,

there is a basis for establishing a DRV for *trans* fat. A few comments suggested waiting until the IOM/NAS completes its report on DRIs for macronutrients. A few comments noted that listing *trans* fat on a separate line with no % DV would be less useful to consumers because they would not be able to determine if the amount were high or low in the context of the daily diet. One comment stated that if there is enough scientific evidence to require the mandatory labeling of *trans* fat, the agency should provide the information that will help consumers to interpret the magnitude of the amount in the food. Additionally, other comments stressed the importance in helping consumers understand the relevance of the nutrient amount in the context of the total diet.

One comment objected to the option of having a separate line for *trans* fat on the basis of consumer confusion. It said that adding a fourth line of fatty acid information would confuse consumers because they would have to look at several separate values when comparing food products. This comment also was concerned that the use of a separate line would not encourage the food industry to reduce "heart-unhealthy" fat in the food product.

FDA agrees with comments that point out that there are chemical differences between saturated and *trans* fatty acids. The agency noted these differences in its November 1999 proposal when it proposed to include the amount of *trans* fat in the declaration of saturated fat. The intent was to assist consumers in understanding the cholesterol-raising properties of the food by declaring the two fatty acids under the name "saturated fat" without changing the definition of saturated fat, but FDA acknowledged that this action "may confuse consumers and lead some to misclassify *trans* fatty acids as saturated fats" (64 FR at 62746 62755). The agency is persuaded by the large number of comments on this issue that the proposed action was, in fact, interpreted by many as incorrectly classifying the two different fatty acids as "saturated fat" and that it is necessary to disassociate *trans* fat from saturated fat to prevent misleading consumers in this way.

FDA also acknowledges that while the two types of fatty acids have similar effects on LDL-C, there are other physiological distinctions between them. Because the overall weight of scientific evidence in support of the finding that consumption of *trans* fat, like saturated fat, contributes to increased LDL-C levels increasing the risk of CHD, was sufficiently compelling

did not focus on other physiological effects of *trans* fat. While studies on a variety of physiological effects of *trans* fat are ongoing and results preliminary, the agency is persuaded by comments that the declaration of *trans* fat on a separate line will best accommodate future scientific development. This will be helpful if future research more clearly elucidates the physiological mechanisms of each and confirms that *trans* fat does have adverse effects on other CHD risk factors or health conditions that differ significantly from saturated fat.

As pointed out by comments, doing so has the advantage of being consistent with: (1) The format used to list the other subcomponents of total fat, namely saturated, polyunsaturated and monounsaturated fats; (2) the declaration of quantitative amounts contiguous to the listing of the nutrient rather than in a footnote; and (3) the agency's regulatory precedent of classifying nutrients based on their chemical definition or structure. Consistency with the existing format can be expected to assist consumers in recognizing *trans* fat as a subcomponent of total fat. It will also be responsive to consumer interest in knowing the full breakout of fatty acids since, when poly- and monounsaturated fats are declared, the amounts for saturated, *trans*, polyunsaturated, and monounsaturated fats will add up to the amount of total fat except for minor deviations that may result from application of rounding rules in § 101.9(c)(2).

The agency agrees with the majority of the comments that the scientific evidence is not sufficient to support the establishment of a DRV for *trans* fat at this time. The comments that attempted to suggest a basis for doing so did not suggest particular values or submit scientific evidence to justify the establishment of such values. FDA emphasizes that existing DRVs are based on quantitative dietary intake recommendations developed from extensive scientific evidence that establishes values that will promote public health (58 FR 2206 at 2217). DRVs have not been based on international recommendations, which may not be germane in the United States, or on average dietary intake levels, which may not represent healthy dietary consumption patterns. The FDA is not aware of any international recommendations that it could rely on, nor did the comment provide any such specific recommendations. The agency has relied extensively on reports from the IOM/NAS in developing the current Reference Dietary Intake (RDIs) and

report on DRIs for macronutrients (Ref. 140) did not make quantitative recommendations for *trans* fat for establishing a DRV. Accordingly, in the absence of a scientific basis or recommendation by an authoritative body, FDA is not establishing a DRV for *trans* fat. FDA intends to revisit this issue when there is more scientific information that the agency can use to establish an appropriate reference level for *trans* fat intake.

The agency recognizes that the absence of a DRV, and thus, the absence of a % DV for *trans* fat on food labels, nutrition educators will need to direct efforts at educating consumers further about the effects of *trans* fat on LDL-C levels and CHD risk. However, because of the public health impact of CHD in the United States, the agency believes it is necessary to proceed at this time with this final rule to list *trans* fat in nutrition labeling so that consumers will have quantitative information to use in implementing dietary guidelines to cut back on *trans* fat. By adding quantitative information on *trans* fat content, consumers will have information to use in comparing products and making diet selections that will reduce their intake of *trans* fat in the context of their daily diet by substituting lower *trans* fat products for those previously consumed that were higher in *trans* fat.

The agency does not believe it would be any more difficult for consumers to look at a separate line for information on *trans* fats than it has been for any other separate fat listing. Listing them separately will allow consumers to readily see levels of each in food products and make decisions accordingly. In addition, the agency stated earlier that it believes public awareness about *trans* fat has increased since publication of the November 1999 proposal as a result of media attention, press releases, label statements, and industry announcements. FDA concludes that this increased awareness, in conjunction with an education program about the change, will allow consumers to use this new information to help maintain healthy dietary practices and will minimize any confusion caused by the change. To maximize the impact of declaring *trans* fat in the Nutrition Facts panel, a coordinated educational effort among public health professionals and organizations focusing on all three cholesterol-raising dietary components, i.e., saturated fat, *trans* fat, and cholesterol, will be required. Such a program is discussed in Comment 28

The comment that was concerned that use of a separate line for *trans* fat would not encourage industry to reduce "heart-unhealthy" fats did not present any data to show the effectiveness of the various options in achieving this goal. Following implementation of mandatory nutrition labeling rules in 1993, the industry reformulated many foods products to reduce levels of nutrients about which consumers were concerned (Ref. 96). Accordingly, FDA believes that the required addition of information on *trans* fat content to nutrition labels, coupled with a consumer education program on the health effects of dietary *trans* fat, will provide incentive to the food industry to minimize the level of *trans* fat present in individual food products. Some parts of the food industry have responded to consumer concerns, e.g., levels of *trans* fat in margarine products have been lowered (Ref. 104), and companies have announced plans to use reformulated fats that are lower in *trans* fat (Refs. 149 and 150). The agency believes that requiring *trans* fat labeling will prompt others in the food industry to reformulate some of their products to offer lower *trans* fat alternatives.

Accordingly, FDA is revising § 101.9(c) by adding paragraph § 101.9(c)(2)(ii) to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. This new paragraph requires the listing of *trans* fat on a separate line under the statement for saturated fat. As is the case for all subcomponents of total fat, it is to be indented and separated by a hairline, with the amount expressed as grams per serving to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g. If the serving contains less than 0.5 g, the content must be expressed as 0, except when the statement "Not a significant source of *trans* fat" is used. In addition, the agency is clarifying that the word "*trans*" may be italicized to indicate its Latin origin. This provision to allow for italics provides an exception to § 101.9(d)(1)(ii)(A) that requires that a single easy-to-read type style be used throughout the nutrition label. Therefore, paragraph (d)(1)(ii)(A) is being revised to state that "except as provided for in paragraph (c)(2)(ii) of this section," a single easy-to-read type style is to be used throughout the nutrition label.

As a result of adding paragraph (c)(2)(ii) for *trans* fat, the agency is redesignating current paragraph (c)(2)(ii) (polyunsaturated fat) as paragraph (c)(2)(iii) and current paragraph (c)(2)(iii) (monounsaturated fat) as

(Comment 17) In response to the November 2002 reopening of the comment period on the November 1999 proposal to require a footnote stating "Intake of *trans* fat should be as low as possible" when *trans* fat is listed, FDA received some comments that supported the proposed footnote statement. A few comments noted that the proposed footnote was needed to raise consumer awareness and understanding about the relevance of *trans* fat in the diet and to assist them in making healthy food choices. Another comment stated that the footnote is consistent with the IOM/NAS report on macronutrients. Two of the comments strongly recommended that the footnote be modified to state that "Combined total intake of saturated and *trans* fats should be as low as possible." The comments argued that the footnote proposed by FDA gives undue emphasis to *trans* fat and will cause some consumers to evaluate products based on the content of *trans* fat instead of on the content of both *trans* and saturated fats, as is recommended in dietary guidance. One of the comments included the results of a national online survey that tested the communication effectiveness of the proposed footnote relative to no footnote and to the alternative footnote "Combined total intake of saturated and *trans* fats should be as low as possible." Respondents were faced with a food comparison that required them to take both saturated fat and *trans* fat into account to correctly identify the "more healthful" of two food products, described by the comment as the product with the lowest total amount of saturated and *trans* fats combined. The two foods being compared were both high in saturated fat (70% DV (14 g) and 35% DV (7 g) saturated fat) but the food highest in saturated fat (14 g) had no *trans* fat (food 1) while the one with half as much saturated fat (7 g) had 2g of *trans* fat (food 2). With no footnote, over half of the respondents who identified a product as more healthful (57 percent) correctly identified the more healthful food (food 2) and 12 percent chose food 1. In the presence of the FDA proposed footnote, 39 percent of the respondents who identified a product as more healthful incorrectly chose food 1 as more healthful, presumably focusing on the zero *trans* fat content in the higher fat food, with only 45 percent choosing the food with the lowest total amount of saturated and *trans* fats combined. In the presence of the alternative footnote, which mentioned the need to keep the intake of both saturated and *trans* fats low a majority of respondents again

more healthful, with 17 percent choosing food 1.

The majority of the comments strongly opposed the proposed footnote statement and recommended that FDA drop the footnote and finalize the quantitative (grams per serving) label declaration of *trans* fat on a separate line below saturated fat with no % DV. Several comments stated that the proposed footnote statement is inconsistent with the IOM/NAS macronutrient report and incorrectly establishes a de facto DV or UL of zero for *trans* fat intake that the IOM/NAS never intended to establish. Some of these comments explained that the proposed footnote statement takes into consideration part of the recommendation from the IOM/NAS report that recommends the intake of *trans* fat be as low as possible, while ignoring the part that states “* * * while consuming a nutritionally adequate diet.” The comments claimed that the omission of the latter part of the recommendation significantly changes the meaning of the statement and the recommendation of the IOM/NAS, namely that the IOM did not intend to recommend that *trans* fat be totally eliminated from the daily diet. These comments noted that the IOM/NAS report did not establish an UL for *trans* fat despite the relationship between intake of *trans* fat and CHD stating that *trans* fatty acids are unavoidable in ordinary, nonvegan diets, and to attempt to eliminate them would require significant changes in dietary intake patterns which may result in unknown and unquantifiable health risks. The comments went on to say that the IOM committee indicated that “[I]t is possible to consume a diet low in *trans* fatty acids by following the dietary guidance provided in Chapter 11” of their report. The comments concluded that the proposed footnote statement is inconsistent with the IOM/NAS report and could mislead consumers into substituting more foods with saturated fat in an effort to avoid foods containing *trans* fat.

Similarly, several comments described the proposed footnote statement as an unjustified warning statement on the label of foods that contain *trans* fat. Some of these comments stated that consumers will perceive the footnote as a de facto % DV of zero and will not understand the meaning of the portion of the proposed footnote statement “as low as possible;” consumers will perceive it as a warning to avoid *trans* fat-containing foods at all costs. Several comments stated that the footnote would be misleading because

relative impact of saturated fat (by thinking up to 20 g, i.e., the DV for saturated fat, is heart healthy) compared to *trans* fat (thinking *trans* fat intake must be kept to zero to be heart healthy). Some of these comments mentioned that the dietary recommendation to reduce saturated fat is a well established goal of federal agencies and other health organizations and that Americans consume much more saturated fat than *trans* fat. The comments stressed, therefore, that any footnote statement on the nutrition label about *trans* fat should not undermine the important health message consumers have learned over the years about limiting saturated fat intake.

Comments also criticized the proposed footnote for being more prescriptive than, and inconsistent with, other Federal Government dietary recommendations, such as the Dietary Guidelines for Americans 2000 and the NCEP Adult Treatment Panel III Report, 2001. According to the comments, the recommendations of these reports support the need for Americans to choose diets that are low in saturated fat and cholesterol and moderate in fat while reducing, not eliminating, dietary consumption of *trans* fat.

Comments also pointed out that the IOM/NAS report gives essentially identical advice for saturated fat and cholesterol as it gives for *trans* fat, yet FDA’s proposed footnote singled out only their recommendation for *trans* fat. The comments argued that this placed undue emphasis on the role of *trans* fat in heart health.

Many of the comments expressed concern that the proposed footnote statement is potentially misleading to consumers and will undermine the key goals of this rulemaking. To that end, the comments strongly recommended that FDA drop the proposed footnote statement from the final rule and take time to conduct consumer research to determine the impact of the proposed footnote statement on consumers’ understanding and comprehension. A few comments cited FDA’s obligation under the 1990 amendments (paragraph 2(b)(1)(A)) 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.” The comments argued that the proposed footnote statement should be consumer tested to ensure that the nutrition information provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. The majority of

footnote statement commented that even in the absence of a DV, consumers can still find quantitative information useful (similar to the listing of monounsaturated and polyunsaturated fats on the nutrition label).

Many of the comments recommended that FDA not move forward with the proposed footnote until the IOM/NAS completes a study, which is underway, of the uses of DRIs in nutrition labeling. The comments noted that the IOM is under contract with FDA, USDA and Health Canada to assess the objectives, rationale, and recommendations for the methodology for selecting reference values for nutrition labeling of foods based on DRIs and will identify guiding principles for use in setting reference values for nutrients on the food label. The comments also noted that the IOM committee is expected to complete its work on this project in mid-2003 and to issue a report in September 2003.

One comment stated that the prescriptive nature of the proposed footnote may also violate international obligations of the United States under the World Trade Organization (WTO). The comment stated that WTO’s Agreement on the Sanitary and Phytosanitary (SPS) Measures requires that SPS measures intended to protect human health be based upon sound science. The comment questions this regarding the proposed footnote statement because it implies a benefit to consumers who avoid consuming *trans* fat foods when the IOM/NAS suggests that eliminating *trans* fats entirely in the diet would lead to greater harm by impeding dietary intake of essential nutrients. The comment also stated that if the proposed footnote statement was not a SPS measure, it would violate WTO’s Agreement on Technical Barriers to Trade, which requires that “technical” regulations fulfill a legitimate purpose and be no more trade restrictive than necessary. The comment expressed the opinion that the proposed footnote statement oversimplifies and misrepresents the IOM/NAS report on which it is based and that the statement is more trade restrictive than necessary because alternatives to such a footnote statement, such as a consumer education program, are available to assist consumers in understanding the quantitative *trans* fat labeling in the absence of a DV.

Some comments expressed concern that the proposed footnote statement would provide a disincentive to the industry such that many foods would be reformulated to reduce or remove *trans* fat but, as a result, saturated fat content would be increased. Other comments

label space for the proposed footnote statement. One comment stated that the Nutrition Facts panel would no longer be simple and uncluttered and, as a result, consumers would be discouraged from reading the label. Other comments complained that the 30-day comment period for the November 2002 proposal was inadequate to address footnote issues and to conduct needed consumer research.

Many of the comments stated that FDA did not carry its burden under the first amendment. The comments argued that the proposed footnote statement fails to serve a substantial government interest in alleviating a genuine public harm, does not directly advance that interest and is not narrowly tailored. Several comments stated that the footnote statement is tantamount to a warning statement and is misleading.

Some comments stated that the use of the footnote statement would be establishing a new precedent by providing guidance, not just quantitative information on the Nutrition Facts panel. They argued that there were no consumer data to show that the footnote will help consumers understand the information. Comments stated that the agency had such data when it decided on the Nutrition Facts panel labeling format that only included quantitative information and should have consumer data here, where a new precedent is being considered.

Lastly, a few comments opposed FDA's offer to consider exercising our enforcement discretion to allow products to begin declaring *trans* fat and include the proposed footnote statement prior to publication of the final rule. One comment stated that the agency should publish a "clarification notice" to stop companies that are changing their labels now.

The agency is persuaded by comments that the statement it proposed may have unintended consequences. It was not FDA's intent to distract consumers from dietary guidance to minimize intake of saturated fat, but rather, in the absence of a DV for *trans* fat, to inform consumers of recommendations concerning its consumption.

While the online survey was small, its results support concerns expressed by the food industry that some consumers would interpret the footnote as a de facto DV of zero or as a warning statement that they should avoid all *trans* fat. The agency agrees with comments that this interpretation is inconsistent with dietary guidance given in the IOM/NAS report to keep intake of *trans* fat "as low as possible

adequate diet" (Ref. 140), as well as guidance in the Dietary Guidelines 2000 to cut back on saturated and *trans* fats when reducing total fat intake (Ref. 87) or in the 2001 NCEP report to keep the intake of *trans* fatty acids low (Ref. 89). FDA also agrees that these scientific reviews have similar dietary recommendations for the intake of saturated fat and cholesterol that are important for consumers to take into consideration when making decisions about heart-healthy dietary choices. The agency addressed only *trans* fat in the footnote statement, not because saturated fat or cholesterol had different recommendations or were less important, but because they have established DVs from which to determine the % DV for nutrition labeling purposes.

The agency agrees with comments that support consumer testing to ensure that information on the food label provides meaningful guidance to consumers and drives the market in a nutritionally beneficial direction. FDA concludes, therefore, that based on arguments presented in the comments, that while the footnote would provide guidance on dietary recommendations for *trans* fat, it is premature to require the use of the proposed footnote statement in the nutrition label without further research. Consumer research would likely need to provide information on the impact of the statement in a footnote on consumers' food selections.

Accordingly, as a result of concerns expressed in the comments, asserting that consumers may place undue emphasis on *trans* fat information relative to other heart-unhealthy fats from the presence of the *trans* fat proposed footnote, the agency is not proceeding at this time to incorporate a requirement for a footnote statement in this final rule. Instead, FDA is issuing an ANPRM elsewhere in this issue of the **Federal Register** that will solicit comment and additional consumer research on the use of a footnote and the language that may be used in a footnote to better reflect the dietary recommendations given in the previously-mentioned scientific reviews. The ANPRM will also 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 to establish disclosure

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 consumer's understanding about cholesterol-raising lipids. In light of the need for consumer research to evaluate consumers' understanding of the totality of dietary recommendations that address the selection of foods for a heart-healthy diet, the agency notes in the ANPRM that it intends to conduct such research and looks forward to receiving additional research from other interested parties.

In the meantime, as noted in the preceding comment, FDA is issuing this final rule to require the quantitative declaration of *trans* fat in the Nutrition Facts panel. To help consumers understand more about this heart-unhealthy fat, the agency plans to initiate consumer education programs about this final rule following publication (see Comment 28). As noted earlier, most comments that opposed the proposed footnote stated a belief that even in the absence of a DV, consumers can still find quantitative information useful, and pointed to current labeling of mono- and polyunsaturated fats. In light of previous research that shows that consumers often use information on the Nutrition Facts panel to compare levels of nutrients in two or more foods, FDA concludes that it is important to proceed to list the quantitative information on *trans* fat at this time so that consumers will have information to use in comparing products and making dietary selections to reduce their intake of *trans* fat. The agency believes a footnote or other labeling approach about saturated fat, cholesterol, and *trans* fat may provide additional assistance to convey the relative importance of each of these fats to consumers in a manner which enables them to understand their relative significance, to each other and in the context of a total daily diet. However, because of the public health impact of CHD in the United States and the additional time it will take to conduct the necessary consumer research, the agency concludes that it is essential to proceed at this time to mandate the listing of the quantitative information on *trans* fat so that consumers will be able to use that information to help maintain healthy dietary practices and to address an added footnote statement at a later time.

FDA acknowledges concerns,

2002 notice (67 FR 69171) to reopen the comment period, about the shortness of the comment period and requests to extend the comment period. However due to the high level of interest in the public health and economic aspects of this rule, the agency did not believe it was in the public interest to provide for additional time for comment. A longer comment period, however, will be provided for the ANPRM being published elsewhere in this issue of the **Federal Register**.

(Comment 18) A few comments requested that the term “*trans* fatty acids” not be used interchangeably with “*trans* fat” as proposed in § 101.9(c)(2)(i)(B) in the November 1999 proposal. These comments stated that the term “fatty acid” would be confusing to consumers and is inconsistent with the terminology used in nutrition labeling and claims for other fatty acids, i.e., “saturated fat,” “polyunsaturated fat,” and “monounsaturated fat.” The comments stated that while “fatty acid” is technically correct, labels should use the easier term to understand, i.e., “*trans* fat.”

The agency agrees that there should be consistent terminology used on the food label and notes that proposed § 101.9(c)(2)(i)(B), which dealt primarily with the proposed footnote about *trans* fat content, is deleted from this final rule. The agency did not move the sentence providing for the use of the term “*trans* fatty acids” to new § 101.9(c)(2)(ii). Therefore, the term “fatty acids” is not to be used on the Nutrition Facts panel.

Conforming Amendments

Because this final rule is making *trans* fat a mandatory nutrient to be placed on a separate line in nutrition labeling, there are a number of conforming amendments throughout § 101.9 that must be made. Section 101.9(c) requires that information on mandatory nutrients, such as saturated fat and *trans* fat, be included in all nutrition labeling unless otherwise excepted from such labeling as provided for in specified paragraphs.

Special provisions within § 101.9(c) allow for shortened formats that provide manufacturers flexibility to omit noncore nutrients (i.e., mandatory nutrients other than calories, total fat, sodium, total carbohydrate, and protein) that are present in insignificant amounts from the list of nutrients and group them in a summary statement at the bottom of the label that states “Not a significant source of _____” (see 58 FR 2079 at 2083, Comment 8, January 6,

found in § 101.9(c)(1)(ii) for calories from fat, § 101.9(c)(2)(i) for saturated fat, § 101.9(c)(3) for cholesterol, § 101.9(c)(6)(i) for dietary fiber, § 101.9(c)(6)(ii) for sugars, and § 101.9(c)(8)(iii) for vitamin A, vitamin C, calcium, or iron. For consistency with the labeling scheme for these other noncore mandatory nutrients, new § 101.9(c)(2)(ii) provides that if the *trans* fat content is not required and, as a result, not declared, the statement “Not a significant source of *trans* fat” must be placed at the bottom of the table of nutrient values. Also, for added consistency, new § 101.9(c)(2)(ii) will point to an exception to this requirement under § 101.9(f). Section 101.9(f) provides for a simplified format to be used on labels of products containing insignificant amounts of more than half the nutrients required to be in the Nutrition Facts label. Except as specified in § 101.9(f)(4), products that qualify for the simplified format do not have to use the statement “Not a significant source of _____” for noncore nutrients that are omitted from the label under § 101.9(c). An example of such an exception would include when nutrition claims are made for the product.

Current § 101.9(c)(2)(i) requires label declaration of saturated fat content information on a separate line (the “Not a significant source of _____” statement would not be an option), if claims are made about fat or cholesterol and if “calories from saturated fat” is declared. In the November 1999 proposal, § 101.9(c)(2)(i) was amended to also require label declaration of saturated fat content information when claims are made about fatty acids. Current § 101.9(c)(2)(i) did not include claims about fatty acids because at the time that regulation was proposed (56 FR 60478, November 27, 1991), it was thought unnecessary since no claims were proposed for fatty acids that were present at less than 0.5 g per reference amount. However, when the “saturated fat free” claim was established in the final rules (58 FR 2302 at 2331), FDA inadvertently did not amend § 101.9(c)(2)(i) to require the declaration of saturated fat content on a separate line when fatty acid claims were made. As a result, the declaration of saturated fat content was not required when “saturated fat free” claims were made. This is inconsistent with regulations governing claims for all other nutrients that require the listing of the nutrient that is the subject of the claim within the Nutrition Facts panel so that consumers can easily find quantitative

a product. Because no comments objected to the proposed requirement in the November 1999 proposal for a label declaration of saturated fat content when fatty acid claims are made, which would require that saturated fat content be listed when a “saturated fat free” claim is used, FDA is finalizing this part of the regulation as proposed. Similarly, new § 101.9(c)(2)(ii) also requires label declaration of *trans* fat content information if claims are made about fat, fatty acids, or cholesterol.

In reference to the statement “Not a significant source of _____” that is to be placed at the bottom of the list of nutrient values, the agency proposed in the November 1999 proposal (64 FR 62746 at 62757) to remove the phrase “in the same type size” in § 101.9(c)(2)(i) where it refers to the size of the statement. This action was intended to correct a technical error in the regulations caused by the fact that current § 101.9(d)(1)(iii) allows the statement, along with all footnotes, to be in type size no smaller than 6 point type while it requires the listing of nutrient values to be in type size no smaller than 8 point type. Accordingly, the phrase “in the same type size” in § 101.9(c)(2)(i) would require the “Not a significant source of _____” statement to be in 8 point type, conflicting with § 101.9(d)(1)(iii). This technical error was addressed in amendments published on August 18, 1993 (58 FR 44063 at 44065–66). To correct the problem, FDA stated at that time (58 FR 44063 at 44065–66) that it was removing the sentence from § 101.9(c)(8)(iii) that required the “Not a significant source of _____” statement to be in the same type size as nutrients listed in the Nutrition Facts panel. However, the agency failed to notice the same error in § 101.9(c)(2)(i), (c)(3), (c)(6)(i), and (c)(6)(ii). Inadvertently, the conflicting sentence was never removed from § 101.9(c)(8)(iii), nor were the statements requiring “in the same type size” removed from any of the other paragraphs. In this final rule, FDA is making the correction in § 101.9(c)(2)(i) and in new § 101.9(c)(2)(ii). The agency intends to remove the phrase “in the same type size” from the remaining sections of § 101.9(c) in the future.

In addition, current nutrition labeling rules provide exemptions for select nutrients when food products qualify for simplified formats (see § 101.9(f)).

FDA is revising § 101.9(f) that pertains to the use of a simplified format when a food product contains insignificant amounts of seven or more of the mandatory nutrients. This section implements section 403(q)(5)(C) of the

insignificant amounts ... of more than one-half the nutrients required * * * to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary." Current regulations considered 13 required nutrients (calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron) and calculated "more than one-half" to mean that seven or more nutrients must be at insignificant levels for a product to use the simplified format (58 FR 2709 at 2140, comment 173). Accordingly, in conformance with the statutory requirements, the inclusion of *trans* fat as a mandatory nutrient results in a total of 14 required nutrients. This new total necessitates changing the number of nutrients that must be present in insignificant amounts in § 101.9(f) from seven to eight to qualify a food for the simplified format. Therefore, FDA is revising § 101.9(f) to state "The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron * * *"

FDA is modifying sample labels throughout § 101.9 to be consistent with the revisions described previously. The citations for the sample labels that have been modified are as follows: § 101.9(d)(11)(iii) (the tabular display of the nutrition label), paragraph (d)(12) (the full nutrition label), paragraph (d)(13)(ii) (an example of an aggregate nutrition label), and paragraph (e)(5) (nutrition information presented for a food "as purchased" and "as prepared"). Likewise, the sample labels in § 101.9(j)(13)(ii)(A)(1) and (j)(13)(ii)(A)(2) (tabular display and linear displays, respectively, of nutrition labels for foods in packages with a total surface area available to bear labeling of 40 or less square inches) are also being revised to include *trans* fat.

Other conforming amendments to § 101.9 that are required as a result of this rulemaking include revisions to paragraphs (g)(5) and (g)(6) that inform the industry of how FDA will determine compliance with this section. Paragraph (g)(5) addresses those nutrients for which dietary guidance generally recommends limitations on intake. Accordingly, FDA will include *trans* fat as one of the nutrients that are deemed

of the act if the nutrient content of the composite sample is greater than 20 percent in excess of the value for that nutrient declared on the label. Likewise, § 101.9(g)(6) is being revised to state that reasonable deficiencies in a food of calories and specified nutrients, including *trans* fat, under labeled amounts are acceptable within current good manufacturing practice.

Section 403(q)(5)(F) of the act specifies that dietary supplement products shall bear nutrition labeling "in a manner which is appropriate for the product and which is specified in regulations..." Accordingly, FDA issued regulations in § 101.36 that specify the nutrition information that must be on the label or labeling of dietary supplements (62 FR 49826, September 23, 1997). In the November 1999 proposal, FDA proposed to amend § 101.36 to maintain consistency in the nutrition labeling of conventional foods and of dietary supplements. Comments unanimously supported revising § 101.36 to be consistent with § 101.9 as it pertains to the provisions for *trans* fat. Accordingly, FDA is revising paragraph § 101.36(b)(2)(i) to provide for *trans* fats in the nutrition labeling of dietary supplements.

This final rule also impacts on the voluntary nutrition labeling program of raw fruits, vegetables, and fish in that § 101.45(a)(2) requires that nutrients be declared in accordance with § 101.9. However, because section 403(q)(4)(A) of the act requires the Secretary, and by delegation FDA, to furnish nutrition information for that program and the agency has proposed to update those values (67 FR 12918, March 20, 2002), the agency is deferring action on § 101.45 until a final rule is published on that rulemaking.

C. Definition of *Trans* Fatty Acids

In the November 1999 proposal, FDA defined *trans* fatty acids as "unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration (64 FR 62746 at 62757).

(Comment 19) Most of the comments on the definition of *trans* fat supported the proposed definition that excludes fatty acids with conjugated bonds, stating that *trans* fatty acids with conjugated bonds are metabolized differently than those with nonconjugated bonds and that this definition adequately identifies the fatty acids intended to be covered by the rule. A few comments recommended that *trans* fatty acid precursors of conjugated linoleic acid (CLA) should also be excluded from the definition. These

acid (*trans*-11 18:1), which is the dominant *trans* fatty acid in products of ruminant origin (e.g., cows' milk), can be desaturated in the body and converted to CLA. For this reason, the comments recommended that *trans* fatty acids of ruminant origin not be included in the definition of *trans* fatty acids.

Other comments stated that *trans* fatty acids with conjugated bonds should be included in the definition of "*trans* fatty acids."

Another comment requested that FDA explicitly state that the rules on the labeling and claims for *trans* fatty acids apply equally to naturally occurring *trans* fats.

FDA notes that the comments requesting that *trans* vaccenic acid and other *trans* fatty acids of ruminant origin be excluded from the definition of *trans* fatty acids and that fatty acids with conjugated bonds be included focused on functional or metabolic aspects of these compounds (e.g., their metabolic transformations to other types of fatty acids) rather than on their actual chemical structures. Since most of the comments agreed with the proposed definition, which identifies *trans* fatty acids by their chemical structures, the agency is taking no action in response to suggestions to define *trans* fatty acids by their functional attributes. Thus for the purposes of this rule, the origin of the *trans* fatty acid does not matter. *Trans* vaccenic acid, a *trans* fatty acid with a single double bond, and other *trans* fatty acids of ruminant origin with either a single double bond or nonconjugated double bonds are included in this chemical definition of *trans* fatty acids. *Trans* fatty acids with conjugated bonds will not be included because they do not meet the Agency's regulatory chemical definition of *trans* fatty acids which is "all unsaturated fatty acids that contain one or more isolated double bonds in a *trans* configuration." FDA notes also that while the proposal combined saturated fat and *trans* fatty acids on a single line, this final rule provides for a separate line for *trans* fat. The declarations of saturated fat and *trans* fat will now be separate and both declarations will be based on chemical definitions of these components. Again, *trans* fatty acids, regardless of origin, that meet the above definition are to be included in the label declaration of *trans* fat.

FDA notes that, in classifying fatty acids, the IOM report on macronutrients uses a chemical definition of *trans* fatty acids that differs from FDA's regulatory chemical definition. The IOM report includes all fatty acids with a double bond in the *trans* configuration in the

140). Thus, the IOM definition includes both conjugated and non-conjugated double bonds in the *trans* configuration, whereas FDA's definition only includes *trans* fatty acids with nonconjugated double bonds. In addition, the IOM report considers conjugated linoleic acid as a collective term for geometric and positional fatty acids in which the double bonds (*trans* and/or *cis*) are conjugated. In the IOM report, the categories, *trans* fatty acids and conjugated linoleic acid, overlap. Under FDA's definition, conjugated linoleic acid would be excluded from the definition of *trans* fat. Thus, using FDA's regulatory chemical definition, the categories "*trans* fatty acids" and "conjugated fatty acids" are mutually exclusive. The definition of *trans* fatty acids, excluding fatty acids with conjugated double bonds, is consistent with the way that *cis* isomers of polyunsaturated fatty acids are defined in redesignated § 101.9(c)(2)(iii).

D. Methodology

(Comment 20) One comment asked whether the Association of Official Analytical Chemists (AOAC) Official Method 996.01 can be used for measuring *trans* fat in foods. The comment noted that, at present, AOAC Official Method 996.01 is the ideal method for the measurement of total fat, saturated fat, and mono- and polyunsaturated fat in foods. The comment noted further that AOAC Official Method 996.01 was originally intended for cereal products containing 0.5–13 percent total fat and that recently, a study by Ali et al. (Ref. 30) demonstrated its applicability to all types of food matrices with fat contents ranging from 0.7 to 97.5 g/100 g food. The comment noted that the method of Ali et al. (Ref. 30) used an SP-2560 fused silica capillary column (100 meters (m) x 0.25 millimeter (mm)) and can be used for the accurate determination of *trans* fatty acids. The comment noted that if appropriate gas chromatography (GC) operating conditions are selected, the SP-2560 column as well as columns of similar polarity give a very good separation of *cis* and *trans* isomers.

FDA notes that, as currently written, AOAC Official Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified (i.e., 30 m x 0.25 mm id., 0.2 µm film, non-bonded 90 percent cyanopropyl, 10 percent phenyl siloxane) is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids. Ali et al., (Ref. 30) modified the method and used a 100 m

100 m x 0.25 mm id., 0.20 µm film thickness) to obtain better separation of isomers in food samples. Specifically, better resolution in the complex 18:1 and 18:2 regions was obtained with the longer column. FDA has found that when appropriate operating conditions are selected, the SP-2560 column and other columns of similar polarity give a very good separation of *cis* and *trans* isomers. We point out, however, that the modification described by Ali et al., (Ref. 30) has not been subjected to a collaborative study and is not an official method.

It is important to note that FDA regulations do not specify the methodology that firms are to use in obtaining values for nutrition labeling purposes. Rather, under § 101.9(g)(2), FDA determines compliance with nutrition labeling rules by using appropriate analytical methods "as given in the 'Official Methods of Analysis of the AOAC International' 15th Ed. (1990) or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures." Firms may choose to use a method other than that which the agency uses to determine compliance, but the firm would be subject to, for compliance purposes, a method the agency considers appropriate under § 101.9(g). With respect to analysis of fats (including *trans* fat), FDA laboratories utilize the most recent editions (including revisions of methods from the Association of Official Analytical Chemists International (AOACI; *Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; AOAC International, Gaithersburg, MD) (Ref. 143) and the American Oil Chemists Society (AOCS; *Official Methods and Recommended Practices of the AOCS*, 2002–2003 Methods-Additions and Revisions, AOCS Press, Champaign, IL) (Ref. 144)).

(Comment 21) Several comments asked that FDA recognize AOAC Method 996.06 as modified in the *Journal of the Association of Official Analytical Chemists* in January 2000, as a suitable method for the analysis of *trans* fatty acids for food labeling purposes.

FDA points out that recommendations for the modification of AOAC Official Method 996.06 (Ref. 105) were published in the *Journal of the Association of Official Analytical Chemists* (Ref. 106). The recommendations are based on the work of DeVries et al. 1999 (Ref. 107). DeVries and coworkers report that while quantitation of fat in foods has been performed successfully with AOAC

situations have been encountered that render the following method note inaccurate: "For any unknown or uncalibrated peaks, use the nearest calibrated fatty acid response factors and conversion factors" (Ref. 107). Specifically, the identification of extraneous compounds and availability of additional standard fatty acid methyl esters combined with mass spectral data led to the recommendation of modifications in AOAC Official Method 996.06.

Specific recommendations for modifications include recommendations that the column requirements for the method be changed to a performance-based specification such that a capillary column capable of separating adjacent peaks of C18:3 and 20:1 and the fatty acid methyl ester trio of adjacent peaks of C22:1, C20:3 and C20:4 with a resolution of 1 or greater be used. Column SP-2560, 100 m x 0.25 mm with a 0.20 µm film was identified as a suitable column.

The recommendations referenced in the paragraph above have now been incorporated into AOAC Method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002; chapter 41.1.28A) (Ref. 105). This method is suitable for use in a wide range of food matrices for measuring *trans* fat for labeling purposes.

AOAC Method 996.06 cited above for *trans* fat analysis is the most current AOAC gas chromatography method available and FDA will consider it an appropriate method under § 101.9(g)(2) for determining compliance with nutrition labeling provisions for *trans* fat. AOAC Method 996.06 is not included in the 15th edition (1990) of *Official Methods of Analysis of AOAC International* (which is incorporated by reference in § 101.9(g)(2)) because the process of development and validation of this method was not completed until 1996. Therefore, AOAC Method 996.06 as it is reported in Revision 1, 2002 of the 17th edition of *Official Methods of Analysis of AOAC International* (Ref. 105) may be used as an "other reliable and appropriate analytical procedure" as provided for in § 101.9(g)(2). FDA intends to propose amendments in the future on the edition of the AOAC method listed in § 101.9(g)(2) and other needed revisions of § 101.9.

(Comment 22) One comment noted that detection methodology is not sophisticated enough to accurately measure *trans* fat in all food products. The comment stated that significant work is needed to validate the AOCS methods for food matrices other than fat

FDA disagrees with this statement. While the agency recognizes that AOCS methods have not been extended to cover matrices other than fats and oils, the AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105) is suitable for the analysis of *trans* fat in a wide range of foods of varying fat content. As noted in comment 19, above, AOAC Method 996.01 is not suitable for quantifying *trans* fatty acids for food labeling purposes because the capillary column specified is not sufficiently long to obtain adequate separation of the *cis* and *trans* fatty acids.

(Comment 23) A few comments recommended that FDA consider listing amounts of *trans* fat to the nearest tenth or hundredth of a gram, rather than to the nearest 0.5 g. One of these comments stated that Canada has established a rounding limit of 0.1 g for food labeling indicating that analytical methods are capable of detecting that amount.

FDA disagrees with these recommendations. FDA notes that while these recommended levels might be quantifiable by laboratories using GC methodology such as that described in AOAC method 996.06 (*Official Methods of Analysis of AOAC International*, 17th edition, Revision 1, 2002) (Ref. 105), they will pose a problem for laboratories that are set up to quantify *trans* fatty acids by infrared spectroscopy (IR) methodology because the detection limits of the currently available IR methods are higher than those of the GC methods. More importantly, however, there are no unambiguous methods for confirming the very low levels suggested by the comment.

Moreover, FDA notes that the increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat. Therefore, the agency is finalizing § 101.9(c)(2)(ii) to state that *trans* fat shall be expressed, as proposed, to the nearest 0.5 g increment below 5 g and to the nearest gram increment above 5 g.

(Comment 24) One comment noted that the IR method of choice in the November 1999 proposal, AOCS Recommended Practice Cd 14d-96 (Ref. 45), generally overestimates *trans* fat at low levels because of interferences and issues with both accuracy and detection limits. The comment noted further that the AOCS GC method Ce 1f-96 (Ref. 46) has better sensitivity, but has not been validated for many types of food products and that significant work is needed to validate this method for other

FDA agrees that the detection limits of the AOCS GC method (Ce 1f-96) (Revised 2002, Ref. 146) are lower than those of the AOCS IR recommended practice (Cd 14d-96) (Revised 1999, Ref. 145). FDA notes that AOCS Recommended Practice Cd-14d-96 is applicable to the determination of isolated *trans* double bonds in natural or processed oils and fats with *trans* levels equal or greater than about 0.8 percent. The lower limit of quantitation for this IR recommended practice may be higher (i.e., the method may be less accurate for determination of low levels of *trans* fat) for complex systems such as commercial food products (Ref. 145).

The AOCS Official Method Ce 1f-96 (Ref. 146) is designed to evaluate the level of *trans* isomers formed during refining or during hydrogenation of vegetable oils or fats and the scope of the method does not extend beyond these matrices. FDA notes that the recent improvements in AOAC Official Method 996.06 as referenced in Revision 1, 2002 (Ref. 105), have resulted in the applicability of this GC method to a wide range of food products.

(Comment 25) One comment asked if *trans* fat values below 0.5 g are to be declared as "0," how FDA will address the labeling of foods like butter, where *trans* fat content fluctuates seasonally above and below 0.5 g per serving. The comment stated that FDA should err on the side of conservatism and require that labeling be based on the highest levels found in such products over the entire year.

FDA has long recognized that variations occur naturally in the nutrient content of foods. The compliance procedures that FDA follows, which are found in § 101.9(g)(2), provide that a sample for nutrient analysis must consist of a composite of 12 subsamples, taken one from each of 12 randomly chosen shipping cases. FDA will then analyze the nutrient content of this composite test sample. Upon determination of the laboratory analyses, FDA uses the compliance procedures set forth in § 101.9(g)(5) and (g)(6) to determine if the values declared for those nutrients that have recommended dietary limits, such as saturated fat and cholesterol, misbrand the label. The content of a sample composite of these nutrients is in compliance if the analyzed value is no more than 20 percent greater than the value declared on the label. Stated another way, for nutrients listed in § 101.9(g)(5), the ratio between the nutrient level obtained by laboratory analysis and the product's label value,

than 120 percent for the product to be in compliance. For example, if the laboratory value is 4 grams, and a product's label value is 2 gram, the ratio $(4/2) \times 100 = 200$ percent. This value is greater than 120 percent, hence, the product is out of compliance.

FDA did not address this issue in the proposal because the declaration of "saturated fat" included *trans* fats, and saturated fats are addressed in § 101.9(g)(5) and (g)(6). Now that FDA is requiring that *trans* fat be declared in the main body of the nutrition label (i.e., the amount of *trans* fat is not in a footnote), FDA is making a conforming amendment to § 101.9(g)(5) and (g)(6) to include *trans* fatty acids.

FDA's policy since the 1970s assigns the manufacturer the responsibility for assuring the validity of a product label's stated nutrient values (Ref. 108). Accordingly, the source of the data used to calculate nutrition labeling values is the manufacturer's prerogative, but FDA's policy recommends that the nutrient values for labeling be based on product composition, as determined by laboratory analysis of each nutrient. If a manufacturer knows that a nutrient is likely to vary over seasons or due to other factors (e.g., location, growing conditions, product transport, or processing practices), in order to assure compliance, the manufacturer should analyze samples of the product over the various seasons or relative to other factors to account for variability of nutrient content.

To ensure that label values will accurately represent the nutrient content of food products to consumers and also have a high probability of being in compliance with nutrition labeling regulations, FDA recommends the calculation of a one-sided 95 percent prediction interval as the most appropriate and the preferred method to use in computing label values (Ref. 108).

Prediction intervals take into account the variability of a nutrient. Mean values do not. A manufacturer of a product, like butter, whose *trans* fat content fluctuates seasonally, would want to analyze samples of *trans* fat during each season and statistically consider using 95 percent prediction intervals to calculate the nutrition label value for *trans* fat. A predicted value on a nutrition label may sometimes indicate a level of a nutrient such as saturated fat at a higher level than is actually in the product, but it will never show a lower level than the product contains. While sometimes predicted values and mean values round to the same nutrient level, products bearing

have a lower probability of meeting FDA compliance requirements.

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

In its November 1999 proposal, FDA proposed a definition for the nutrient content claim "*trans* fat free" and proposed limits on the amounts of *trans* fat wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. Several comments to that proposal requested that the final rule define the claim "reduced *trans* fat" or amend the claim "reduced saturated fat" to require a reduction of saturated and *trans* fats combined. To address this issue, the agency reopened the comment period (65 FR 75887) to consider "reduced *trans* fat" and "reduced saturated and *trans* fat" claims.

With regard to the specific definitions, FDA proposed that "*trans* fat free" and "saturated fat free" should be defined as less than 0.5 g *trans* fat and less than 0.5 g saturated fat per reference amount and per labeled serving; "low saturated fat" as 1 g or less of saturated fat and less than 0.5 g of *trans* fat per reference amount and not more than 15 percent of calories from saturated fat and *trans* fat combined; "reduced saturated fat" as at least 25 percent less saturated fat and at least 25 percent less saturated fat and *trans* fat combined; "lean" as 4.5 g or less of saturated fat and *trans* fat combined; and "extra lean" as less than 2 g of saturated fat and *trans* fat combined. In addition, cholesterol claims were allowed only on foods containing 2 g or less of saturated fat and *trans* fat combined, and disqualifying and disclosure levels were set at 4 g or less of saturated fat and *trans* fat combined. FDA did not propose to define "low *trans* fat."

The comments relating to claims were very diverse and indicated strongly opposing views. With regard to the "*trans* fat free" claim, some comments favored the proposed definition, while other comments suggested increasing the saturated fat limit, eliminating the saturated fat limit, or not defining this claim. Similarly, some comments supported the "saturated fat free" claim, while other comments recommended that the *trans* limit be increased to 2 g. For "low saturated fat" some comments favored the proposed definition, while others suggested increasing the *trans* fat limit as high as 2 g. One comment recommended that this claim be less than or equal to 1.5 g of saturated and

A number of comments supported having a "reduced *trans* fat" claim and others were against it. The vast majority of the comments in favor of this claim suggested that *trans* fat be reduced by at least 25 percent, but there was little agreement on the secondary saturated fat criterion. The comments ranged from no limit on saturated fat, to no increase in the level of saturated fat, a limit of less than or equal to 2 g, or at least a 25 percent reduction. The comments on "reduced saturated" fat were similar to the comments on "reduced *trans* fat" in that there was no agreement on the level of the secondary criterion, i.e., *trans* fat for this claim. In addition, some comments recommended having the claim "reduced saturated and *trans* fats" for greater flexibility, while others opposed such a claim. Of those in favor, some comments recommended a reduction of at least 25 percent in saturated and *trans* fats combined, one comment favored a 33 to 50 percent in saturated and *trans* fats combined, and one comment wanted a 25 percent reduction in saturated fat and a 25 percent reduction in *trans* fat.

Finally, the comments on disclosure and disqualifying levels were equally divergent. Some comments favored the proposed criterion of 4 g or less of saturated and *trans* fats combined, while others recommended a limit of 4 g of saturated fat and 4 g of *trans* fat, or believed that there should be no limit on *trans* fat. One comment stated that *trans* fat thresholds should be incorporated into the criteria defining nutrient content claims and health claims only to the extent that such criteria are necessary to prevent the claim from misleading consumers. The comment stated that this is the approach FDA applied in establishing the saturated fat thresholds for cholesterol content claims in § 101.62(d) and is an appropriate construct for nutrient content claims about *trans* fat.

The objections in the comments against the proposed definitions were generally based on scientific, legal, or economic arguments. Some of the comments believed that the agency is acting in advance of sufficient scientific justification, while others stated that the agency should have acted sooner. There was disagreement as to whether the adverse effects of *trans* fat are comparable to that of saturated fat. Some of the comments stated that the proposed definitions assume that *trans* fat and saturated fat are "bioequivalent." These comments particularly objected to changing the disclosure and disqualifying level of 4 g of saturated fat to 4 g of saturated and

current level constant and including *trans* fat). These comments argued that the effects of saturated fat and *trans* fat have not been proven to be the same on a gram-for-gram basis and, therefore, should not be treated interchangeably. Other comments stated that there is no scientific evidence showing any adverse effects on serum cholesterol levels or cardiovascular health from *trans* fat in a mixed diet to support FDA's proposed definitions for nutrient content claims.

Other comments argued that the proposed claims should be included in the final rule for public health reasons, while others argued that less restrictive claims would benefit the public health to a greater extent because they would encourage more reformulation. Some of these comments pointed out that the "*trans* fat free" claim, in particular, is not meaningful because very few foods could meet the proposed criteria and therefore would not be used enough to be helpful.

Several comments asserted that FDA did not meet its burden under the first amendment because the threshold levels proposed by FDA for *trans* fat for certain nutrient content and health claims, which, if exceeded, would prohibit the use of the claims on food and have the effect of restricting the use of specific claims that would be truthful and not misleading. The comments reasoned that FDA could only limit claims where the level of *trans* fat in a food product would make the claim misleading. Further, the comments reasoned that, before FDA could prohibit a claim, FDA would need to establish that the use of a disclaimer on the label or the disclosure of *trans* fat on the label could not prevent the claim from being potentially misleading.

Economic concerns regarding the proposed nutrient content claims are discussed in section IX of this document.

FDA has carefully reviewed the comments and finds that it has insufficient scientific information at this point in time to support a decision on the appropriate definition for the nutrient content claims discussed in the November 1999 proposal and the December 5, 2000, notice to reopen the comment period. The comments that expressed a preference for a specific threshold level of *trans* fat for various claims did not provide a scientific rationale to support the level. In the past, the development of definitions for nutrient content claims and the establishment of disclosure and disqualifying levels generally have been dependent upon scientific agreement of appropriate quantitative reference

nutrient that is the subject of the claim. In proposing nutrient content claims, the agency stated that "With the exception of the term "sugar free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs" (56 FR 60421 at 60429, November 27, 1991). The approach of having an appropriate reference value for daily consumption provides a consistent and quantitative basis for defining claims. As stated in section V of this document, in the absence of the type of quantitative information from authoritative scientific groups on which the agency could support the establishment of a DRV for *trans* fat, the agency is providing for mandatory *trans* fat labeling, without a %DV. The agency does not believe that the current level of scientific evidence supports the establishment of such a value for *trans* fat at this time. Many comments supported this position. As a result of the absence of an appropriate reference value for *trans* fat, the agency has been hampered in developing an integrated approach that responds to the issues raised in the comments. Accordingly, the agency is withdrawing those sections of the November 1999 proposal pertaining to the establishment of a definition for "*trans* fat free," consideration of "reduced *trans* fat" and "reduced saturated and *trans* fat" claims and limits on the amounts of *trans* fatty acids wherever saturated fatty acid limits are placed on nutrient content claims, health claims, or disclosure and disqualifying levels. FDA plans to continue to evaluate the evolving science and, when the science has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims, it will proceed to do so through a new rulemaking. FDA will seek to ensure that it acts consistent with its obligations under the first amendment to allow truthful and nonmisleading speech.

As discussed under comment 17, FDA is issuing an ANPRM elsewhere in this issue of the *Federal Register* that will solicit comment 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 to establish disclosure and disqualifying criteria for

VII. Other Issues

(Comment 26) Several comments requested that FDA defer rulemaking on *trans* fat labeling until both FDA and USDA are able to concurrently take this action.

FDA consulted with USDA and both agencies agree that it is important that nutrition labeling rules for both agencies be consistent and that labeling of *trans* fat is necessary to assist consumers in maintaining healthy dietary practices. USDA is considering a similar policy for *trans* fat labeling based on the view that the approach to nutrition labeling should be consistent, but currently does not have a rulemaking on *trans* fat labeling on its regulatory agenda. Because *trans* fat levels are expected to be higher in foods regulated by FDA, as compared to foods under USDA jurisdiction, and because FDA has a citizen petition on the labeling of *trans* fat, FDA has determined that it is necessary to proceed with this final rule based on the public health interest. FDA notes that it is committed to cooperating with USDA, as needed, on *trans* fat labeling in any future action that USDA may consider.

(Comment 27) Some comments requested that *trans* fat not be used in restaurant food or its use be reduced.

These comments are outside the scope of this rule on the nutritional labeling of *trans* fat. This rulemaking is about *trans* fat labeling and not about whether or not *trans* fat is used in food generally or in particular food products. Although restaurant foods are not required to provide full nutrition labeling, they are required under § 101.10 (21 CFR 101.10), "Nutrition Labeling of Restaurant Foods," to provide information on nutrients that are relevant to any nutrient content claims made. Further guidance on labeling of restaurant foods may be found in "Questions and Answers Volume II, A Guide for Restaurants and Other Retail Establishments" (Ref. 111).

(Comment 28) A number of comments to the November 1999 proposal and the November 2002 notice reopening the comment period of the November 1999 proposal stated that there is a great need for consumer education about *trans* fatty acids and the nutrition label.

FDA agrees that consumer education will be needed as a result of this final rule so that consumers are better able to utilize the new *trans* fat labeling information to assist them in maintaining healthy dietary practices. Since the first edition of "Dietary Guidelines for Americans" in 1980 (Ref. 112), Americans have been advised to

the risk of heart disease. This message has also been a major factor in the National Cholesterol Education Program, which has been in existence since 1985 (<http://www.nhlbi.nih.gov/about/ncep/index.htm>) that focuses on individuals at higher risk for CHD. Some success of these educational programs was demonstrated by the third National Health and Nutrition Examination Survey (Ref. 89) conducted during 1988–94, that showed that the public's intake of saturated fat has declined since the previous survey conducted from 1976–80 (Ref. 113). Also, the 1994–96 CSFII showed a decline in the public's intake of saturated fat since a previous survey conducted in 1989–91 (Ref. 142). Therefore, in introducing new messages about *trans* fatty acids, FDA intends to work with existing public health programs to build upon the extensive work done by them to educate consumers about saturated fatty acids and cholesterol and their relationship to heart health.

The agency also plans to initiate a variety of outreach and consumer education programs about this final rule following publication. Electronic dissemination of this information will be provided at FDA's Web site and briefings will be provided to representatives of a variety of health professionals, government agencies, industry representatives, trade associations, and press and consumer groups so that they can communicate *trans* fat information to their constituencies. To assist in this effort, education and press materials will be developed to facilitate communication to consumers about changes they will see as *trans* fat is added to the nutrition label and how they can use that information in their efforts to maintain a healthy diet.

(Comment 29) A few comments suggested using color coding to help consumers quickly recognize unhealthy products, including those containing *trans* fat. One of the comments mentioned applying this technique to ingredient listing and another comment said that a graphic could show the proportion of saturated, *trans*, polyunsaturated, and monounsaturated fats. The latter comment noted that horizontal color bars were used quite successfully in the introduction of canola oil in the United States.

These comments are outside the scope of this final rule on the nutrition labeling of *trans* fatty acids. The agency notes that manufacturers are free to use color bars on the product label outside of the Nutrition Facts panel (i.e., the

in their products, provided it is done in a manner that is not misleading, but the panel itself is to be in compliance with this final rule.

(Comment 30) FDA received only one comment in response to the November 1999 proposal to deny the petitioner's request to require that "partially hydrogenated" fat be listed on food labels as "partially saturated" fat (64 FR 62746 at 62762). The comment concurred with the agency's tentative conclusion to deny the request stating that "partially hydrogenated" fat is the most appropriate terminology for use on food label ingredient statements.

The agency concurs with the comment and, accordingly, is denying this request.

(Comment 31) Although a great many comments supported CSPI's petition in general, these comments did not specifically address the petitioner's request to limit "vegetable oil" claims to foods that are low in saturated and *trans* fats combined.

In the November 1999 proposal, the agency referred to § 101.65(c)(3), which states, in part, that a claim "that a food is made only with vegetable oil is a claim that the food is low in saturated fat," and tentatively concluded that the petitioner's request was being addressed by the action taken in the proposed rule to limit the amount of *trans* fat in foods bearing "low in saturated fat" claims (64 FR 62746 at 62762). However, in this final regulation those sections of the proposed rule pertaining to limiting the amount of *trans* fat in foods making a "low in saturated fat" claim are being withdrawn. Therefore, the agency is not restricting "vegetable oil" claims as proposed or as petitioned at this time.

As discussed in section VI of this document, FDA plans to proceed with a new rulemaking pertaining to limits on the amount of *trans* fat in claims relating to saturated fat when the science on *trans* fat has evolved to a point where the agency believes it can proceed with scientifically-based definitions and levels for these claims.

VIII. Effective Date

In the November 1999 proposal, the agency proposed that any final rule that may issue based upon the proposal become effective in accordance with the uniform effective date for compliance with food labeling requirements that is announced by notice in the **Federal Register** and that it not be sooner than 1 year following publication of any final rule based on the proposal. Also, the agency said it will not object to

(Comment 32) FDA received several comments about the effective date for a final rule. One comment stated that the proposed effective date was appropriate while a few other comments recommended that it be sooner than proposed. Several comments suggested that the effective date be 24 months after publication of the final rule or January 1, 2004, whichever comes later. Some comments, however, requested that the effective date be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that it was important for small businesses to be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Many small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs including loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow these companies to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers. At least one comment requested that the effective date be one year after establishment of an official AOAC method for measuring *trans* fatty acids in complex food matrices.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the effective date at January 1, 2006, the next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. Extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

The agency notes that there are several methods for measuring the amounts of *trans* fat in food products including but not limited to AOAC Method 996.06, as modified (17th edition of the "Official Methods of Analysis of the AOAC International") (Refs. 105 and 106). Consequently, the agency does not believe that there is any need to extend the effective date because of the lack of appropriate methodology.

Although the effective date of the

encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover. The agency will not object to voluntary compliance immediately upon publication of the final rule.

IX. Final Regulatory Impact Analysis

FDA has examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, Office of Management and Budget (OMB) has determined that this final rule is a major rule for the purpose of congressional review.

A. The Current Situation and the Need for This Regulation

Current nutrition labeling regulations do not allow manufacturers to disclose information about *trans* fat content of their products in the Nutrition Facts panel of product labels. The regulation, in § 101.9(c) reads, in part, "No nutrients or food components other than those listed in this paragraph as either

included within the nutrition label.” Some of the nutrients listed are total fat, saturated fat, polyunsaturated fat (voluntary), and monounsaturated fat (voluntary). Prior to publication of this final rule *trans* fat was not included as either mandatory or voluntary, and therefore, no information about *trans* fat could have been included in the Nutrition Facts panel.

As explained in the November 1999 proposal and in section IV of this document, there is a scientifically established link between the consumption of *trans* fat and CHD. As described in table 1 of this document, for purposes of economic analysis, FDA estimated *trans* fat intake based on dietary intakes reported in a national food consumption survey. FDA estimates that average *trans* fat intake from partially hydrogenated fat is about 2.03 percent of energy, and average total *trans* fat intake, including *trans* fat of ruminant origin, is about 2.55 percent of energy. Because *trans* fat increases serum LDL-C (“bad” cholesterol), reducing *trans* fat intake reduces CHD risk. The amount of risk reduction depends on what replaces *trans* fat in the diet (64 FR 62746 at 62768 to 62770). For example, as shown later in this section, reducing *trans* fat intake by 0.1 percent reduces CHD risk by 0.072 to 0.163 percent.¹ CHD is a common disease in the general U.S. population, with about 1.1 million heart attacks annually, 40 percent of them fatal (Ref. 134). Therefore, a small decrease in risk corresponds to a large number of heart attacks and deaths prevented. Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.05 percent), prevents approximately 600 heart attacks per year, including 200 fatal heart attacks. Preventing these heart attacks is valued at \$4.1 billion per year (present value discounted at 7 percent).

Although the effect of *trans* fat on LDL-C and CHD risk is the primary basis for *trans* fat labeling, *trans* fat may also increase CHD risk by lowering high-density lipoprotein cholesterol (HDL-C) (“good” cholesterol). In a second method for estimating the health benefits of *trans* fat labeling, the expected changes in LDL-C and HDL-C can be considered together (64 FR

62746 at 62768 to 62770). For example, as shown later in this section, each 0.1 percent of energy decrease in *trans* fat intake reduces CHD risk by 0.237 to 0.293 percent.² Thus, as shown later in this section, reducing *trans* fat intake by about 0.04 percent of energy (projected to decrease CHD risk by about 0.1 percent), prevents approximately 1,200 heart attacks, including 480 fatal heart attacks, annually, valued at \$8.3 billion per year (present value discounted at 7 percent).

This final regulation is needed to amend existing regulations so that manufacturers will be able to provide important health-related information to consumers regarding the amount of *trans* fat in food products.

FDA believes that the requirements of this final rule will provide consumers with information they need so that they may consider the amount of *trans* fat in products in their food purchasing decisions. Increased consumer attention to *trans* fat content because of nutrition labeling may also provide an incentive to food manufacturers to reduce the amount of *trans* fat in their products.

B. Regulatory Alternatives

In the analysis of the proposed rule, FDA listed a number of regulatory alternatives regarding *trans* fat, including: (1) Take no new regulatory action; (2) take the proposed regulatory action; (3) propose to permit the voluntary labeling of *trans* fat and to permit *trans* fat nutrient content claims; (4) alter the proposed regulatory action—propose reporting of *trans* fat on a separate line below saturated fat; (5) alter the proposed regulatory action—propose to report *trans* fat differently than in the proposal; (6) expand the proposed regulatory action—propose “low *trans* fat” and “reduced *trans* fat” claims; (7) expand the proposed regulatory action—propose labeling at food service establishments. We evaluated these regulatory alternatives in the economic discussion of the proposed rule, although we lacked sufficient data to evaluate all of the options quantitatively. FDA received no comments on the economic discussion of these alternatives, so we do not include them in this document. In addition to the alternatives described in the proposed rule, FDA considered and

asked for comments on a proposed required footnote. Because the agency is withdrawing the proposed requirement for a footnote and intends to ask for comments in an ANPRM published elsewhere in this issue of the **Federal Register**, we will not estimate the costs and benefits of that option in this document.

C. Changes Resulting From This Rule

As stated in the analysis to the proposed rule (64 FR 62746 at 62764), to estimate the impacts of this rule, FDA is following the general approach used to estimate the health benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA is estimating: (1) The changes in *trans* fat intakes that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits.

1. Changes in Existing Labeling Regulations

This final rule requires the mandatory declaration in the nutrition label of the amount of *trans* fat present in foods. According to this final rule, the amount of *trans* fat must be on a separate line immediately under the amount of saturated fat, but it will not include a % DV that is required for some of the other mandatory nutrients, such as saturated fat. These changes must be made within a period of 30 months. This change to the existing regulations will increase the information available to consumers that they can use to maintain a healthy diet. It will also change the constraints and incentives faced by producers of food.

The final rule will increase the information provided to consumers on food packages. This change in the nutrition label will reduce the cost to consumers of obtaining information on the *trans* fat content of food. FDA anticipates that, once the rule takes effect, consumers will use information on the Nutrition Facts panel to adjust their purchasing practices among foods, consistent with their consumption preferences.

The final rule will also change the incentives and constraints that food producers face in manufacturing and marketing their products. Because these provisions will not be effective until months after publication of the final rule, food manufacturers can use the time between publication of the final rule and its effective date to study the

¹ Using Method 1 (LDL-C), described later in section IX.E, and the factors shown in tables 8 and 9 below, replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.072 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat ($-0.1 \times 0.74 \times 0.7 \times 1.4 = -0.072$) and by 0.163 when replaced with half *cis*-

² Using Method 2 (LDL-C and HDL-C), replacement of 0.1 percent of energy from *trans* fat would decrease CHD risk by 0.237 percent when replaced with the same percent of energy from half *cis*-monounsaturated fat and half saturated fat ($-0.1 \times -0.47 \times -2.5 \times 1.4 = -0.165$ and -0.072 plus $-0.165 = -0.237$) and by 0.293 when replaced with half *cis*-monounsaturated fat and half *cis*-polyunsaturated

composition of their products, to anticipate the response of consumers and competitors to the new information, to change the labeling, and possibly to change the composition of their existing food products. Even after the effective date of the rule, food manufacturers will observe the response of consumers to the information on *trans* fat, and some may develop and market new products with less *trans* fat than similar existing products.

FDA assumes that producers will decide whether or not to change the composition of existing products on a product-by-product basis, depending on expected private returns. They will choose to reformulate the existing products when the expected private benefits exceed the expected private costs of reformulating the products. In other words, if a product is expected to lose market share without reformulation because of the new disclosure, then manufacturers will compare the private costs from decreased sales to the cost of reformulation.

2. Anticipated Changes in *Trans* Fat Intake

FDA anticipates that, taken together, changes in food purchases by consumers and reformulation by producers in response to this rule will result in an overall decrease in *trans* fat intake in the U.S. population. In the November 1999 proposal, FDA developed four scenarios to demonstrate potential quantitative changes in *trans* fat intake (64 FR 62746 at 62767). FDA also estimated the current *trans* fat intake of the population as a starting point for its scenarios for projected intake changes.

a. *Revised estimate of current trans fat intake.* In section IV of this document, FDA discussed the uncertainties associated with estimates of *trans* fat intake from: (1) National food consumption survey, (2) national disappearance data, and (3) food frequency questionnaires done in observational studies of U.S. population groups. Although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this economic analysis. Estimates of intake based on national disappearance data generally overestimate intake due to losses in processing and use, and food groups derived from disappearance data correspond to commodities rather than to foods as consumed. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an

disappearance data. Estimates of *trans* fat intake based on food frequency questionnaires may have the advantage of having been validated versus biomarkers such as *trans* fat content of adipose tissue. Such estimates are suitable for their intended use in ranking and classifying *trans* fat intake of subjects in observation studies. However, food frequency questionnaires are not necessarily designed to provide accurate absolute (numerical) intake estimates. As described in the November 1999 proposal (64 FR 62746 at 62753), estimates of nutrient intakes based on food frequency data may be subject to systematic bias toward either over- or underestimation of intake, depending on the design of the food frequency questionnaire (Ref. 27). Available estimates of *trans* fat intake from food frequency questionnaires in observational studies are lower than estimates of *trans* fat intake from a national food consumption survey (Ref. 26), as summarized in the November 1999 proposal (64 FR 62746 at 62752 to 62753) and in section IV of this document. Additionally, the available food frequency results pertain to the intake of specific U.S. population groups in the observation studies, not to the overall U.S. population. Therefore, an estimate based on a national food consumption survey was better suited to the present analysis than was an estimate based on food frequency questionnaires done in observational studies. One disadvantage of an estimate based on a national food consumption survey is that, as described in section IV, food intake is generally under-reported in consumption surveys (Ref. 26). Therefore, intake of *trans* fat, in grams, estimated from a national consumption survey is likely to underestimate actual intake. However, intake of *trans* fat from national consumption survey data is likely to underestimate actual intake to a lesser extent than does the lower reported intake of *trans* fat from food frequencies done in observation studies. Additionally, intake of *trans* fat, as a percent of total energy, from a national consumption survey is more likely to be an unbiased estimate (Ref. 26).

As described in the November 1999 proposal (64 FR 62746 at 62765), information on *trans* fat content of foods is limited, and there have been few estimates of *trans* fat intake based on national dietary surveys using food records or recalls. As described in section IV of this document and in the November 1999 proposal (64 FR 62746 at 62752 and 62765), an available

on CSFII 1989–91, reported mean *trans* fat intake of 5.3 g/day (d) (2.6 percent of energy). However, for the purposes of economic analysis, FDA needed to estimate the mean intake of *trans* fat from specific food groups. Therefore, in the November 1999 proposal, FDA indirectly estimated *trans* fat intake based on a report from the Research Triangle Institute (RTI) (Ref. 73). The RTI report used a special 1995 USDA database of *trans* fat content of foods (Ref. 40), together with the mean intake of food groups from USDA's CSFII 1994–96, and matched the CSFII 1994–96 food groups with Standard Industrial Classification (SIC) Codes for food product categories. FDA limited its estimate to foods with *trans* fat from partially hydrogenated fats and oils (64 FR 62746 at 62765). (Although *trans* fat does occur naturally in dairy foods, it is generally present in dairy products at less than 0.5 g *trans* fat per serving, and therefore most dairy products would not have been affected by the November 1999 proposal (64 FR 62746 at 62775)).

In the November 1999 proposal, FDA estimated that current average *trans* fat intake from hydrogenated fat was 2.91 percent of energy (calories) for adults, which is about 7.62 g/d for men and 5.54 g/d for women (Ref. 73 and 64 FR 62746 at 62765). Among food product categories, average *trans* fat intake of adults, as a percent of energy, was: margarine, 0.39 percent; bread/cake, 0.67 percent; cookies/crackers, 0.98 percent; other food groups, 0.87 percent. The estimated intake of *trans* fat from margarine included FDA's adjustment based on the assumption that approximately 30 percent of margarines currently on the market had already been reformulated to remove *trans* fat.

(Comment 33) Comments generally agreed that FDA's estimate of current *trans* fat intake was reasonable and in the range of other estimates of *trans* fat intake. Comments from the margarine industry agreed with FDA's overall estimate of *trans* fat intake from margarine but stated that FDA had overestimated the percent of margarines (30 percent) that had already been reformulated to remove *trans* fat. One comment indicated that the proportion of margarines with less than 0.5 g *trans* fat per serving is about half of FDA's estimate, or 15 percent of margarines. Some comments pointed out the importance of *trans* fat intake from food groups that were not itemized separately in FDA's summary table, including chips and snacks and French fried potatoes. Because FDA had restricted its estimate to *trans* fat intake from partially hydrogenated fats and oils,

regarding whether naturally-occurring *trans* fat of ruminant origin would be regulated by the provisions of the proposed rule. One comment from a manufacturer agreed with FDA that the USDA *trans* fatty acid database contains relatively few foods. This comment recommended that a large database be developed of *trans* fat food values that have been analyzed using standardized methods, and that the database be used to establish reference or "normative" intake data on *trans* fat in the U.S. population. The comment stated that this information would be helpful in developing a Daily Value for *trans* fat intake. A comment from the dressings and sauces industry disagreed with FDA's statement that "some salad dressings contain substantial amounts of *trans* fatty acids" (64 FR 62746 at 62752). The comment stated that the oils used in dressing and sauce products contain less than one percent *trans* fatty acids. Additionally, according to the comment, the contribution of *trans* fat of ruminant origin is negligible in dressings and sauces that contain dairy products, as demonstrated in the reference cited by FDA regarding *trans* fat in salad dressings (Refs. 29 and 30).

FDA's original estimate that about 30 percent of margarine had been reformulated to remove *trans* fat was based on an informal market survey in the Washington, DC area (Ref. 80 and 64 FR 62746 at 62781). FDA accepts the comment's estimate that 15 percent of margarines currently on the market contain less than 0.5 g per serving. In its own estimate of total intake, FDA did include the contribution to average *trans* fat intake of other food groups containing partially hydrogenated fat, such as chips and French fried potatoes. These food groups were itemized in the RTI report (Ref. 73) but FDA summarized them under "All other" in the November 1999 proposal.

In response to the comments requesting clarification about whether

naturally-occurring *trans* fat of ruminant origin would be regulated by this rule. FDA reiterates that this final rule applies to all FDA-regulated foods and covers all fatty acids that meet the regulatory definition of "*trans* fatty acids," regardless of origin. Naturally occurring *trans* fat in dairy products and in ruminant meat (e.g., meat from cows and sheep) present in FDA-regulated food products will be subject to this rule. FDA did not include *trans* fat of ruminant origin in its original intake estimate in the November 1999 proposal because, in these products, *trans* fat is generally present at less than 0.5 g per serving and declaration of the amount of *trans* fat in these products would not have been required by the November 1999 proposal. As noted later in this section, we have revised our estimate of *trans* fat intake and extended our revised estimate to include *trans* fat of ruminant origin. Although FDA agrees with the comment stating that development of a large database of *trans* fat food values would be beneficial, database development is beyond the scope of the present rulemaking. FDA agrees with the comment regarding the *trans* fat content of dressing and sauces and acknowledges that FDA's earlier statement about *trans* fat in salad dressings (64 FR 62746 at 62752) was inaccurate. However FDA's earlier statement was part of a general summary of possible limitations of data regarding *trans* fat intake of the population, and was not incorporated into FDA's estimates of *trans* fat intake in the November 1999 proposal. As noted previously, FDA based its estimates of *trans* fat intake on the special 1995 USDA database of *trans* fat content of selected foods.

As described previously in this section, although there are uncertainties associated with each type of estimate, FDA chose estimation of *trans* fat intake based on a national food consumption survey as most suitable for use in this

economic analysis. In reevaluating its November 1999 *trans* fat intake estimate based on a national survey, CSFII 1994–96, FDA notes that the CSFII 1994–96 food group categories used to generate the estimate were very broad (Refs. 73 and 114) and the match between the broad CSFII food group categories and the SIC Codes was not always exact. Recently, USDA has published more detailed tables of food group intake for CSFII 1994–96 (Ref. 115). FDA has used the new tables to recalculate its estimate of average *trans* fat intake in the United States. For clarity, FDA now includes the itemized *trans* fat intake for the various food groups rather than creating a summary category for "All other." FDA has also extended its estimate to incorporate *trans* fat of ruminant origin. FDA has estimated the intake of *trans* fat from margarine from the USDA intake data, without assumptions regarding the percent of margarine that may have been reformulated to remove *trans* fat. We will describe our assumptions about current margarine reformulation in later sections of this document.

The revised estimate of average *trans* fat intake of adults in the United States for this economic analysis is shown in table 1 of this document. The revised estimate is slightly lower than that in the November 1999 proposal. Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. Major sources of *trans* fat intake as a percent of energy include margarine, 0.42 percent; cake and related products, 0.61 percent; cookies and crackers, 0.25 percent; fried potatoes, 0.21 percent; chips and snacks, 0.12 percent; and household shortening, 0.11 percent.

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS

CSFII 94–96 ¹	Men	Women	All	All
Mean daily energy intake, kcal ²	2455	1646	2058	
Mean daily <i>trans</i> fat intake ^{3,4}				
Food group	Grams	Grams	Grams	% of energy
Hydrogenated products				
Total yeast bread	0.475	0.330	0.404	0.177%
Cakes, pies, doughnuts, sweet rolls, biscuits, muffins, quick breads, pancakes, waffles, tortillas	1.607	1.163	1.391	0.607%
Cookies, crackers	0.624	0.515	0.571	0.249%
Ready to eat breakfast cereal	0.093	0.074	0.084	0.037%
French-fried, home-fried potatoes	0.635	0.332	0.486	0.213%

TABLE 1.—AVERAGE *Trans* FAT INTAKE OF U.S. ADULTS FROM FOOD GROUPS—Continued

CSFII 94–96 ¹	Men	Women	All	All
Pourable and mayo type salad dressing	0.181	0.136	0.159	0.069%
Total candy containing chocolate	0.048	0.040	0.044	0.019%
Total margarine	1.072	0.859	0.967	0.423%
Household shortening	0.277	0.222	0.250	0.109%
Total hydrogenated products	5.357	3.886	4.637	2.026%
Animal products				
Total milk, including on cereal	0.125	0.085	0.105	0.046%
Ice cream and ice milk	0.092	0.057	0.075	0.033%
Total cheese and cottage cheese	0.227	0.148	0.188	0.083%
Total beef, ground and not ground	0.569	0.319	0.447	0.195%
Total frankfurter and lunch meat	0.360	0.188	0.276	0.121%
Total fluid and sour cream	0.061	0.044	0.052	0.023%
Total butter	0.071	0.049	0.060	0.026%
Total animal products	1.505	0.890	1.203	0.527%
Total all products	6.862	4.776	5.840	2.553%

¹ Continuing Survey of Food Intakes of Individuals, 1994–1996

² kcal. kilocalories

³ Source of *trans* fat content of foods: Ref. 40.

⁴ Source of food intake data: Smiciklas-Wright H., D.C. Mitchell, S.J. Mickle, A.J. Cook and J.D. Goldman. Foods Commonly Eaten in the United States. Quantities per Eating Occasion and in a Day, 1994–1996. U.S. Department of Agriculture NFS Report No 96–5, pre-publication version, 2002. www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html.

The revised estimate of *trans* fat intake based on CSFII 1994–96 and shown in table 1 is slightly lower than the estimate in the November 1999 proposal (64 FR 62746 at 62765). Table 1 shows that average *trans* fat intake from partially hydrogenated vegetable oils is about 5.36 g/d for men and 3.89 g/d for women, or about 2.03 percent of energy. Adding the *trans* fat of ruminant origin gives an overall total *trans* fat intake of 6.86 g/d for men and 4.78 g/d for women, about 2.55 percent of energy. For comparison, FDA also calculated the *trans* fat intake based on CSFII 1989–91, using the same method as for the estimate based on CSFII 1994–96 (Ref. 116 and 117). The overall total *trans* fat intake from CSFII 1989–91 is 6.47 g/d for men, 4.51 g/d for women and 5.32 g/d for all adults, or 2.71 percent of energy (not shown in table 1), very similar to the 6.86 g/d for men and 4.78 g/d for women and 5.84 g/d for all adults, or 2.55 percent of energy intake based on CSFII 1994–96 (table 1 of this document) (Ref. 116). FDA's estimates of 2.55 percent of energy from *trans* fat based on CSFII 1994–96 and 2.71 percent of energy based on CSFII 1989–91 can be compared with other available estimates from national food consumption surveys. FDA's estimates are very similar to the intake estimated by Allison et al. based on CSFII 1989–91 (Ref. 26), using a different method. As described in the November 1999 proposal, Allison et al. reported that average *trans* fat intake for persons age 3 and older was 2.6 percent of energy, or 5.3 g/d (64 FR 62746 at 62752 and

Allison et al. linked the special 1995 USDA database of *trans* fat content of foods to the food intake reported by each individual in CSFII 1989–91 (Ref. 26). They also separated the ingredients in food mixtures, so that the *trans* fat content of the ingredients could be included in the total intake. These researchers reported the *trans* fat intake for various age and gender groups in the United States, but did not report the amount of *trans* fat contributed by various foods and food groups. To make its estimate, FDA began with USDA reports of average intake of food groups in CSFII 1989–91 and 1994–96 (Refs. 115 and 117). In its reports, USDA also separated the ingredients in food mixtures. For example, in CSFII 1994–96, USDA found that the average intake of margarine reported separately by survey participants was 2.8 g/d. However, when margarine, used as an ingredient in other foods, was added to the total, the average margarine intake rose to 7.0 g/d. FDA then linked the average intake of the food groups with the *trans* fat content of foods from the special 1995 USDA database (Ref. 40) to give the *trans* fat intake estimate in table 1 of this document. The similarity of the estimates of FDA and of Allison et al. can be explained by use of common data—the CSFII intake report and the 1995 USDA *trans* fat database. Linking the two data sets resulted in comparable overall *trans* intake, whether linked at the level of each individual's intake by Allison et al., or linked at the level of average intake of food groups by FDA.

FDA's estimates are also similar to a recently-published estimate from

survey, the National Health and Nutrition Examination Survey III (NHANES III), 1988–94 (Refs. 152 and 153). The estimate from NHANES III for mean *trans* fat intake for age 20 to 59 was 5.6 g/d or 2.2 percent of energy (mean energy intake was 2,325 kcal/d, and $(5.6 \text{ g/d} \times 9 \text{ kcal/g} \times 100) / 2,325 \text{ kcal} = 2.2$ percent of energy).

b. *Projected change in trans fat intake.* In the November 1999 proposal, we developed four scenarios of projected changes in *trans* fat intake due to labeling. Scenario 1 demonstrated the effect of the hypothetical removal of all of the *trans* fat originating from partially hydrogenated fats and oils, corresponding to a decrease of 2.91 percent of energy from *trans* fat. Scenarios 2 through 4 predicted three possible levels of product reformulation, together with an estimate of consumer behavior. We estimated that *trans* fat intake would have decreased by 0.58 percent of energy, 0.50 percent of energy and 0.42 percent of energy in Scenarios 2, 3 and 4, respectively (64 FR 62746 at 62767). For each scenario, the full health benefits would have been realized years after the rule took effect: 10, 8, and 3 years after the effective date for Scenarios 2, 3, and 4. These time periods included the time for reformulation and the 3 years that would have passed before changes in diet would have begun to reduce the risk of CHD.

Consumer awareness

(Comment 34) Several comments suggested that FDA overstated consumer response to the proposed change to food

footnote might be ignored. Some comments said that consumers rarely look at any nutrition information beyond calories and total fat and that consumer concerns about fat have dwindled. One comment argued that consumers have not significantly altered their dietary habits because of the implementation of the 1990 amendments. One comment stated that educated consumers probably already know enough to look for and avoid *trans* fat. There was also one comment arguing that shelf labeling is more likely to attract consumer attention than are product labels, and the use of shelf labeling is probably more prevalent than that of product labels. One comment stated that FDA has underestimated consumer awareness of *trans* fatty acids. Another comment stated that consumer awareness is likely to increase as *trans* fat dietary recommendations accumulate and consumer education devotes more attention to *trans* fat.

FDA is not going forward with the proposed asterisk for saturated fat and footnote listing the amount of *trans* fat. Instead, this final rule requires *trans* fat to be listed on a separate line immediately below saturated fat. Consumers who look at the Nutrition Facts panel for information on total fat and its fatty acid subcomponents are likely to notice the information on *trans* fat.

In the November 1999 proposal, FDA used results of earlier research and estimated that direct consumer choice in response to *trans* fat labeling would result in a 1 percent decrease in *trans* fat intake (64 FR 62746 at 62766). This final rule requires that the amount of *trans* fat be declared in nutrition labels on a separate line immediately under the line for saturated fat. This placement of *trans* fat is more prominent than the footnote specified in the November 1999 proposal and may be more readily noticed by consumers. In the November 1999 proposal, the amount of *trans* fat was to be included in the amount and % DV declared for saturated fat. This association of *trans* fat with saturated fat, which also may have assisted consumers in using the information on *trans* fat, is absent in this final rule. Also, as a result of this final rule, consumer response to *trans* fat information will be based solely on the declaration of the amount of *trans* fat in grams. As discussed in section V of this document, there will not be information on a % DV for *trans* fat. In the November 1999 proposal, the agency proposed to define the nutrient content claim for "*trans* fat free" and also proposed that the amount of *trans* fat be

placed on nutrient content claims, health claims, or disclosure and disqualifying levels. As explained in sections V and VI of this document, this final rule does not establish definitions for nutrient content claims about *trans* fat and does not place *trans* fat limits on claims regarding saturated fat, cholesterol or other nutrients. In summary, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature of the final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features in the final rule may tend to decrease the magnitude of consumer response to the *trans* fat information.

Based on previous research, the November 1999 proposal projected a 1 percent decrease in *trans* fat intake from direct consumer choice in response to *trans* fat labeling (64 FR 62746 at 62766). This overall 1 percent decrease in *trans* fat intake could be thought of as a 2.2 percent decrease in *trans* fat intake by the 45 percent of consumers shown in previous research to use food labels to make purchase decisions (Refs. 68 and 74) (64 FR 62746 at 62766).

In the process of evaluating these comments about consumer awareness, FDA has identified additional data relevant to these issues. In the 1999 Discovery Health survey, 66 percent of those responding to the survey knew that saturated fat was related to disease and 31 percent knew that partially hydrogenated fat was related to disease (Ref. 118). In the 2001–2002 Consumer Attitudes About Nutrition survey, 83 percent of respondents reported that saturated fat is unhealthy, 46 percent reported that *trans* fat is unhealthy and 44 percent reported that hydrogenated fat is unhealthy (Ref. 135). These results indicate that survey respondents were about half as likely to know that partially hydrogenated fat was "unhealthy" or related to disease as to know that saturated fat was related to disease. If these surveys are representative of the population, this indicates a significant level of awareness of the health effect of partially hydrogenated fat, and its component, *trans* fat, even though consumers have very little easily obtainable information on *trans* fat and even though nutrition education efforts, until very recently, have focused on saturated fat to the exclusion of *trans* fat. Once nutrition education efforts

once consumers have information on nutrition labels about *trans* fat content, consumer awareness of the relationship between saturated fat, *trans* fat, and cholesterol and heart disease will increase. Another recent study, by Kim et al., estimated that food label use has a large effect on nutrient intake. (Ref. 119) This study reported that 73 percent of individuals surveyed use nutrition labels and look for information on saturated fat.

In the study by Kim et al., 73 percent of individuals surveyed who use nutrition labels and look for information on saturated fat had 15 percent lower saturated fat intake than those who did not use nutrition labels. This corresponds with an overall 11 percent decrease ($0.15 \times 73 \text{ percent} = 11 \text{ percent}$) in saturated fat intake because of nutrition labeling. Thus, the study by Kim et al. gave a high estimate of an 11 percent decrease in saturated fat intake because of nutrition labeling and FDA's earlier research gave a low estimate of a 1 percent decrease in saturated fat intake.

The Discovery Health study and the Consumer Attitudes About Nutrition survey indicated that consumer awareness of a nutrient-disease relationship involving *trans* fat was about half as prevalent as consumer awareness of a nutrient-disease relationship involving saturated fat. Accounting for the lower prevalence of awareness of the nutrient-disease relationship for *trans* fat, would reduce, by about one-half, the estimates for decreases in saturated fat intake. This would give a high estimate of a 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake because of labeling.

The estimates for decreases in *trans* fat intake due to nutrition labeling may also be affected by the features of this final rule. As noted previously, the prominence of the declaration of *trans* fat in this final rule may tend to increase the magnitude of consumer response to the *trans* fat information. However, the magnitude of consumer response to the *trans* fat information may decrease because there is no link with saturated fat or with a % DV and there are no changes in existing regulations regarding claims. Recognizing that different features of this final rule may tend to either increase or decrease consumer response to the *trans* fat information, FDA acknowledges considerable uncertainty in incorporating the features of this final rule into its estimate of the consumer response to *trans* fat labeling. One possibility is that the increased and

of the rule will be about equal and will cancel each other out. This would leave a high estimate of 5.5 percent decrease and a low estimate of a 0.5 percent decrease in *trans* fat intake as discussed above. However, for the purpose of this final analysis, FDA has chosen a very low estimate of consumer response to the new label. FDA is using an estimate even lower than the low estimate above: a decrease of 0.1 percent of *trans* fat intake. The actual change that occurs may be larger. However, FDA chose this amount so as not to overestimate benefits of this rule. To the extent that actual consumer response is higher than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

i. *Margarine reformulation.* In the November 1999 proposal, in scenarios 2 through 4, FDA estimated that 30 percent of margarine products had already been reformulated to eliminate *trans* fat, and that all of the remaining margarine products would be reformulated to remove *trans* fat by the effective date for *trans* fat labeling.

(Comment 35) A comment stated that FDA had overestimated the proportion of margarine that had already been reformulated and said that the actual amount was about 15 percent of margarine products. Several comments disagreed with FDA's estimate that all margarine would reformulate by the effective date for *trans* fat labeling. These comments noted that reformulation is very expensive, requires a long time to accomplish, and would, under certain circumstances, require the use of more expensive inputs. Other comments stated that private benefits of reformulating margarine products would not exceed the private costs for manufacturers unless the margarine products could make nutrient content claims. These comments gave a number of examples to demonstrate that even reformulated margarines were not likely to be able to comply with the proposed definitions for nutrient content claims.

FDA accepts the comment about current margarine products. For this analysis, FDA estimates that about 15 percent of margarine has already been reformulated to remove *trans* fat. In response to the comments about projected margarine reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation. In that analysis, FDA did not include higher ingredient costs for margarine reformulation, because the price of reformulated margarine products that are already on the market

products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, in response to the comments, FDA acknowledges that, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs.

As noted earlier regarding consumer response to *trans* fat labeling, the declaration of *trans* fat in this final rule is prominent and straightforward. This feature may tend to increase the incentives for manufacturers to reformulate their products to be lower in *trans* fat. However, the provisions of this final rule also do not link *trans* fat with saturated fat or with a % DV for *trans* fat and do not change existing regulations regarding claims. The absence of these features may tend to decrease the incentives for manufacturers to reformulate their products to be lower in *trans* fat in comparison to the incentive that would have been introduced by the proposed rule. Therefore, in response to the comments regarding projected margarine reformulation, FDA recognizes that different features of this final rule may tend to either increase or decrease the incentive for reformulation in comparison to the incentive that would have been introduced by the proposed rule.

Although FDA acknowledges considerable uncertainty in the likelihood of additional margarine reformulation, FDA is aware of evidence suggesting that at least some margarine products are likely to reformulate in response to *trans* fat labeling. As stated in the analysis for the proposed rule, in several European countries, the actual, demonstrated market response to consumer concern about *trans* fat is that margarine products have been reformulated to reduce or eliminate *trans* fat (64 FR 62746 at 62781) (Refs. 102, 124, 125, and 127). Also, many people who now consume margarine products do so in order to consume a more heart-healthy product than butter. Because the rule would require the prominent declaration of the amount of *trans* fat on a separate line below saturated fat, these margarine consumers are likely to search for margarine products with lower levels of both saturated fat and *trans* fat. Additionally, publicity generated about the issue by consumer groups and the media has highlighted margarine as a source of *trans* fat and has given prominent attention to reformulated margarine products. As more margarine

groups may shift their focus to those remaining margarine products that have not reformulated. This suggests that with sufficient information on *trans* fat content consumers are likely to pressure margarine producers to reduce *trans* fat. This consumer pressure will generate some competitive pressures among margarine producers to reduce *trans* fat content even in the absence of nutrient content claims.

In response to comments received, because of the absence of *trans* fat claims in this rule, and recognizing the uncertainty, FDA is using a low estimate of margarine reformulation in this final rule. FDA estimates that reformulation will reduce the *trans* fat content of margarines as a whole by 10 percent due to *trans* fat labeling. Because the *trans* fat in margarine accounts for about 0.36 percent of energy intake, this reduction corresponds to a decrease in *trans* fat intake of 0.036 percent of energy. The actual decrease may be larger, but FDA chose this lower amount so as not to overestimate benefits of this rule. The additional 10 percent margarine reformulation will mean that, including previous reformulations, about 23 percent of *trans* fat will have been removed from margarine. This estimated reduction is far lower than the 100 percent reduction seen in several European countries. The estimated 10 percent reformulation has the advantage of being an underestimate. To the extent that more *trans* fat is removed from margarine than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

ii. *Reformulation of other products.* In two scenarios in the November 1999 proposal, FDA projected that some baked products would be reformulated to remove *trans* fat (64 FR 62746 at 62767). In that analysis, the baked products were separated into two categories corresponding to SIC codes: breads, cakes and similar products (SIC code 2051) and cookies and crackers (SIC code 2052). Considering the *trans* fat contributions of the two categories of baked goods (64 FR 62746 at 62765), the overall projected reformulation of baked goods corresponded to a 5 percent reduction in *trans* fat intake in scenario 3 and a 10 percent reduction in scenario 2.

(Comment 36) A number of comments stated that FDA had overestimated the proportion of baked goods products that would reformulate or the proportion of *trans* fat that could realistically be removed from baked goods by reformulation. Some comments noted that reformulation was very expensive, required a long time to accomplish, and

require the use of more expensive inputs. Some of these comments, from the shortening or baked products industries, gave examples of recently developed commercial shortenings that were lower in *trans* fat than currently used shortenings. Several comments stated that, although alternative shortenings exist, they may not be a practical solution for reformulation because of expense or limited supply of the alternative shortenings and because time and expense for product development for reformulation would still be needed. Other comments stated that the private benefits of reformulation would not exceed private costs unless the declaration of *trans* fat on the food label was on a separate line on the Nutrition Facts panel or was in some way more prominent than in the November 1999 proposal. Some comments emphasized the disadvantages of reformulation for the cookies and crackers category, stating that FDA's estimate of 15 percent reduction in *trans* fat from those products was an overestimate.

In response to the comments about difficulties of reformulation, FDA notes that the analysis for the November 1999 proposal did include the cost of reformulation and the time needed for reformulation, but did not include higher ingredient costs for reformulation. In the long run, ingredient costs may not actually increase, because of increased industrial capacity to produce ingredients made with new technologies. In response to the comments about the cookies and crackers category, FDA acknowledges that its own projection of much higher reformulation for this category than for other baked products may have been unrealistic. Also in response to the comments, FDA notes that the emergence of commercial shortenings with lower *trans* fat content indicates that the reformulation of some baked products is feasible. Moreover, within these baked product categories there is a significant variation in *trans* fat content. Therefore, products with significantly higher than average amounts of *trans* fat compared with competing products will face competitive pressures to reduce the amount of *trans* fat in their products. In response to the comment about prominence of *trans* fat on the nutrition label, FDA notes that, in this final rule, the declaration of *trans* fat is prominent and straightforward, on a separate line below *trans* fat.

After consideration of the comments and our own re-evaluation, we continue to believe that ultimately, some

reformulated in most subcategories: Crackers, cookies, biscuits, tortillas, quick breads and muffins, doughnuts and sweet rolls, cakes, pies, pancakes and waffles. (In the categories of yeast breads and rolls, it is unlikely that reformulation will occur because yeast breads are relatively low in fat and typically contain less than 0.5 g *trans* fat per labeled serving.) However, there were disparate views among the comments regarding the availability of reformulated shortenings and the technical difficulty of baked product reformulation. Therefore, because of this uncertainty, we have opted for a more conservative approach and are not including a quantitative estimate of reformulation of baked goods in the analysis of the benefits and cost of *trans* fat labeling. We chose not to include a quantitative estimate of reformulation of baked goods so as not to overestimate the benefits of this rule. To the extent that reformulation of baked goods does occur, this analysis will underestimate the benefits of *trans* fat labeling.

Because of the existence of commercial shortenings with lower *trans* fat content, as pointed out in comments, FDA evaluated whether *trans* fat labeling might also result in reformulation of household shortenings to be lower in *trans* fat. Current household shortenings are lower in *trans* fat than current commercial shortenings, with some household products having only about half as much *trans* fat as some commercial products. This fact suggests that the potential for lowering the *trans* fat content of household shortening is not as great as the potential for lowering the *trans* fat in current commercial shortenings. However, some household shortenings are currently making comparative saturated fat claims related to butter, and household shortenings may experience competitive pressure from some reformulated stick margarines due to *trans* fat labeling. Because of the uncertainty, FDA chose not to include a quantitative estimate of reformulation of household shortening so as not to overestimate benefits of this rule. To the extent that reformulation of household shortening does occur, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 37) Some comments discussed reformulation of other products, including potato chips, corn chips and similar snacks, microwave popcorn, and candy. Several of these comments emphasized the difficulty of reformulating products in these categories because of the expense, the time required, and the need for costly

suggested that, because of the difficulties of reformulation, *trans* fat labeling would put these categories of products at a competitive disadvantage. Other comments suggested that FDA's projected decrease in *trans* fat intake was an overestimate because *trans* fat labeling would not apply to a major source of *trans* fat: foods eaten at restaurants, especially French fried potatoes.

FDA did not project quantitative decreases in *trans* fat intake due to reformulation of other products, such as chips, microwave popcorn and candy, because these products contribute a smaller proportion of *trans* fat intake and because FDA did not have enough information to make quantitative reformulation estimates for these product categories. FDA is aware of the development of stable frying oils low in *trans* fat and suitable for chips, and notes that there is interest in development of fats and oils lower in *trans* fat for many product categories (Refs. 120 to 122 and 151). At least one manufacturer has announced the reformulation of its snacks and chips to decrease *trans* fat (Ref. 150). To the extent that these product categories reformulate to decrease *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

FDA acknowledges that a large proportion of the U.S. French fried potato intake is consumed in restaurants. Foods typically consumed in restaurants also include other food sources of *trans* fat. Restaurant food is not subject to mandatory nutrition labeling requirements, unless a nutrition-related claim is made. In its estimate of reformulation, FDA did not project reformulation of French fries or of baked goods. Therefore, FDA's estimate did not assume reformulation of restaurant foods. However, FDA is aware of some interest by restaurants in using the absence of *trans* fat as a marketing device to gain competitive advantage (Ref. 123). If, as seems possible, frying oils and shortenings are developed for reformulation of packaged foods and become available in the market, they may become competitive choices with traditional fats and oils, even for restaurants that do not wish to use absence of *trans* fat for competitive advantage. To the extent that restaurants adopt reformulated baking and frying oils and purchase other products reformulated to be lower in *trans* fat, the decrease in *trans* fat intake projected in this analysis will be an underestimate.

iii. *Quantitative decrease in intake.* Table 2 of this document summarizes FDA's revised estimate of projected

labeling. In table 2, current *trans* fat intake from margarine is 0.359 percent of energy, reduced 15 percent from the 0.423 percent of energy intake in table 1 of this document to adjust for the estimated 15 percent of margarine that has already been reformulated to remove *trans* fat. This adjustment reduces the total *trans* fat intake from hydrogenated products to 1.96 percent

of energy in table 2, compared with 2.03 percent of energy in table 1. Table 2 shows that, by the effective date of the rule, FDA projects that *trans* fat intake will decrease by 0.0378 percent of energy. This decrease will be composed of 0.0359 percent of energy due to removal of 10 percent of *trans* fat from margarine by reformulation, and an additional 0.0019 percent of energy due

to direct consumer choice. The additional 0.0019 percent of energy represents 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation (1.964 percent - 0.0359 percent = 1.928 percent; 0.1 percent x 1.928 percent = 0.0019 percent).

TABLE 2.—ESTIMATED DECREASES IN *Trans* FAT INTAKE AND CONTRIBUTION FROM FOOD GROUPS DUE TO LABELING, AT EFFECTIVE DATE OF RULE

Food group	Before Effective Date of Rule	Change at Effective Date of Rule	
	Mean daily <i>trans</i> intake ¹	Decrease in <i>trans</i> fat contribution from food group	Decrease in <i>trans</i> fat intake
	Percent of energy from <i>trans</i> fat	Percent decrease in <i>trans</i> fat	Decrease in percent of energy from <i>trans</i> fat
Total Margarine	0.359% ²	10%	0.0359%
Other food groups with partially hydrogenated fats and oils	1.605%	none	
Total from hydrogenated products	1.964%		
Total decrease due to reformulation			0.0359%
Additional decrease due to consumer choice			0.0019% ³
Total decrease			0.0378%

¹ *Trans* fat intake for men and women age 20 and over from CSFII 1994–96, see table 1 of this document.

² *Trans* fat intake from margarine, 0.359 percent of energy, already decreased by 15 percent from intake in table 1, to account for margarine that has already been reformulated to decrease *trans* fat.

³ Estimated decrease due to consumer choice at effective date is 0.1 percent of all remaining *trans* fat from hydrogenated fat after margarine reformulation.

iv. *Substitutions for trans fat.* In the November 1999 proposal, FDA assumed that manufacturers would most likely replace *trans* fat in margarine with: (1) *Cis*-monounsaturated fat, (2) 50 percent *cis*-monounsaturated fat and 50 percent *cis*-polyunsaturated fat, or (3) 50 percent *cis*-monounsaturated fat and 50 percent saturated fat, and that they would most likely replace *trans* fat in baked products with 50 percent *cis*-monounsaturated fat and 50 percent saturated fat (64 FR 62746 at 62771). In making these assumptions, FDA relied, in part, on a report from RTI estimating that current food technology would require the incorporation of about 0.5 g saturated fat for every 1 g *trans* fat removed by reformulation (64 FR 62746 at 62767).

(Comment 38) Some comments stated that FDA had ignored the question of macronutrient substitutions, or had assumed that reformulation would replace *trans* fat with 100 percent *cis*-monounsaturated fat. According to the comments, functional requirements for margarines, shortenings and baked

fat be replaced by saturated fat, and this requirement was not accounted for in FDA's projections for reformulation. Other comments noted FDA's assumptions regarding macronutrient substitutions, but stated that FDA had overestimated the extent to which *trans* fat could be replaced by *cis*-unsaturated fat, because of functional and cost requirements of various products. These comments generally implied that FDA had overestimated the expected amount of reformulation because saturated fat would need to replace *trans* fat in any reformulation. Comments pointed out that the amount of saturated fat, a cholesterol-raising fat, is already declared on the nutrition label. Therefore, according to the comments, replacement of *trans* fat with saturated fat would not provide a competitive advantage or an incentive to reformulate and, with higher total saturated fat, the reformulated product might not meet the criteria for proposed defined nutrient content claims.

In response to the comments, FDA notes that it did consider the type of

and these were accounted for in the mathematical model used to calculate the health benefits (64 FR 62746 at 62771). FDA is aware that there is a range of functional requirements for margarines and spreads, including tub and stick forms and regular and lower fat varieties. Therefore, FDA assumed a range of ingredient substitutions for margarines and spreads, including both saturated and *cis*-unsaturated fat. Replacement of *trans* fat with a range of combinations of saturated and *cis*-unsaturated fat in margarines and spreads is consistent with reports from North America and Europe (Refs. 104, 124, 125, 126, 127, and 128). In a survey of U.S. margarines, tub margarines with *trans* fat less than 0.5 g per serving did not have increased saturated fat compared with other tub margarines (Ref. 104). In the U.S. study, a stick margarine with less than 0.5 g *trans* fat per serving had higher saturated fat than other stick margarines with comparable fat content, but had lower saturated fat plus *trans* fat than the other stick margarines (Ref. 104). FDA is aware that

products and shortenings may not allow the wide range of substitutions possible in margarines and spreads. Rather, the functional requirements for baked products will likely require replacement of at least some of the *trans* fat with saturated fat. This partial replacement of *trans* with saturated fat is consistent with reports by industry observers (Refs. 121 and 122) and with the examples of the alternative commercial shortenings described in several of the comments. In these examples, the shortenings reformulated to be lower in *trans* fat were higher in saturated fat but were lower in total saturated fat plus *trans* fat than were the traditional, nonreformulated shortenings. Under this final rule, products lower in both saturated fat and *trans* fat will have a competitive advantage because the rule requires prominent declaration of both types of fat on the label.

Based on its consideration of the comments and its own evaluation, FDA continues to believe that the likely substitutions for *trans* fat for margarines will be as described in the November 1999 proposal (64 FR 62746 at 62771). FDA does not have enough information to project the substitutions for *trans* fat due to direct consumer choice, and therefore assumes (for simplicity) that direct consumer choice will show the same range of substitutions as does margarine reformulation. We will describe the effects of these substitutions for *trans* fat on the health benefits of *trans* fat labeling in section VI.E of this document.

Because of the functional requirements for baked products, FDA continues to believe that the most plausible replacement for *trans* fat in baked products is 50 percent *cis*-monounsaturated fat and 50 percent saturated fat. However, because of the uncertainty in quantitative estimation of baked product reformulation, FDA is not including baked product reformulation in its quantitative estimate of benefits and costs of *trans* fat labeling. As note earlier, to the extent that baked products are reformulated,

this analysis will be an underestimate of the actual benefits of this rule.

D. Costs

The costs of this rule are the activities that change as a result of this rule. The total cost of these regulations is the sum of the total testing costs, total relabeling costs, and total reformulation costs. All labels must be in compliance with this final rule by a single effective date. All costs are estimated at the effective date, taken to be 30 months from the publication date of this final rule. If the effective date is more than 30 months from the date of publication, then the actual costs of this rule will be lower than estimated here.

1. Products Affected

This final rule covers all food and dietary supplement labeling within FDA's jurisdiction. With a few exceptions, labeling for all FDA regulated foods and dietary supplements will have to be changed by the next uniform effective date following publication of this rule, or about 2 to 3 years after the date of publication. One exception is for products with less than 0.5 g *trans* fat per serving that also use the "simplified format" for labeling and that do not make nutrition claims or declare vitamins or minerals. The labeling for these products will not have to be changed. FDA does not have data to estimate how many products fall into this category, so the cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule. The other exception is for products that sell less than 100,000 units per year in the United States, that are made by firms that have fewer than 100 employees, that do not make nutrition or health claims, and that have filed a notification with FDA in accordance with § 101.9(j)(18). These products are not required to display the Nutrition Facts panel that is being amended by this rule. Again, FDA does not have data to estimate how many products fall into this category, so the

cost estimate does not reflect this exception and is therefore an overestimate of the actual cost of the rule.

To estimate the costs of this rule, FDA has used the FDA Labeling Cost Model developed for FDA under contract by RTI International in April 2002 (Ref. 129). This labeling model has more current data than the previous labeling cost model developed for the implementing rules of the 1990 amendments (Ref. 74). The model indicates that there are approximately 308,000 food and dietary supplement stock keeping units (SKUs) sold in the United States in categories for which some products will need to be relabeled. A SKU is a specific product sold in a specific size. For example, there is one SKU for 16 ounce (oz) containers of Brand X Diet Peach Tea. The same brand and flavor of tea (a product) in a 12 oz container would be another SKU, and a 12 oz container of the same brand but different flavor of tea would be still another SKU. The model also indicates that there are about 154,000 products potentially affected by this rule. Table 3 of this document shows the data on the number of SKUs and products affected. From the categories listed in table 3 as "Selected Baking Ingredients," "Selected Candy," "Selected Condiments, Dips and Spreads," and "Selected Dressings and Sauces," FDA excluded products, such as baking powder, bottled water, gum, jam, and vinegar, that qualify for the "simplified" format and are certain not to be affected by this rule. Even with these products removed, this estimate is still certain to be an overestimate of the actual SKUs and products affected by this rule because FDA has imputed costs to all products and SKUs within these broad product categories. Labels on many products categories such as "Selected Beverages" and "Dietary Supplements" are not likely to need to be changed. However, FDA has no basis to make better estimates of the actual number of products and SKUs affected by this rule.

TABLE 3.—NUMBER OF SKUs AND PRODUCTS AFFECTED BY PRODUCT CATEGORY

Product Categories	Number of SKUs	Number of Products
Baked Goods	47,200	29,600
Selected Baking Ingredients	7,700	3,300
Baby Foods	1,100	800
Selected Beverages	32,100	8,400
Breakfast Foods	3,600	2,400

TABLE 3.—NUMBER OF SKUs AND PRODUCTS AFFECTED BY PRODUCT CATEGORY—Continued

Product Categories	Number of SKUs	Number of Products
Selected Candy	20,600	12,200
Selected Condiments, Dips and Spreads	15,200	2,300
Dairy Foods	33,800	22,100
Desserts	10,700	7,200
Dietary Supplements	29,500	9,800
Selected Dressings and Sauces	14,200	11,300
Eggs	5,800	1,800
Entrees	10,300	7,900
Fats and Oils	3,100	1,900
Fruits and Vegetables	25,100	2,500
Seafood	6,800	4,200
Side Dishes and Starches	18,000	13,200
Snack Foods	17,800	10,000
Soups	3,700	2,800
Weight Control Foods	1,300	700
Total	307,600	154,400

2. Testing Costs

In the proposed analysis, FDA assumed that all product formulations that include partially hydrogenated oil as an ingredient would be tested to determine the quantity of *trans* fat (except for margarine products, which were all expected to reformulate). Some comments stated that FDA's estimate of the number of products that would need to be tested was too low because products in other categories than those acknowledged by FDA could potentially contain a reportable amount of *trans* fat. Indeed, other comments stated that all products would have to be tested for *trans* content. FDA disagrees with the comment that all products need to be tested because manufacturers will know that some products do not contain *trans* fat, but does agree that more products

need to be tested than previously estimated. In the proposed analysis, FDA estimated costs for testing only for the estimated portion of products containing partially hydrogenated oil in several categories of foods anticipated to be most affected by the rule (an estimated 42,000 products). In this final analysis, based on information in the FDA Labeling Cost Model (Ref. 129), FDA estimates that about 154,000 food products in categories that could possibly include *trans* fat will be tested for *trans* fat content as a result of this rulemaking.

In the proposed rule, FDA used a per product cost of testing for *trans* fat of \$200. Some comments stated that this estimate is too low. They stated that tests had to be calibrated for each type of food to demonstrate accuracy of the test in the food matrix. FDA notes that

manufacturers of many different types of foods have already had their products tested, so that much of the calibration has already been done. The new Labeling Cost Model includes data on the cost of testing for *trans* fat. Included in the analytical testing estimate is the cost of testing two samples of the product, one hour of labor to prepare and package the product (at \$14.73 per hour) and delivery charges for one two-pound package delivered overnight (at \$26.30). The labor cost estimate was based on the average total compensation (wages and benefits) for handlers, equipment cleaners, helpers, and laborers in manufacturing industries. Overhead beyond benefits on the time to prepare a sample for testing is negligible. The model reports a range of testing costs for *trans* fat given in table 4.

TABLE 4.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS

	Low	Medium	High
Cost per Product	\$261	\$291	\$371
Total Testing Cost	\$40,298,000	\$44,930,000	\$57,282,000

One comment suggested that butter and other products with high butter fat

contain a reportable amount of naturally occurring *trans* fat, and that therefore,

testing these products. In this final analysis, FDA has included testing and labeling costs for all dairy products

including butter and other products that are high in butter fat.

3. Relabeling Costs

In the analysis of the proposed rule, FDA estimated that 39,000 SKUs were associated with the 32,000 products that would change their information panels at a cost of \$30 million. During the comment period reopened November 2002, FDA received comments that we would have to reestimate the relabeling costs for the final rule. Under this final rule many more labels will have to be changed than under the proposed rule.

FDA has used the new Labeling Cost Model to reestimate the relabeling costs of this final rule. Based on information in the model, three-quarters of the labels normally will be scheduled to be changed during the 30 month compliance period. FDA estimates that about 78,000 (25 percent) of the almost 308,000 SKUs will have to be changed earlier than would have been planned without this rule. Included in the cost of relabeling are administrative, graphic design, pre-press preparation, printing and engraving, and the lost value of

discarded labels. Across product categories, the average low relabeling cost per SKU is about \$1,100 and the average high relabeling cost per SKU is \$2,600. The reported estimated costs of changing labels varies within a product category because different packaging converters and food manufacturers reported different costs to RTI International. Table 5 shows the total SKUs changed earlier than planned and the total estimated costs of relabeling per product category and for the entire industry.

TABLE 5.—RANGE OF RELABELING COSTS BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	12,500	\$10,941,000	\$16,137,000	\$27,231,000
Baking Ingredients	1,700	\$1,615,000	\$2,380,000	\$3,899,000
Baby Foods	200	\$164,000	\$249,000	\$404,000
Selected Beverages	9,000	\$11,871,000	\$16,659,000	\$25,437,000
Breakfast Foods	1,000	\$801,000	\$1,237,000	\$2,044,000
Selected Candy	4,100	\$4,801,000	\$6,974,000	\$10,846,000
Selected Condiments, Dips and Spreads	3,700	\$4,026,000	\$5,970,000	\$9,283,000
Dairy Foods	8,700	\$10,744,000	\$16,025,000	\$25,032,000
Desserts	3,500	\$2,762,000	\$4,263,000	\$7,042,000
Dietary Supplements	8,100	\$13,449,000	\$20,110,000	\$34,041,000
Selected Dressings and Sauces	2,800	\$2,908,000	\$4,352,000	\$6,757,000
Eggs	2,400	\$1,983,000	\$2,896,000	\$5,086,000
Entrees	2,400	\$2,012,000	\$3,078,000	\$5,032,000
Fats and Oils	800	\$759,000	\$1,160,000	\$1,848,000
Fruits and Vegetables	7,500	\$7,426,000	\$10,915,000	\$17,882,000
Seafood	1,400	\$1,732,000	\$2,541,000	\$3,786,000
Side Dishes and Starches	4,100	\$3,361,000	\$5,124,000	\$8,494,000
Snack Foods	3,600	\$3,604,000	\$5,288,000	\$8,499,000
Soups	700	\$809,000	\$1,194,000	\$1,854,000
Weight Control Foods	200	\$196,000	\$283,000	\$489,000
Total	78,400	\$85,964,000	\$126,835,000	\$204,986,000

4. Margarine Reformulation Costs

One consequence of this regulation will be the reformulation of some foods to reduce levels of *trans* fat. Because those changes in food composition are attributable to this rule, the costs of reformulation are counted here. The benefits to consumers of being able to choose reformulated foods containing

VLE of this document. In the analysis of the proposed rule, FDA estimated the average reformulation would cost \$440,000 per product and would take a full year. Some comments stated that reformulation was very expensive, required a long time to accomplish and would, under certain circumstances, require the use of more expensive inputs. No comments contradicted

of reformulation or provided information to change that estimate, so FDA will continue to use a per product reformulation cost of \$440,000. In the proposed analysis FDA assumed that only large firms would reformulate. There was no controversy over this assumption.

As mentioned previously, based on comments, FDA estimates that 15

already been reformulated to eliminate *trans* fat. For margarine reformulation, FDA has estimated no increase in ingredient costs, because the price of reformulated margarine products that are already on the market is no higher than the price of margarine products containing 0.5 g or more per serving of *trans* fat. The different ingredients used in the products appear to have had no impact on the cost of production. However, as greater numbers of products are reformulated, the increased demand for the substitute ingredients may increase costs. However, given that

increases in costs of inputs, if any, have not been passed on with a change in 15 percent of margarine products, it seems quite reasonable that an additional smaller change (10 percent) will not result in significant increases in ingredient costs.

Therefore, FDA estimates that 10 percent of the margarine products that have not yet been reformulated will be reformulated to reduce *trans* fat content to less than 0.5 g per serving. We assume that reformulating 10 percent of margarine products will result in a 10 percent reduction in the average *trans* fat content of margarine as a product

category. The reformulation will therefore reduce the *trans* fat content of margarines as a whole by 10 percent. In the analysis for the proposed rule, FDA estimated that there were 820 margarine products. Data in the new Labeling Cost Model indicate only 300 margarine products. The new data was used to estimate that 30 margarine products will reformulate as the result of this rule from 8 (10 percent of 84) to 82 (10 percent of 820), if 10 percent of the total number of margarine products are reformulated. Table 6 shows the cost of margarine reformulation.

TABLE 6.—COST OF MARGARINE REFORMULATION

Cost of Reformulating per Product	\$440,000
Products Reformulating	30
Total Cost	\$13,200,000

FDA has not attempted to estimate the ongoing increased cost of substitutes for partially hydrogenated oil. Competition provides producers with incentives to use the least expensive ingredients that are acceptable for the quality of product they are making. Therefore, in general, any change in existing formulations (such as is expected to occur as a result of this rule) can increase the cost of ingredients. Even a very small increase in the price of a minor ingredient can amount to an increase in production costs of millions of dollars when multiplied by millions of units. However, there is good reason to believe

that, in the long run, ingredient costs may not increase. To the extent that producers rely on newly formulated ingredients made with new technologies, the price of these ingredients largely depends on the industrial capacity to produce them. As the demand for such ingredients increases, producers will have more incentive to increase capacity and the prices of these ingredients will fall. In the case where producers make use of different mixes of oils, agricultural inputs are well known for being able to be supplied in greater and greater quantities without an increase in price.

FDA does not have sufficient information on the types of substitutes that will be used, on the volume of substitutes that will be needed, or on the future price of the substitutes at the time that reformulation is completed.

5. Cost Summary

Costs for testing, relabeling, and reformulation are all expected to occur by the first effective date of the final rule, or about 2 to 3 years after publication. Table 7 shows the estimates of total cost.

TABLE 7.—RANGE OF COSTS BY CATEGORY AND TOTAL COST

Cost Category	Low	Medium	High
Testing	\$40,298,000	\$44,930,000	\$59,282,000
Relabeling	\$85,964,000	\$126,835,000	\$204,986,000
Reformulation	\$13,200,000	\$13,200,000	\$13,200,000
Total	\$139,000,000	\$185,000,000	\$275,000,000

FDA acknowledges that there is a significant degree of uncertainty in the cost estimates provided here. The most significant source of potential divergence from the reported estimates would be an ongoing increased cost of substitutes for partially hydrogenated oil for producers of reformulated products. FDA has not included any costs for this item in this analysis, so that, if substitute oils do cost more, the costs here are underestimates.

Reformulation is a second significant

include the number of products that will be reformulated, the cost of reformulation, the number of abandoned attempts at reformulation, the length of time actually needed to reformulate products, and the degree to which the reformulation of some products reduces the cost of reformulating other products of the same or different type. The estimates that are provided in this analysis might be either over- or underestimates of the actual costs of reformulation

A third major area of uncertainty includes the number of labels that will be changed. Actual costs are likely to be lower than those estimated here because this analysis estimated costs based on broad categories of products some of which will not have to change their labels.

E. Benefits

To estimate the health benefits of *trans* fat labeling in the November 1999 proposal, FDA followed the general

benefits for the implementation of the 1990 amendments (56 FR 60856 at 60869, November 27, 1991). Accordingly, FDA estimated: (1) The changes in *trans* fat intake that would result from labeling changes; (2) the changes in health states that would result from changes in *trans* fat intakes; and (3) the value of changes in health states in terms of life-years gained, number of cases or deaths avoided and dollar value of such benefits. The rule may generate other benefits, but we do not quantify them. For example, consumers who are aware of the risks associated with *trans* fat will more readily find information on the *trans* fat content of various foods. The value of the reduction in search time for those consumers is an additional benefit of this final rule.

1. Changes in *Trans* Fat Intake

FDA has estimated the current *trans* fat intake of the population and the estimated changes in *trans* fat intake. Based on comments received and on its own reevaluation, FDA revised its estimate of current *trans* fat intake, shown in table 1 (section IX.C) and its projected estimate for changes in *trans* fat intake due to labeling (table 2, section IX.C). The estimate projects quantitative decreases in *trans* fat intake with implementation of the final rule, and discusses the qualitative replacement of *trans* fat by other types of fat.

2. Changes in Health States

In the November 1999 proposal, FDA used two methods to estimate the potential decrease in CHD likely to result from decreased intake of *trans* fat in response to the labeling change.

a. *Method 1.* Decrease in CHD risk due to decreased serum concentrations of LDL-C.

b. *Method 2.* Decrease in CHD risk due to decreased serum concentrations of LDL-C and increased serum concentrations of HDL-C. FDA also reviewed the association of CHD risk with *trans* fat intake found in large prospective observational cohort studies.

As described in section IV of this document, in the November 1999 proposal FDA concluded that the effects of *trans* fatty acids on serum LDL-C should be the primary criterion for whether *trans* fatty acids influence CHD risk. In Method 1, FDA used changes in the primary criterion, serum LDL-C, to evaluate the effects of *trans* fat intake on CHD risk (64 FR 62746 at 62768). Additionally, as described in section IV of this document although FDA did not

relationships among *trans* fat intakes and adverse effects on HDL-C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, the economic analysis used changes in both HDL-C and LDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C (64 FR 62746 at 62769).

Section IV of this document notes that observational epidemiological studies can provide evidence of an association between a risk factor and a disease, but cannot establish direct cause and effect. Therefore, FDA considered the evidence from observational epidemiological studies, including large prospective (cohort) studies, as indirect evidence for a relationship between *trans* fat intake and CHD risk. In the November 1999 proposal, FDA found that the prospective studies of *trans* fat intake and CHD risk consistently reported a greater risk of CHD attributable to *trans* fat intake than would be accounted for by either Method 1 (changes in LDL-C) or by Method 2 (changes in both LDL-C and HDL-C) (64 FR 62746 at 62770 to 62771). The estimates in Method 1 and Method 2 are calculated using factors from regression equations summarizing the results of short-term feeding trials (intervention studies). In the intervention studies, *trans* fat is fed to people for a few weeks, changes in serum lipids are measured, and it is assumed that the CHD risk associated with *trans* fat intake occurs through the mechanism of changes in LDL-C and possibly HDL-C. In contrast, the prospective studies measure actual CHD occurrence in a large group of people over a period of years, and describe all CHD risk associated with *trans* fat intake, regardless of the mechanism of action by which *trans* fat intake may be associated with CHD. Thus, the results of the prospective studies suggest that there may be additional mechanisms by which *trans* fat contributes to CHD risk. Because prospective studies do not show direct cause and effect, and because the relative risks determined in observational studies are imprecise, FDA did not use the results of the prospective studies in quantitative estimates of changes in *trans* fat intake and CHD risk. However, FDA noted that, if there are additional mechanisms by which *trans* fat contributes to CHD risk, as suggested by the prospective studies, then the actual benefits may be

Method 1 (changes in LDL-C) or Method 2 (changes in LDL-C and HDL-C) (64 FR 62746 at 62771).

As described in the November 1999 proposal (64 FR 62746 at 62768 and 62769), the regression equations of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) were based on five intervention studies that made, in total, six dietary comparisons between consumption of *trans* fat and cis-unsaturated fat (Refs. 7, 8, and 11 through 13). The regression equation for LDL-C showed that each additional percent of energy from *trans* fat was predicted to increase LDL-C by 1.5 mg/deciliter (dL) (0.040 millimol/liter) ($R^2 = 0.86$, $p = 0.0028$) when substituted for the same percent of energy from cis-monounsaturated fat, holding total energy intake constant. The regression equation for HDL-C showed that each additional percent of energy from *trans* fat was predicted to decrease HDL-C by 0.4 mg/dL (0.013 millimol/liter) ($R^2 = 0.88$, $p = 0.0019$), when substituted for the same percent of energy from cis-monounsaturated fat. The regression lines were forced through the origin because a zero change in intake will produce a zero change in lipoprotein concentrations (Refs. 62, 69, and 154). In carrying out the regression, differences between diets in fatty acids other than *trans* fat and cis-monounsaturated fat were adjusted for by using regression coefficients from a previous meta-analysis of 27 intervention studies (Ref. 65).

Sample calculations using Method 1 and Method 2 are summarized in table 8 in this document. The table illustrates a decrease in *trans* fat intake of 0.1 percent of energy (calories) and shows the factors FDA used to relate a given decrease in *trans* fat intake to a corresponding change in CHD risk. To estimate the change in CHD risk with change in *trans* fat intake, for each type of serum lipid, LDL-C and HDL-C, we multiplied the change in *trans* fat intake by three factors, representing: (1) the change in serum lipid with change in *trans* fat intake, (2) the change in CHD risk with change in serum lipid, and (3) an adjustment for regression dilution. Table 8 shows that, for Method 1, based on changes in LDL-C, replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-monounsaturated fat would decrease CHD risk by 0.147 percent (-0.1 percent of energy from *trans* fat x 1.5 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.147 percent change in CHD risk). Based on changes in HDL-C, replacement of 0.1 percent of

CHD risk by 0.140 percent (-0.1 percent of energy from *trans* fat x -0.4 mg HDL-C/dL per percent of energy from *trans* fat x -2.5 percent change in CHD risk per mg HDL-C/dL x 1.4 adjustment factor for regression dilution = -0.140 change

in CHD risk based on changes in HDL-C). For Method 2, based on changes in both LDL-C and HDL-C, the decrease in CHD risk would be 0.287 percent (-0.147 percent based on LDL-C plus -0.140 percent based on HDL-C = -0.287

percent based on LDL-C + HDL-C). FDA used these estimation methods to project the decrease in CHD risk in the November 1999 proposal (64 FR 62746 at 62767).

TABLE 8.—SAMPLE CALCULATION FOR CHANGE IN CHD RISK WITH SUBSTITUTION OF *Cis*-MONOUNSATURATED FAT FOR *Trans* FAT

Estimation Method	Change in <i>Trans</i> Intake (% of Energy)	Type of Serum Lipid	Factor for Change in Serum Lipids (mg/dL per 1% of Energy)	Factor for Change in CHD Risk (% per mg/dL)	Factor for Adjustment of Regression Dilution	Change in CHD Risk (%)
Method 1 LDL	-0.1	LDL	1.5	0.7	1.4	-0.147
Method 2 LDL + HDL	-0.1	LDL	1.5	0.7	1.4	-0.147
		HDL	0.4	-2.5	1.4	-0.140
		LDL+HDL				-0.287

In the scientific literature, *cis*-monounsaturated fat is commonly used as a reference point in describing effects of *trans* fat intake. Therefore, FDA first estimated the effect on CHD risk by assuming that a given amount of *trans* fat would be replaced by the same amount of *cis*-monounsaturated fat in the diet (table 8 in this document and 64 FR 62746 at 62767). However, it is likely that *trans* fat in the diet would actually be replaced by a combination of *cis*-monounsaturated fat, *cis*-polyunsaturated fat, and saturated fat. Therefore, FDA also considered the changes in LDL-C and HDL-C associated with replacement of *trans* fat by different types of fatty acids or carbohydrate (64 FR 62746 at 62767 to 62770). Table 9 in this document summarizes the factors for changes in LDL-C and HDL-C with different macronutrients and combinations of macronutrients replaced by *trans* fat. The first four columns of data show the factors for substitution of *trans* fat for 100 percent of individual types of fatty acids or carbohydrate. We project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. By combining the factors in the first four data columns, we obtained the factors for substitution of *trans* fat for combinations of different fatty acids and carbohydrate, shown in the last three data columns.

We generated the factors in table 9 by combining the results of two sets of metaanalyses. Table 9 shows the result of linking: (1) The regression equation coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69), for substitution of *trans* fat for *cis*-monounsaturated fat

coefficients of Mensink and Katan (Ref. 65), for substitution of saturated and *cis*-unsaturated fat for carbohydrate. The regression equations of Mensink and Katan (Ref. 65) were based on 27 observational studies of dietary comparisons for each of carbohydrate, saturated fat, *cis*-polyunsaturated fat and *cis*-monounsaturated fat. The regression equation for LDL-C included 57 dietary comparison data points from 24 studies, and showed that, holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase LDL-C by 1.28 mg/dL (0.033 millimol/liter) ($p < 0.001$), each additional percent of energy from *cis*-monounsaturated fat was predicted to lower LDL-C by 0.24 mg/dL (0.006 millimol/liter) ($p = 0.114$) and each additional percent of energy from *cis*-polyunsaturated fat was predicted to lower LDL-C by 0.55 mg/dL (0.014 millimol/liter) ($p = 0.002$). The regression equation for HDL-C included 59 dietary comparison data points from 25 studies, and showed that holding total energy intake constant, when substituted for one percent of energy from carbohydrate, each additional percent of energy from saturated fat was predicted to increase HDL-C by 0.47 mg/dL (0.012 millimol/liter) ($p < 0.001$), each additional percent of energy from *cis*-monounsaturated fat was predicted to increase HDL-C by 0.34 mg/dL (0.009 millimol/liter) ($p < 0.001$) and each additional percent of energy from *cis*-polyunsaturated fat was predicted to increase HDL-C by 0.28 mg/dL (0.007

millimol/liter) ($p < 0.001$). Comparison with the observed data showed that the predicted regression lines explained 64 percent of the variation in changes in LDL-C and 88 percent of the variation in changes in HDL-C. Coefficients of Mensink and Katan (Ref. 65) are expressed as substitution of each type of macronutrient for carbohydrate, but the coefficients of Katan et al. (Ref. 62) and Zock et al. (Ref. 69) are expressed as substitution of *trans* fat for *cis*-monounsaturated fat. For comparability with the coefficients for *trans* fat, we expressed the coefficients of Mensink and Katan in terms of substitution of each type of macronutrient for *cis*-monounsaturated fat. As stated in the November 1999 proposal (64 FR 62746 at 62769), when substituted for one percent of energy from *cis*-monounsaturated fat, saturated fat raised LDL-C by 1.52 mg/dL, *cis*-polyunsaturated fat lowered LDL-C by 0.31 mg/dL, and carbohydrate raised LDL-C by 0.24 mg/dL. When substituted for one percent of energy from *cis*-monounsaturated fat, saturated fat raised HDL-C by 0.13 mg/dL, *cis*-polyunsaturated fat lowered HDL-C by 0.06 mg/dL, and carbohydrate lowered HDL-C by 0.34 mg/dL. We then combined these coefficients with the coefficients for *trans* fat, to obtain the changes in lipoprotein levels with *trans* fat substituted for different macronutrients, as shown in table 9.

Table 9 also gives examples of changes in CHD risk with replacement of 0.1 percent of energy from *trans* fat by different macronutrients and combinations of macronutrients. Table 8 shows the general method and illustrates the calculation of estimated

of *trans* fat by cis-monounsaturated fat. To account for each type of macronutrient substitution, we used the corresponding factors from table 9 for changes in serum lipids. For example, for cis-polyunsaturated fat, table 9 gives the factor, 1.81 mg LDL-C/dL, for replacement of 1 percent of energy from cis-polyunsaturated fat by *trans* fat. For Method 1, based on changes in LDL-C, the replacement of 0.1 percent of energy from *trans* fat with the same percent of energy from cis-polyunsaturated fat would decrease CHD risk by 0.177 percent (-0.1 percent of energy from *trans* fat x 1.81 mg LDL-C/dL per percent of energy from *trans* fat x 0.7 percent change in CHD risk per mg LDL-C/dL x 1.4 adjustment factor for regression dilution = -0.177 percent change in CHD risk). As noted previously, we project that, due to *trans* fat labeling, *trans* fat will be replaced by combinations of different types of fatty acids or carbohydrate. The changes in

CHD risk associated with specific combinations of fatty acids or carbohydrate are shown in the last three data columns. The first four data columns show the change in CHD risk associated with each individual type of fatty acid and carbohydrate. The column showing *trans* fat replaced by 100 percent saturated fat is included in table 9 for completeness in illustrating the data and methods we used to estimate changes in CHD risk with different macronutrient substitutions. The inclusion of this column does not indicate that FDA projects that *trans* fat will be replaced by 100 percent saturated fat, or that FDA would encourage such an inappropriate substitution. Rather, the substitutions for *trans* fat that FDA considers most likely are shown later, in table 10. As mentioned earlier, and in the November 1999 proposal (64 FR 62746 at 62769), the economic analysis used changes in both LDL-C and HDL-C as a

second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C. To allow readers to reproduce all of our estimated changes in CHD risk, table 9 shows changes in CHD risk based on Method 2, LDL-C and HDL-C, as well as Method 1, LDL-C. In addition, the cells that show a decrease in CHD due to a 100 percent replacement of *trans* fat for saturated fat represent the relationship between HDL-C and CHD, a relationship that is more uncertain than the causal relationship between LDL-C and CHD. FDA accounted for the replacement of *trans* fat with different combinations of macronutrients by projecting a range of changes in health states in terms of life-years gained, number of cases or deaths avoided, and dollar value of such benefits (64 FR 62746 at 62771-62773).

TABLE 9.—SUMMARY OF CHANGES IN SERUM LIPIDS AND CHD RISK WITH DIFFERENT MACRONUTRIENT SUBSTITUTIONS
CHANGE IN SERUM LIPIDS WITH REPLACEMENT OF *Trans* FATTY ACID BY DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	Cis-monounsaturated Fatty Acid	Cis-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half cis-monounsaturated and half cis-polyunsaturated	Half cis-monounsaturated and half saturated	Half cis-monounsaturated and half carbohydrate
Change in Serum Lipid When Replaced by <i>Trans</i> Fat	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy	mg/dL per 1% of energy
LDL	1.5	1.81	-0.02	1.26	1.66	0.74	1.38
HDL	-0.4	-0.34	-0.53	-0.06	-0.37	-0.47	-0.23

B. CHANGE IN CHD RISK WITH REPLACEMENT OF *Trans* FATTY ACIDS BY DIFFERENT TYPES OF FATTY ACIDS OR CARBOHYDRATE

Macronutrient	Cis-monounsaturated Fatty Acid	Cis-polyunsaturated Fatty Acid	Saturated Fatty Acid	Carbohydrate	Half cis-monounsaturated and half cis-polyunsaturated	Half cis-monounsaturated and half saturated	Half cis-monounsaturated and half carbohydrate
Change in CHD Risk With Replacement of <i>Trans</i> Fat	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy	Percent per 0.1% of energy
Method 1, LDL	-0.147	-0.177	0.002	-0.123	-0.162	-0.073	-0.135
HDL	-0.140	-0.119	-0.186	-0.021	-0.130	-0.163	-0.081
Method 2, LDL + HDL	-0.287	-0.296	-0.184	-0.144	-0.292	-0.235	-0.216

(Comment 39) As described previously in this document, FDA received numerous comments in support of the November 1999 proposal. Several of these comments noted specifically that labeling of *trans* fat has

health benefits. A number of comments noted that consumption of *trans* fat increases the risk of CHD by increasing total blood cholesterol and LDL-C, and that *trans* fat labeling would enable consumers to decrease their *trans* fat

of CHD. Some comments added that, because *trans* fat also increases the risk of CHD by decreasing HDL-C, therefore the health benefits of *trans* fat labeling would be greater than the benefits associated with the effect of *trans* fat on

specifically stated that the prospective studies suggest that there may be other biological mechanisms by which *trans* fat contributes to CHD, in addition to the effects of *trans* fat on LDL-C and HDL-C. These comments therefore supported the possibility that the actual benefits of *trans* fat labeling may be greater than FDA's estimate using either Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C).

Other comments, which were opposed to the November 1999 proposal or some of its provisions, questioned FDA's conclusions regarding the net health benefits of *trans* fat labeling. Some comments stated that the potential harm to the public remedied by *trans* fat labeling was not sufficient to outweigh the cost burden to specific industries. These comments suggested that, although *trans* fat was shown to increase LDL-C in some studies, the evidence was inconclusive on how to quantify the increase in LDL-C and CHD risk due to *trans* fat intake and on whether the increase in LDL-C and CHD risk due to *trans* fat intake was large enough to justify the benefits of *trans* fat labeling. Some comments suggested that FDA's estimate of health benefits of *trans* fat labeling was too high. One comment stated that it is premature to conclude that *trans* fat intake lowers HDL-C because many intervention studies showed that *trans* fat intake causes only a small decrease or has no effect on HDL-C. The comment implied that consumption of *trans* fat may not increase CHD risk by decreasing HDL-C. A few comments cited an FDA statement from the November 1999 proposal that no dose-response relationship had been demonstrated between *trans* fat intake and CHD (64 FR 62746 at 62752). The comments argued that, therefore, it is not possible to project quantitative health benefits due to *trans* fat labeling. One comment also stated that the health benefits estimate was inaccurate because it did not account for either other CHD risk factors, such as obesity, or other CHD prevention efforts.

A few comments questioned whether health benefits could result from *trans* fat labeling because the intakes of *trans* fat were very high and not representative of U.S. intakes of about 5.3 g/d (3 percent of calories). Some comments stated that, even if *trans* fat has adverse health effects at higher levels of intake, there is no clinical evidence that lower levels of intake, such as 0.5 g *trans* fat in a serving of a food product, has any adverse effect. These comments therefore questioned

from labeling of *trans* fat present in relatively small amounts in individual foods. Other comments suggested that the emphasis on *trans* fat in the proposed labeling regulations was out of proportion to the emphasis on saturated fat, because the overall amount of saturated fat in the diet is approximately five times that of *trans* fat. The comments stated that, therefore, decreased *trans* fat intake has much less potential for lowering CHD risk than does decreased saturated fat intake, and this should be considered when estimating the health benefits of *trans* fat labeling.

Regarding the comments that questioned whether the increase in LDL-C and CHD risk due to *trans* fat intake could be quantified and whether the increase in LDL-C and CHD risk due to *trans* fat intake were as large as those due to saturated fat, FDA stated in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL-C and CHD risk equivalent to saturated fat on a gram-for-gram basis. FDA noted that interpretation of the intervention studies is complicated because, in the individual studies, *trans* fatty acids replace other dietary fatty acids that also affect serum cholesterol levels (64 FR 62746 at 62751). This evaluation was based on a review and analysis of the individual studies, it was not done for purposes of an economic analysis. To overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62768–62770). As noted in section IV of this document, and in the November 1999 proposal, the regression equations do predict a very similar increase in LDL-C with each one percent of energy increase in either saturated fat or *trans* fat. Thus, table 9 in this document shows that the change in LDL-C is negligible when one percent of energy from *trans* fat is substituted for saturated fat. Therefore, FDA disagrees with the comments that stated that the increases in LDL-C and CHD risk due to *trans* fat intake could not be quantified and were not as large as those due to saturated fat and that FDA's estimate of these health benefits of *trans* fat labeling was too high.

Regarding the comment suggesting that it is premature to conclude that

IV of this document states that Federal Government advisory groups (Refs. 88 to 90, 140) and an advisory group of health professionals (Ref. 91) have stated that substitution of *trans* fat for saturated fat lowers HDL-C. Specifically, the Dietary Guidelines 2000 Advisory Report states that *trans* fatty acids tend to lower a protective form of serum cholesterol (HDL cholesterol) (Ref. 88). NCEP 2001 states that randomized clinical trials show that when *trans* fatty acids are substituted for saturated fatty acids, HDL cholesterol levels are lower, with a dose response effect observed (Ref. 89). The IOM/NAS states that the preponderance of the data suggest that hydrogenated fat/*trans* fatty acids, relative to saturated fatty acids, result in lower HDL cholesterol concentrations (Ref. 90). AHA 2000 states that it has been established that dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL cholesterol (AHA 2000, p. 2306) (Ref. 91). Therefore, FDA disagrees with the comment that it is premature to conclude that *trans* fat intake may lower HDL cholesterol levels. Section IV of this document, and in the November 1999 proposal, placed primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL-C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL-C and LDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C (64 FR 62746 at 62769).

Regarding the comments discussing FDA's statement in the November 1999 proposal (64 FR 62746 at 62752) that no dose response relationship had been demonstrated between *trans* fat intake and CHD, this statement referred to the effect of *trans* fat on CHD risk in the observational studies, not to the effect of *trans* fat on LDL-C which was used to estimate the health benefits in Method 1 (LDL-C) and Method 2 (LDL-C and HDL-C). FDA's statement was a generalization regarding the observational studies overall, including both case control studies and prospective observational studies. However, the four large prospective studies did all show dose-response relationships between *trans* fat intake and CHD risk, but in two of the studies the dose-response relationship was not statistically significant in all analyses. In the Nurses Health Study, the dose

and 14 years of followup was highly statistically significant (Refs. 21 and 38). In a Finnish study, the dose response relationship of *trans* fat with risk of CHD death was significant ($p = 0.004$), but was not significant for risk of major coronary event ($p = 0.158$) (Ref. 20). In a study of U.S. men, the dose response relationship was significant after statistical adjustment for major CHD risk factors ($p = 0.01$) but was not significant after additional adjustment for dietary fiber ($p = 0.2$) (Ref. 19). Therefore, the prospective studies were consistent with a dose-response relationship, although the relationship was not statistically significant in all analyses. Moreover, as discussed previously in this section, FDA's quantitative estimate of health benefits was not based on the prospective studies, but was based on the regression equations summarizing the results of the intervention feeding studies (tables 8 and 9 in this document and 64 FR 62746 at 62757–62770). The regression equations summarizing the effect of *trans* fat on LDL-C and HDL-C in the intervention studies did not account for dose-response relationships discussed in the November 1999 proposal and found in section IV of the document. Additionally, the regression equations used by FDA in this document and in the November 1999 proposal were for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130). Therefore, FDA does not agree with the comment that it is not possible to calculate health benefits because there is no dose-response relationship for the adverse effects of *trans* fat.

FDA disagrees with the comment that the health benefits estimate did not account for other CHD risk factors. In the health benefits estimate, FDA used the factors shown in table 8 to calculate the amount of CHD risk associated with the expected amount of change in LDL-C and HDL-C. These factors were derived from large population studies of serum lipids and CHD risk, in which statistical methods accounted for other positive and negative risk factors for CHD.

Regarding the comment about the level of *trans* fat intake in the intervention studies, Section IV of this document explains that, because of uncertainty in intake estimates, caution must be exercised to avoid over-interpretation of the available dietary intake estimates and their relationship to the *trans* fat levels used in the intervention trials. However, in

some specific examples of intervention studies with lower *trans* fat intake. One example is the study of Judd et al., 1998 (Ref. 34), which found a significant increase in LDL-C with a difference in *trans* fat intake of 1.5 percent of calories between the *trans* fat test diet (3.9 percent of calories from *trans* fat) and the comparison diet (2.4 percent of calories from *trans* fat). Another example is the study of Lichtenstein and coworkers (Ref. 82) which studied six test diets and reported a positive coefficient, i.e., a linear trend, for the association of the change in LDL-C levels among diets with the change in *trans* fat intake (including *trans* fat changes of 0.4 percent and 2.8 percent of calories). Such a linear trend does suggest that *trans* fat intakes below 3 percent of calories may influence LDL-C levels, and thus, CHD risk. Therefore, significant increases in LDL were found in several intervention studies with *trans* fat intake at or below the reported average intake for the U.S. population.

FDA disagrees with the comment that disclosure of *trans* fat content in a food product will not result in the public health benefits of *trans* fat labeling. Health benefits may not result from labeling of *trans* fat present in relatively small amount in individual foods. As described earlier in sections III and V of this document, FDA does not need to demonstrate adverse health effects of 0.5 g *trans* fat in a food product in order to justify requiring disclosure of 0.5 g *trans* fat on food labels. Rather, FDA determined that the consistent provision of *trans* fat information on foods consumed throughout the day is of public health importance and can assist consumers in maintaining healthy dietary practices. Further, FDA has determined that the absence of *trans* fat information on foods requiring mandatory labeling would be misleading. However, for the purposes of economic analysis, the health benefits of decreasing *trans* fat intake by 0.5 g can be estimated quantitatively. In a 2,000 calorie diet, 0.5 g *trans* fat corresponds to approximately 0.2 percent of energy. (This correspondence holds because 1 g of fat = 9 kcal, so $(0.5 \times 9 \times 100)/2000 = 0.2$ percent of energy). Using the factors in table 8, replacement of 0.2 percent of energy from *trans* fat with *cis*-monounsaturated fat would decrease CHD risk by 0.29 percent based on LDL-C and 0.57 percent based on LDL-C and HDL-C. Because CHD is so common in the U.S. population, a relatively small decrease in risk corresponds to a large number of cases and deaths avoided and large dollar value of such benefits, as

this document. Awareness of *trans* fat contributions from food products containing 0.5 g and above will assist individual consumers in maintaining healthy dietary practices, reducing the average 2.6 percent of energy from *trans* fat consumed throughout the day.

FDA agrees with the comments that average saturated fat intake in the United States is about 5 times greater than average *trans* fat intake. FDA stated in the November 1999 proposal that it did not want to distract consumers from years of dietary guidance messages about saturated fat (64 FR 62746 at 62755). But the potential health benefits from decreasing *trans* fat intake compared with decreasing saturated fat intake do not depend solely upon the average total amount of each in a diet. The potential health benefits also depend upon the feasibility of decreasing intake of saturated fat compared with *trans* fat. Average U.S. saturated fat intake in 1999 was about 13 percent of energy and decreased to 11 or 12 percent of energy by the mid-2000s (Ref. 110). Many of the heart benefits and health benefits associated with saturated fat intake could be decreased to the level of the targeted 10 percent of energy. The targeted decrease in saturated fat intake of one or two percent of energy can be compared with the average *trans* fat intake of 2 percent of energy from partially hydrogenated fats and oils. Labeling of *trans* fat will create new potential for decreased *trans* fat intake by providing an incentive to food manufacturers to reduce the amount of *trans* fat in their products and by providing consumers with information they need to include *trans* fat content in their food purchasing decisions.

(Comment 40) Among the comments that supported the potential public health benefits of *trans* fat labeling, many noted that benefits would result from provision of *trans* fat information on product labels so that consumers could incorporate this information into their purchasing decisions. Several comments also specifically noted the likelihood that *trans* fat labeling would result in reformulation of products to be lower in *trans* fat, and suggested that the public health benefits would be large because reducing *trans* fat intake as a result of reformulation requires little effort by consumers. However, some comments did not agree that *trans* fat labeling would be read or understood by consumers, or that the labeling would affect purchasing decisions. These comments suggested that the net health benefits of *trans* fat labeling would be much smaller than FDA's estimate.

products could be reformulated in a manner that would result in net health benefits. Some of these comments stated that *trans* fat is beneficial because foods with *trans* fat replace foods with higher amounts of saturated fat. Some comments stated that feasible reformulations that would lower *trans* fat would also increase saturated fat, thereby reducing or eliminating health benefits. Other comments emphasized that manufacturers need competitive incentives in order to incur the costs of reformulation, and did not agree that the Nutrition Facts panel and label claims in the November 1999 proposal provided sufficient incentives for reformulation.

In the November 1999 proposal, FDA based its estimate of health benefits on scenarios of projected decreases in *trans* fat intake due to labeling and reformulation. As summarized in section VI.C of this document, FDA received specific comments regarding the likely decrease in *trans* fat intake due to expected consumer responses to the final rule and may also be to the proposed labeling of product categories. In addition, on the comments received, on the provisions of this final rule and on its own reevaluation, FDA has revised its estimate of the expected decrease in *trans* fat intake due to labeling (table 2, section VI.C). Because of uncertainties regarding the magnitude of consumer response to *trans* fat labeling we have chosen a very low estimate of consumer response to the new label, a decrease of 0.1 percent of *trans* fat intake (section VI.C.). As described in section IV of this document, current dietary guidance does not consider *trans* fat to be beneficial, but recommends that intake of both *trans* fat and saturated fat should be limited. When products containing partially hydrogenated fats or oils are reformulated to lower the *trans* fat content, functionality may require the reformulated products to have more saturated fat than the original product. However, as shown in a number of examples included with comments, the total amount of saturated fat plus *trans* fat in the reformulated product is commonly lower than in the original product. Substitution of the reformulated product for the original product in the diet would have net health benefits using Method 1, LDL-C, and even higher health benefits using Method 2, LDL-C and HDL-C. FDA acknowledges that different products have different functionality requirements for fats and oils, and the constraints on reformulation

stick margarines and spreads, household shortenings, frying fats for snacks and chips, and baking fats for cookies, crackers, cakes and other baked goods. FDA has summarized specific comments regarding reformulation alternatives in section IX.C of this document, has taken these into account in projecting the expected amount of margarine reformulation (table 2), and is accounting for the replacement of *trans* fat with different combinations of macronutrients in its models for calculating changes in valuation of health states in section IX.E.3 of this document. Therefore, FDA does not agree with the comments that feasible reformulations would eliminate health benefits by increasing saturated fat. In section V of this document, FDA stressed the importance of providing information on *trans* fat on the nutrition label to assist consumers in choosing healthier diets. As described in section IX.E.3 of this document, in response to comments regarding reformulation, FDA recognizes that different features of this final rule may lead to other reasonable estimates of the benefits of reformulation. Therefore, because of this uncertainty, in this analysis FDA is using a deliberately low estimate, 10 percent, for the decrease in *trans* fat intake due to margarine reformulation. Also, FDA is not using a quantitative estimate for any decrease in *trans* fat intake due to reformulation of baked products or of other products containing hydrogenated fats and oils. To the extent that the decrease in *trans* fat intake due to reformulation is greater than FDA's estimate, this analysis will underestimate the benefits of *trans* fat labeling.

(Comment 41) As summarized in section IV.9 of this document, one comment recommended that comparisons of the health effects of saturated fat and *trans* fat should be explicit and consistent throughout the final rule. The comment noted that in FDA's November 1999 proposal, the preliminary regulatory impact analysis estimated that the effects of *trans* fat and saturated fat on LDL-C were similar for a given percent of energy, but the review of the science did not make a gram-for-gram comparison of the effects of saturated and *trans* fat. The comment stated that if there is uncertainty about the comparative effects of saturated fat and *trans* fat on LDL-C, then this should be reflected in FDA's estimate of health benefits. The comment also noted that, in the preliminary regulatory impact analysis, use of Method 2, LDL-C and HDL-C, would approximately

trans fat labeling, compared with Method 1, LDL-C. The comment suggested that if the adverse health effects of *trans* fat are approximately double those of saturated fat, this should be taken into account in the provisions for labeling and claims. This comment also suggested that FDA had misinterpreted the relative risk results of the prospective observational studies and questioned whether these studies actually indicated that the risk of CHD due to *trans* fat intake was much greater than would be expected due to LDL-C and HDL-C. According to the comment, relative risk estimates in prospective studies depend on the base risk used for comparisons. Individuals in some study groups, such as the Nurses Health Study, may have lower overall CHD risk than individuals in the general population because the participants are volunteers whose lifestyles may be healthier than average. A systematic difference between the study and general populations may result in inaccuracies when the relative risk from the study population is related to the absolute risk in the general population. FDA will examine its final November 1999 proposal to reopen the *trans* fat comment period questioned the scientific validity of certain of the observations and conclusions in the IOM/NAS report. The comments stated that the IOM/NAS report relied upon a regression equation in an article by Ascherio et al. (Ref. 83), published in the NEJM, for its observation that *trans* fatty acids may have a more adverse effect on CHD risk than saturated fatty acids and for its conclusion that, similar to saturated fatty acids, there is a positive linear trend between *trans* fatty acid intake and LDL-C and risk of CHD. The comments stated that the Ascherio et al. article was a commentary that was not peer-reviewed and should not be accorded the weight given by the IOM report. Additionally, comments suggested that additional research is needed to establish whether there is a positive linear trend between *trans* fat intake and LDL-C. The comments asserted that there may be an alternate explanation for the results described by Ascherio et al., and mentioned unpublished work done at the University of Cincinnati. The comments did not mention the existence of any other evidence for a linear trend between *trans* fat intake and LDL-C, and implied that, in the absence of the Ascherio article (Ref. 83), there would be no basis for the existence of such a linear trend.

As stated in section IV.9 of this document, regardless of whether FDA

trans fat on LDL-C and CHD risk for the science section or the regulatory impact section, the basic conclusion about those effects is the same. That is, both *trans* fatty acids and saturated fatty acids raise LDL-C levels, a major risk factor for CHD risk. FDA did state in the review of the science in the 1999 proposal (64 FR 62746 at 62753) that the available studies did not provide a definitive answer about whether *trans* fat has an effect on LDL-C and CHD risk equivalent to saturated fat on a gram-for-gram basis. However, as stated previously in both this section and section IV of this document, to overcome the difficulties in interpreting individual intervention studies, in the November 1999 proposal FDA used regression equations based on a meta-analysis of intervention trials to quantitatively estimate the relationship between *trans* fat and LDL (Refs. 62, 65, and 69) in its calculation of the health benefits of *trans* fat labeling (64 FR 62746 at 62763-62770). The regression equations do not include very small amounts of *trans* fat (less than 1 percent of energy intake) in either saturated fat or *trans* fat. The regression equations used by FDA in this document and in the November 1999 proposal are appropriate for purposes of making a quantitative estimate of the health benefits as part of an economic analysis and are consistent with newer regression equations in a study published in 2001 (Ref. 130).

As previously described in this section and in section IV of this document, although FDA did not place primary reliance upon the relationships among *trans* fat intakes and adverse effects on HDL-C and CHD risk in deciding that nutrition labeling was warranted, FDA also recognizes this possible relationship, so concerns about possible adverse effects cannot be ignored. Therefore, we used changes in both HDL-C and LDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule was the effect of *trans* fat on LDL-C (64 FR 62746 at 62769). As discussed in section V of this document, because of chemical and physiologic distinctions between saturated and *trans* fats, the agency has reconsidered the position that the two fatty acids should be declared as one combined entity. Declaration of the amount of *trans* fat on a separate line from saturated fat on the nutrition label is consistent with the possibility that the health benefits of *trans* fat labeling may be due to changes

changes in both LDL-C and HDL-C (Method 2).

In response to the comment about relative risk in the prospective studies, FDA acknowledges that relative risk estimates in prospective studies will depend on the base risk used for comparisons and this dependence on base risk may result in inaccuracies when the relative risk is related to the absolute risk in other studies or in the general population. However, FDA does not agree that this difference would change the basic conclusion of the prospective studies, that the CHD risk associated with *trans* fat in the prospective studies is much greater than the CHD risk expected due to either Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C). In the 14-year followup of the Nurses Health Study (Ref. 38), the increased risk of CHD associated with *trans* fat intake compared with carbohydrate intake was more than ten times the increased risk for the same amount of saturated fat compared with carbohydrate. This comparison between *trans* fat and saturated fat is consistent with the results of Method 1 (LDL-C) or Method 2 (LDL-C and HDL-C). In Method 1, *trans* fat would be predicted to be associated with about the same increased risk as saturated fat, and in Method 2, *trans* fat would be predicted to be associated with about twice as much increased risk as saturated fat, comparing both with carbohydrate. This comparison was within a single study, so the difference between the results of this study and what would have been expected due to Method 1 or 2 cannot be attributed to any differences in baseline risk between studies. Moreover, although participants in large prospective studies have different baseline risks of CHD, the increased risk associated with known risk factors is often reasonably consistent across many of the studies. For example, the increased CHD risk associated with saturated fat for female nurses from 1980 to 1994 (Ref. 38) was quite similar to that for male employees of Western Electric Co. from 1958 to 1976 (Ref. 67) (64 FR 62746 at 62771). The changes in CHD risk associated with total cholesterol and HDL-C for male physicians from 1982 to 1987 was comparable to that for men and women from Framingham, MA in the 1970s (Ref. 131).

A meta-analysis of the relative risk of CHD associated with *trans* fat intake was recently published (Ref. 102). The meta-analysis used the results of prospective observational studies in four cohorts: Women in the United States, men in the United States, men in

The results showed a pooled variance-weighted relative risk of 1.25 (95 percent confidence interval 1.11 to 1.40) for CHD associated with 2 percent of energy intake from *trans* fat. For 0.1 percent of energy intake from *trans* fat, the meta-analysis results would predict a relative risk of 1.0112 (confidence interval 1.0052 to 1.0170). That is, for 0.1 percent of energy intake from *trans* fat, the increase in CHD risk would be 1.12 percent (confidence interval 0.52 to 1.70 percent). In comparison, the largest change in CHD risk shown in table 9, associated with 0.1 percent of energy intake from *trans* fat, is 0.162 percent using Method 1 and 0.292 percent using Method 2. Thus, the increase in CHD risk for 0.1 percent of energy intake from *trans* fat based on a meta-analysis of prospective studies is larger than the associated CHD risk estimated using either Method 1, LDL-C or Method 2, LDL-C and HDL-C. (The calculation of relative risk for different levels of *trans* fat intake is based on taking the natural logarithm of 1.25 for 2 percent of energy intake from *trans* fat, dividing that by the log of 1.0112 for 0.1 percent of energy intake from *trans* fat, and then taking the antilogarithm of $1.25 \div 0.223, 0.1116$, the coefficient for 1 percent of energy from *trans* fat; $0.1116 \times 0.1 = 0.0112$, the coefficient for 0.1 percent of energy from *trans* fat; the antilogarithm of $0.0112 = 1.0112$, the relative risk associated with 0.1 percent of energy from *trans* fat.)

Thus, FDA disagrees with the comment about relative risk in the prospective studies, and maintains that the prospective studies do suggest that there may be additional mechanisms, besides changes in LDL-C and HDL-C, by which *trans* fat contributes to CHD risk. However, as discussed previously in this section, and in the November 1999 proposal (64 FR 62746 at 62771), FDA did not use the results of the prospective studies in its quantitative estimate of the health benefits of *trans* fat labeling. The sole use of the prospective studies was to suggest that there may be additional mechanisms by which *trans* fat contributes to CHD. The prospective studies thus indicate the direction of the uncertainty in the benefits estimate: That the actual benefits may be higher than the benefits estimated using Methods 1 and 2.

In response to the comments about the Ascherio et al. regression equation as discussed in the IOM/NAS report (Ref. 140), FDA notes that according to the NEJM, all submissions to the journal are peer-reviewed before publication. The comments did not cite any published articles questioning the 1999

not submit data from the unpublished work that the comments asserted could provide an alternate explanation for the Ascherio et al. results. As noted in section IV of this document, the paper by Ascherio et al. is not the only information that the IOM/NAS used in concluding that *trans* fatty acid consumption should be as low as possible while consuming a nutritionally adequate diet (see comment 3). Additionally, the Ascherio paper is not the only information in the IOM/NAS report that supports a positive linear trend for *trans* fat intake and LDL-C and risk of CHD. For example, as mentioned previously in this section (see comment 39), the study of Lichtenstein et al. (Ref. 82), using six test diets at different levels of *trans* fat intake, found a positive linear trend for *trans* fat intake and LDL-C level. In discussing *trans* fat intake and HDL-C, the IOM/NAS report references work by Zock, Mensink, and Katan (Refs. 69 and 174). These papers pertain not only to HDL-C but also to LDL-C. The work of Zock and colleagues (Refs. 62, 69, and 174) shows a positive linear trend between *trans* fat intake and LDL-C, and a negative linear trend between *trans* fat intake and HDL-C. However, the Lichtenstein *trans* fat intake and LDL-C regression equation showing a negative linear trend between *trans* fat intake and HDL-C.

As noted in section IV and in this section of this document, FDA's primary rationale for *trans* fat labeling is the effect of *trans* fat intake on LDL-C. Additionally, the economic analysis uses changes in both HDL-C and LDL-C as a second method to quantify the effects of *trans* fat intake on CHD risk, with the noted qualification that the primary basis for the rule is the effect of *trans* fat on LDL-C. Therefore, as stated in the November 1999 proposal (64 FR 62746 at 62770), for purposes of economic analysis we used the equations of Zock et al. (Refs. 62 and 69) to estimate the effects of *trans* fat on LDL-C and HDL-C separately and did not use the equation of Ascherio et al. (Ref. 83), which estimates the positive linear trend between *trans* fat intake and the lipid ratio, LDL/HDL. FDA's Method 2, using the equations of Zock et al. (Refs. 62 and 69) for changes in both LDL-C and HDL-C, is different than the method of Ascherio et al. (Ref. 83), which uses changes in the lipid ratio, LDL/HDL. However, what FDA's Method 2 and Ascherio's method have in common is that they each provide a quantitative estimate of the adverse effects of *trans* fat on CHD risk using changes in both LDL-C and HDL-C.

As stated previously in this section (see comment 39), the regression

showing a positive linear trend between *trans* fat intake and LDL-C, are consistent with newer regression equations in a study published in 2001 by Muller et al. (Ref. 130). Thus, there is a body of research, including the work of Ascherio et al. (Ref. 83), Zock et al. (Refs. 62, 69 and 154), Lichtenstein et al. (Ref. 82) and Muller et al. (Ref. 130), that supports the existence of a linear trend for *trans* fat intake and LDL-C levels, consistent with the conclusions of the IOM/NAS (Ref. 140). As discussed in the IOM/NAS report, the existence of a linear trend of saturated fat and LDL-C is very well-established, as shown by three sets of regression equations described in the IOM/NAS report (Ref. 140, Figure 8-3, pp. 8-47 to 8-48). Thus, the existence of a positive linear trend for *trans* fat intake and LDL-C, as shown by a body of research (Refs. 62, 69, 82, 83, 130, and 154) and recognized by the IOM/NAS (Ref. 140), is not unusual, considering that there is also a positive linear trend between saturated fat intake and LDL-C. Therefore, FDA is not concluding that the comments

the existence of the trend between *trans* fat intake and LDL-C is not unusual, considering that there is also a positive linear trend between saturated fat intake and LDL-C. Therefore, FDA is not concluding that the comments that, for the purposes of economic analysis, it is appropriate to quantify the health benefits of *trans* fat labeling using regression equations (Refs. 62 and 69) describing a positive linear trend between *trans* fat intake and LDL-C and a negative linear trend between *trans* fat intake and HDL-C.

(Comment 42) One comment stated that FDA's estimate of benefits of the November 1999 proposal neglected to account for the overall reductions of mortality and morbidity from heart disease that have been occurring in the United States for the past few decades. According to the comment, FDA should have projected the future reduction in heart disease that would be expected in the absence of labeling. With such a projection, the baseline for heart disease morbidity and mortality would be progressively lower over time, and the numbers of heart attacks and deaths avoided due to *trans* fat labeling would be commensurately reduced compared with FDA's estimate. One comment stated that an overall decline in CHD from 1970 to 1990 coincided with a decline in intake of fat and saturated fat. The comment stated that margarine intake (per person) was constant during this period. Therefore, the comment concluded that substituting margarine for high saturated fat and cholesterol products had proved beneficial in decreasing CHD.

FDA agrees that the rate of heart

United States has been decreasing for several decades (Refs. 132 and 133). For example, the age-adjusted death rate from CHD declined from approximately 290 per 100,000 in 1979 to 190 per 100,000 in 1996 (Ref. 133). However, because the risk of CHD is greater at older ages and the U.S. population is aging, the decline in the overall (crude) CHD death rate in this period was more modest, from approximately 225 per 100,000 to 180 per 100,000. Moreover, because of the increase in the total population, the decline in annual CHD deaths in this period was even more modest, from approximately 550,000 to 500,000, about a 10 percent decrease over 17 years. The number of deaths was fairly level during the period, 1992 through 1996. Thus, the baseline number of CHD deaths, as opposed to age-specific rates, has historically declined at a modest rate, and has been fairly level in recent years. Therefore, FDA did not project for this in its projection of heart attacks and deaths avoided due to *trans* fat labeling. In fact, the IOM/NAS report (Ref. 140) states that the overall decline in CHD deaths over the period 1970 to 1990 is not unusual, considering that the overall number of CHD deaths declines in the future, omitting this correction would result in a modest overestimate of the health benefits of *trans* fat labeling.

Regarding the comment about correlations of changes in dietary intake with declines in CHD from 1970 to 1992, information on *trans* fat intake is limited, as noted in section IV of this document. Therefore, although margarine intake was approximately constant, it is not known whether overall *trans* fat intake increased, decreased or remained the same during this period. Furthermore, the causes of the decrease in CHD over this time period have not been identified. Decreases in CHD risk factors, such as serum lipids, and decreases in saturated fat intake probably played a role, but the relative contributions of decreases in various risk factors and changes in medical care for heart attack patients are not adequately explained (Ref. 132). Therefore, FDA disagrees with the comment's conclusion that time trends in CHD incidence demonstrate a beneficial effect of margarine intake on incidence of CHD.

Based on the comments received and its own re-evaluation, FDA is not making any changes in the sample calculations for changes in CHD risk (table 8) or in the factors for changes in serum lipids and the examples of changes in CHD risk and the factors for changes in serum lipids with

(table 9), described earlier in this section. Earlier in this section, FDA has revised its estimate of projected decreases in *trans* fat intake due to labeling (table 2) and discussed the likely substitutions of different types of fat for *trans* fat. Using this information, FDA revised the expected changes in CHD risk due to *trans* fat labeling.

As shown in table 2, a 0.0378 percent of energy decrease in *trans* fat intake is expected to occur by the effective date of the rule. Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows the decreases in CHD risk that would be expected, 3 years after the effective date, for different examples of macronutrient substitutions for *trans* fat. The three specific substitutions shown in table 10 are those that FDA used to represent the range of likely ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-

monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73). Table 10 shows that, using one of these three substitutions, the predicted decrease in CHD risk would range from 0.027 percent to 0.061 percent for Method 1 and from 0.090 percent to 0.110 percent for Method 2.

FDA has identified these likely substitutions, but recognizes that once reformulation begins, different combinations of ingredients may emerge. In order to estimate the health effects of reformulation, however, it is less important to identify the exact formulas to be used than it is to identify the range of possible changes in CHD risk. To estimate the potential health benefits from the reformulation of margarine, FDA used a probabilistic model with a distribution of effects based on the distribution of possible changes in CHD risk associated with the three ingredient substitutions. FDA used

a distribution rather than a weighted average because we did not know which combination was most likely, or what distribution of combinations would emerge. (The formal distribution we used was a BetaPERT, which uses three points: A minimum, an intermediate, and a maximum. The model used the change in CHD risk for a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat as the minimum, the change with 100 percent *cis*-monounsaturated fat as intermediate, and the change for a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.)

As shown in table 10, the probabilistic model of substitutions for *trans* fat predicted a decrease in CHD risk of 0.052 percent using Method 1 and 0.106 percent using Method 2.

Table 10—PREDICTED CHANGES IN CHD RISK DUE TO *Trans* FAT LABELING ACCORDING TO MACRONUTRIENT SUBSTITUTION FOR *Trans* FAT

Time after Effective Date for Final Rule ¹	Decrease in <i>Trans</i> Fat Intake (% of Energy)	Source of Decrease	Substitution for <i>Trans</i> Fat	Risk		
				Method 1, LDL	HDL	Method 2, LDL and HDL
3 years	0.0378	Consumer choice and margarine reformulation	mono	-0.056%	-0.053%	-0.108%
			mono+ poly	-0.061%	-0.049%	-0.110%
			mono+ sat	-0.027%	-0.062%	-0.090%
			Substitution from probabilistic model	-0.052%	-0.054%	-0.106%

¹ The time after the effective date for the final rule includes 3 years for decreases in *trans* fat intake to result in changes in CHD risk.

Approximately 3 years will be needed for predicted changes in *trans* fat intake to result in changes in CHD risk (Ref. 137). Table 10 shows that the 0.0378 percent of energy decrease in *trans* fat intake expected to occur by the effective date of the rule will result, 3 years after the effective date, in a 0.052 percent decrease in CHD risk using Method 1 and a 0.106 percent decrease in CHD risk using Method 2. FDA estimated these decreases in risk using a mathematical model that accounted for the three likely substitutions for *trans* fat in reformulation of margarine and direct consumer choice, discussed previously. Table 10 shows the predicted decrease in CHD risk for each of the substitutions separately, and the overall estimate from the mathematical

3. Value of Changes in Health

In the previous sections, FDA presented potential changes in food markets because of this final rule and described calculations of the decreases in CHD that would result from those market changes. Uncertainties in these analyses include:

- The size of consumer substitutions among existing products;
- The amount of producer reformulation to avoid losing market shares;
- The types of ingredient substitutions producers will make to reduce the amount of *trans* fat in their products; and,
- The decrease in CHD that will result from decreased *trans* fat in the diet.

FDA used three specific substitutions

ingredient substitutions for *trans* fat in margarine: (1) 100 percent *cis*-monounsaturated fat, (2) a mixture of 50 percent *cis*-monounsaturated and 50 percent *cis*-polyunsaturated fat, or (3) a mixture of 50 percent *cis*-monounsaturated and 50 percent saturated fat (Ref. 73).

FDA estimated the benefits from the final rule for two methods. The two methods give low and high estimates of the change in CHD risk brought about by changing intakes of *trans* fat. Method 1 assumes that the reduction in CHD risk associated with reduced *trans* fat intakes comes about only through the reduction in LDL-C. Method 2 assumes that the reduction in CHD risk comes about through a combination of reducing LDL-C and increasing HDL-C

Method 2 results in higher benefit estimates than Method 1.

The reduction in CHD risk is highly uncertain primarily because of the difficulties in estimating the amount of reformulation, consumer response, and the reduction in CHD risk due to a decrease in *trans* intake. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD risk associated with the final rule. The low and high estimated benefits can be interpreted as a range of potential effects. When we lacked direct evidence on uncertain values, we dealt with the uncertainty by choosing values that generated lower-bound estimates of benefits. This practice and the evidence in the previous section both imply that the actual realized benefits may exceed the range given by the two methods.

a. *CHD morbidity and mortality prevented.* FDA calculated the benefits from the final rule as the reduction (from the baseline) in CHD multiplied by the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exist in the population. The AHA estimates that 1.1 million heart attack cases of CHD occur annually, with 40 percent of them fatal (Ref. 134). The average years of life lost per fatal case is 13, or 8 years discounted to the present at 7 percent or 11 years discounted to the present at 3 percent. FDA used these estimates as the baseline for the estimated benefits. The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the final rule. FDA used these estimates in the analysis for the proposed rule, and comments on this are discussed in the previous section on changes in health states. FDA estimated the effects using Method 1, which considers changes only in LDL-C, and using Method 2, which considers changes in both LDL-C and HDL-C.

The benefits are expected to begin 3 years after the effective date. The 3-year lag occurs because a dietary change takes several years to begin to affect the CHD risk (Ref. 137). With Method 1, FDA estimated that 3 years after the effective date, the final rule would annually prevent 600 cases of CHD and

would annually save about 1,920 discounted life years (240 deaths x 8 years) using a 7 percent discount rate, or 2,640 discounted life years (240 deaths x 11 years) using a 3 percent discount rate. With Method 2, FDA estimated that 3 years after the effective date, the final rule would annually prevent 1,200 cases of CHD and 480 deaths, saving about 3,840 discounted life years (480 deaths x 8 years) using a 7 percent discount rate, or 5,280 discounted life years (480 deaths x 11 years) using a 3 percent discount rate. Because the association between *trans* fat consumption and CHD through changes in LDL-C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

For nonfatal cases, FDA estimated the cost to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have underestimated the health benefits from preventing nonfatal cases.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event is about \$22,700 and the total annual costs are \$51.1 billion (Ref. 75). If 1.1 million cases lead to \$22,700 per case, then all these cases cost about \$25 billion. The remaining 13.9 million cases average about \$1,900 per year $((\$51.1 \text{ billion} - \$25 \text{ billion}) / 13.9 \text{ million})$. FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by \$100,000 per life year plus the medical costs of \$22,700 plus \$1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about \$282,000 $((0.29 \times \$100,000 \times 8.4) + (\$1,900 \times 8.4) + \$22,700)$.

b. *Value of CHD morbidity and*

Memorandum to the President's Management Council, OIRA Administrator John D. Graham recommended that agencies, when performing benefit cost-analysis, present results using both VSL and VSLY methods. Below we present estimates using both methods. The Memorandum also recommends that agencies present analyses with larger VSLY estimates for senior citizens. Since many of the beneficiaries of this final rule are senior citizens, larger VSLY values than the ones we have used will increase benefits further.

FDA therefore estimates the benefits of this rule using two approaches that reflect different methods used in the economics literature. First, it calculates benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the number of nonfatal cases prevented multiplied by the costs of nonfatal cases, plus the savings in medical costs associated with reductions in nonfatal CHD. Its second calculation is like the first, except that it values reductions in mortality as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death (rather than the extensions to longevity multiplied by the value of increases in life-years gained), and calculates the value of reducing the number of nonfatal cases as simply the savings in medical costs. This section presents these two approaches in turn, beginning with benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the prevented costs of nonfatal cases and medical costs.

Under the first approach, FDA estimated the costs of nonfatal cases to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years (discounted at 7 percent) and 10.6 discounted years (discounted at 3 percent). FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably

underestimated the health benefits from preventing nonfatal cases.

There are also medical costs for nonfatal cases of CHD. The American Heart Association estimates that the cost of a new CHD case is about \$22,700 and the total annual costs are \$51.1 billion (Ref. 75). If 1.1 million cases lead to \$22,700 per case, then all these cases cost about \$25 billion. The remaining 13.9 million cases average about \$1,900 per year ((\$51.1 billion - \$25 billion) / 13.9 million). FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

Under the first approach, the total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by a value per life year plus the medical costs of \$22,700 plus \$1,900 per year times the discounted life years. FDA estimates the morbidity cost per case to be about \$282,000 ((0.29 x \$100,000 x

8.4) + (\$1,900 x 8.4) + \$22,700), assuming a value of \$100,000 per quality-adjusted life year (VSLY).

In the first approach, FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses \$100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 77) use a similar estimate, and Garber and Phelps (Ref. 157) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that \$100,000 per life year is a reasonable estimate, given that median family income in 2002 was about \$51,000 (Ref. 158). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations

implementing the 1990 amendments. FDA received no public comments on that estimate. To reflect other underlying literature, and following suggestions from other Federal agencies, we begin with an estimate of the value of a statistical life (VSL) of \$6.5 million. This estimate is consistent with the survey by Viscusi and Aldy (Ref. 159) on the premium for risk observed in labor markets. Annuitying this value over 35 years at 3 percent and at 7 percent discount rates, as is consistent with OMB guidance, implies estimates of a value of an additional year of life of about \$300,000 and \$500,000. Therefore, table 11a shows estimated benefits for three estimates of VSLYs: \$100,000, \$300,000 and \$500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs.

TABLE 11A.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	Discount Rate	Number of Discounted Life Years Gained		Mortality Related Benefits Estimated In Year 3 After the Effective Date and Annually Thereafter (in millions)		Total Benefits (in millions)	
		Method 1	Method 2	Method 1	Method 2	Method 1	Method 2
\$100,000	7 percent	1,920	3,840	\$192	\$384	\$234	\$477
\$300,000	3 percent	2,640	5,280	\$792	\$1,584	\$968	\$1,973
\$500,000	7 percent	1,920	3,840	\$960	\$1,920	\$1,127	\$2,295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of \$5 million and \$6.5 million. These values represent reasonable central tendencies for a larger range of VSL estimates reported in the literature: \$1 million to \$10 million (Ref. 159). The two values FDA

uses here are also consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks (Refs. 159 and 160). FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Viscusi and Aldy are

relatively low. Table 11B shows the annual benefits estimated in this way for the two different VSLs using both a 3 and 7 percent discount rate. The totals in the final 2 columns of the table are discounted, so direct multiplication of the previous columns does not give the totals in the final columns.

TABLE 11B.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSL and Discount Rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Expected Nonfatal Cases Averted		Total Benefits Estimated in Year 3 After the Effective Date and Annually Thereafter (in millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
\$5,000,000 (3%)	240	480	\$43,000	360	720	\$1,112	\$2,225
\$6,500,000 (3%)			\$43,000			\$1,442	\$2,884
\$5,000,000 (7%)			\$39,000			\$991	\$1,982
\$6,500,000 (7%)			\$39,000			\$1,285	\$2,570

F. Overview of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated

the sources of information used in making these estimates.

1. Summary of Benefits and Costs

Table 12 shows the timing of the discounted benefits and costs estimated

benefits reported in table 12 are based on a VSLY of \$300,000 and a discount rate of 3 percent. The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time

costs as annualized cost over 20 years (discounted at 3 percent), the medium cost estimate in table 12 comes to about \$12 million per year. With Method 1, the cost per life year saved would be about \$4,500 (\$12 million/2,600 life

years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

	Years After Publication	Effective Date						Cumulative Total as of Year 20	
		2	3	4	5	6	7		
Costs									
Low		\$139	none	none	none	none	none	...	\$139
Medium		\$185	none	none	none	none	none	...	\$185
High		\$275	none	none	none	none	none	...	\$275
Benefits									
Method 1	Annual	none	none	none	\$968	\$940	\$913	...	
	Cumulative				\$968	\$1,908	\$2,821	...	\$13,130
Method 2	Annual	none	none	none	\$1,973	\$1,916	\$1,860	...	
	Cumulative				\$1,973	\$3,889	\$5,784	...	\$26,757

2. Summary of Information Sources for the Final Rule on RTI Labeling of Trans Fat
 Table 12A summarizes the data sources, and assumptions used in

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS

Name of Input	Method or Definition Used	Type of Estimate	Source of Data or Assumption
Current trans fat intake	Total intake, 2.55% of energy, intake from hydrogenated fat, 2.03% of energy (table 1 of this document).	FDA's best estimate from available data	USDA trans fat food composition database, (Ref. 40), USDA food group data from CSFII, 1994-96, (Ref. 115)
Adjustment of trans fat intake for current level of margarine reformulation.	0.063% of energy, decrease in current amount of trans fat intake from margarine (table 2 of this document).	FDA's best estimate from available data.	15% decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation.	0.0359% of energy decrease (table 2 of this document)	Low assumption based on uncertainty.	Assume 10% decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice.	0.0019% of energy decrease (table 2 of this document).	Low assumption based on uncertainty.	Assume 0.1% decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.
Overall change in trans fat intake due to labeling.	0.0378% of energy decrease (tables 2 and 10 of this document).	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine	Sum of two previous values.
Number of products to be tested.	154,000 (table 3 of this document)	High estimate based on uncertainty. Includes many products that have already been tested	Main data sources. RTI labeling cost model (Ref. 129) for number of products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing	\$261 to \$371 (table 4 of this document).	Data.	RTI labeling cost model, Ref. 129.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Percent of SKU label changes that can be coordinated with scheduled labeling changes	84% of branded SKUs, 50% of private label SKUs	FDA interpolation of information on 24 and 36 month compliance period proportions	RTI labeling cost model, Ref. 129
Per product category cost of relabeling.	Varies (table 5 of this document)	Data	RTI labeling cost model, Ref. 129.
Number of margarine reformulated.	30 (table 6 of this document).	Low assumption based on uncertainty	Assume 10% of margarine products reformulate
Per product cost of reformulation.	\$440,000 (table 6 of this document).	Data	Industry supplied information (64 FR 62745 at 62782, November 17, 1999)
Overall change in CHD risk per change in trans fat intake	0.147% decrease in CHD risk per 0.1% of energy decrease in trans fat intake Method 1 (table 8 of this document)	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: $-0.1\% \times 1.5 \times 0.7 \times 1.4 = -0.147\%$, decrease in CHD risk
Overall change in CHD risk per change in trans fat intake.	0.287% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 2 (table 8 of this document)	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: $0.1\% \times -0.4 \times -2.5 \times 1.4 = -0.140\%$, decrease in CHD risk due to change in HDL-C. Add to result from Method 1: $-0.147\% + (-0.140\%) = -0.287\%$, decrease in CHD risk, Method 2
Change in LDL-C with change in trans fat intake	-0.1 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document)	Data	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake	-0.1 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document).	Data	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat.	Various coefficients shown in table 9 of this document	FDA's best estimate from available data	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C.	0.7% increase per 1 mg/dL increase in LDL-C (table 8 of this document)	Data.	Published meta-analyses, Refs. 59, 60, and 61.
Changes in CHD risk with changes in HDL-C.	2.5% increase per 1 mg/dL decrease in HDL-C (table 8 of this document)	Data	Published meta-analyses, Refs. 59, 60, and 61
Adjustment for regression dilution.	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (table 8 of this document).	Data.	Published data, Ref. 64.
Overall change in CHD risk due to labeling.	-0.052%, Method 1; -0.106%, Method 2 (table 10 of this document).	Factors above combined with probabilistic model to account for macronutrient substitutions	BetaPERT distribution, using the change in CHD risk for a mixture of 50% cis-monounsaturated and 50% saturated fat as the minimum, the change with 100% cis-monounsaturated fat as intermediate, and the change for a mixture of 50% cis-monounsaturated and 50% cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.

TABLE 12A.—SUMMARY OF INPUTS, DATA SOURCES, AND ASSUMPTIONS—Continued

Name of Input	Value or Distribution Used	Type of Estimate	Source of Data or Assumption
Time lag between effective date of labeling and first health benefits.	3 years (table 10 of this document)	Data.	3 years for serum lipid changes from dietary change Ref. 137
Heart attacks per year.	Mean 1.1 million cases, std dev. 110,000 cases.	Data for mean Assumption for std dev	Published data, Ref. 134
Percent of heart attacks per year that are fatal	40%	Data	Published data, Ref. 134
Life-years saved.	13, or 8.4 years discounted to the present at 7% (table 10 of this document).	FDA's best estimate from available data	Published data, Refs. 75, 76, and 134
Life-years saved	13, or 10.6 years discounted to the present at 3% (table 10 of this document).	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.
Medical Costs saved per non-fatal case	\$39,000 at 7% discount rate, \$43,000 at 3% discount rate (table 11 of this document).	FDA's best estimate from data and life expectancy calculations	Published data, Ref. 134
Value of Statistical Life Year (VSLY)	\$100,000; \$300,000, \$500,000 (table 11 of this document)	Data and FDA's best estimate from available data.	\$100,000 from Refs. 77 and 68, \$300,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 3%; \$500,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 7% (Ref. 153)
Value of Statistical Life (VSL)	\$5 million, \$6.5 million (table 11 of this document).	Data	General VSL literature (see Ref. 153)

C. Peer Review

FDA submitted this economic analysis to the Interagency Economic Peer Review (IEPR) for peer review. The IEPR is a voluntary review process composed of, but not limited to, Federal economists and analysts who review Regulatory Impact Analyses and Regulatory Flexibility Analyses prior to OMB clearance to improve the quality of economic analysis.

Two Federal economists reviewed this analysis. Their specific comments and FDA's responses are detailed in Ref. 155. FDA made the following changes to the analysis in response to the comments of the reviewers:

- Added several sections to repeat information contained in the analysis that accompanied the proposal to provide more background and context for the reader,
- Made some style changes for clarity,
- Added explanations for how some numbers were calculated,
- Added references for the European market experience with margarine reformulation,

- Addressed the comment on costs more explicitly,

- Explained why the costs of reformulation are included in the analysis,

- Added an introduction describing the plan of the benefits model and the linkages between the various parts of the model,

- Corrected our description of study subjects in the 1994–1996 Diet and Health Knowledge Survey (DHKS) in discussing Ref. 119.

X. Final Regulatory Flexibility Analysis

A. Introduction

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this final rule would have a significant economic impact on a substantial number of small entities.

B. Economic Effects on Small Entities

1. Number and Type of Small Entities Affected

FDA used data from the 1999 County Business Patterns (Ref. 136) to estimate the number of small businesses affected by this rule. Table 13 shows the number of small businesses affected by the North American Industry Classification System (NAICS). The final rule will affect almost all manufacturers of packaged, labeled food sold in the United States, with the exception of exempt manufacturers. The criteria for exemption are: (1) Annual sales of fewer than 100,000 units; (2) no claims or other nutrition information on product labels, labeling, or advertising; (3) fewer than 100 full-time employees; and (4) filing of a notice with the Office of Food Labeling (§ 101.9(j)(18) 2002). FDA has previously estimated that the exemption for all foods would affect about 1.8 percent of FDA regulated foods by volume (see 58 FR 2927 at 2928, January 6, 1993). FDA estimated the effects of exemptions only for the total costs to small businesses.

TABLE 13.—NUMBER OF SMALL ESTABLISHMENTS BY NAICS CODE

Category Description	NAICS Code	No of Establishments
Rice	311212	60
Refined or Blended Fats and Oils	311225	140
Breakfast Cereals and Related Products	311230	60
Chocolate and Confectionery Products Made from Cacao Beans	311320	150
Nonchocolate Confectionery Products	311340	590
Frozen Fruits and Vegetables	311411	230
Frozen Specialties, NEC	311412	380
Specialty Canned Food	311422	140
Dried and Dehydrated Foods	311423	180
Fluid Milk	311511	570
Creamery Butter	311512	30
Cheese	311513	520
Dry, Condensed and Evaporated Milk	311514	210
Ice Cream and Frozen Desserts	311520	420
Fresh and Frozen Seafood	311712	660
Canned and Specialty Products	311812	2760
Frozen Bakery Products	311813	230
Cookies and Crackers	311821	390
Flour Mixes and Dough Made from Purchased Powder	311822	230
Other Snack Foods	311919	400
Mayonnaise, Dressings and Other Prepared Sauces	311941	340
Spices and Extracts	311942	280
Perishable Prepared Food	311991	480
All Other Miscellaneous Food Preparations	311999	850
Pharmaceutical Preparations (NAICS classification for dietary supplements)	325412	880
Total		11,180

2. Costs to Small Entities

FDA calculated the costs to small businesses with the same basic model that we used in section IX.D of this document to estimate the total costs. Although the basic model is the same for large and small firms, the individual components of costs differ for large and small firms. On average, small firms produce fewer products, and market fewer labels. FDA assumes that the estimated margarine reformulation will be done by large producers.

FDA estimated the total costs of the final rule to small business by estimating the individual categories of costs and summing them. The first category is testing costs. Small businesses would need to test their products to determine the amounts of *trans* fats. FDA did not have direct estimates of the number of products produced by the small businesses affected by the final rule. FDA estimated the number of products produced by small businesses by using a sample from

the Enhanced Establishment Database (EED) and assuming that the proportion of all products produced by small businesses was the same as the sample proportion (85 percent). FDA then multiplied the 60,000 products estimated to be tested (table 3 of this document) by the proportion of products produced by small businesses (85 percent) to estimate that 51,000 products will be tested by small businesses. Table 14 shows the range of testing costs for all small businesses.

TABLE 14.—RANGE OF PER PRODUCT AND TOTAL TESTING COSTS FOR SMALL BUSINESSES

	Low	Medium	High
Cost per Product	\$261	\$291	\$371
Total Testing Cost	\$13,311,000	\$14,841,000	\$18,921,000

Under this final rule many more labels will have to be changed than under the proposed rule. FDA has used the new Labeling Cost Model to re-estimate the relabeling costs of this final rule. FDA estimated reprinting costs for information panels on a per label (SKU) basis. FDA assumed that the proportion

of SKUs from small businesses as a whole equaled the proportion in the EED (73 percent). Across product categories the average low relabeling cost per SKU is about \$1,100 and the average high relabeling cost per SKU is \$2,600. The reported estimated costs of changing labels varies within a product

category because different packaging converters and food manufacturers reported different costs to RTI International. Table 15 shows the total estimated costs of relabeling per product category and for all small businesses affected.

TABLE 15.—RANGE OF RELABELING COSTS FOR SMALL BUSINESSES BY PRODUCT CATEGORY

Product Categories	SKUs Changed	Low	Medium	High
Baked Goods	9,100	\$7,987,000	\$11,870,000	\$19,879,000
Baking Ingredients	1,200	\$1,179,000	\$1,737,000	\$2,846,000
Baby Foods	100	\$120,000	\$182,000	\$295,000
Selected Beverages	6,600	\$8,666,000	\$12,161,000	\$18,560,000
Breakfast Foods	700	\$585,000	\$903,000	\$1,492,000
Selected Candy	3,000	\$3,505,000	\$5,091,000	\$7,819,000
Selected Condiments, Dips and Spreads	2,700	\$2,939,000	\$4,358,000	\$6,777,000
Dairy Foods	6,400	\$7,843,000	\$11,698,000	\$18,273,000
Desserts	2,600	\$2,016,000	\$3,112,000	\$5,141,000
Dietary Supplements	5,900	\$9,818,000	\$14,680,000	\$24,850,000
Selected Dressings and Sauces	2,000	\$2,123,000	\$3,177,000	\$4,933,000
Eggs	1,800	\$1,448,000	\$2,114,000	\$3,713,000
Entrees	1,800	\$1,469,000	\$2,247,000	\$3,673,000
Fats and Oils	600	\$554,000	\$847,000	\$1,349,000
Fruits and Vegetables	5,500	\$5,421,000	\$7,968,000	\$13,054,000
Seafood	1,000	\$1,264,000	\$1,855,000	\$2,764,000
Side Dishes and Starches	3,000	\$2,454,000	\$3,741,000	\$6,201,000
Snack Foods	2,600	\$2,631,000	\$3,860,000	\$6,204,000
Soups	500	\$591,000	\$872,000	\$1,353,000
Weight Control Foods	100	\$143,000	\$207,000	\$357,000
Total	57,200	\$62,754,000	\$92,590,000	\$149,640,000

Table 16 of this document shows the total costs to small businesses of the final rule. The adjusted total costs of the

final rule equal the unadjusted total minus 1.8 percent of the total cost of the rule to all businesses (see 58 FR 2927 at

2928, January 6, 1993). The average cost per small business is about \$12,000.

TABLE 16.—TOTAL COSTS FOR SMALL BUSINESSES

Cost Category	Low	Medium	High
Testing	\$34,713,000	\$38,703,000	\$49,343,000
Relabeling	\$62,754,000	\$92,590,000	\$137,891,000
Total	\$97,467,000	\$131,293,000	\$187,234,000
Adjustment for Exemption	-\$1,754,000	-\$2,363,000	-\$3,370,000
Adjusted Total	\$96,000,000	\$129,000,000	\$195,000,000

FDA has attempted to place the burden that these costs will place on small businesses in the context of the entire environment in which small businesses exist. Eastern Research Group under contract with FDA has developed a model for estimating the impact of regulatory costs on the survival of small businesses. (Reference: Eastern Research Group, "Model for Estimating the Impacts of Regulatory Costs on the Survival of Small

Businesses and Its Applications to Four FDA-Regulated Industries," 2002.) This model does not cover the entire range of products covered by this final rule, so it is not possible to estimate the burden of this rule. However, table 16a gives a sense of the impact that this rule may have on three industry categories that have many small businesses. The model estimates the additional number of small businesses that will have negative cash flow as a result of the costs of

complying with a regulation. These estimates are likely to be larger than the actual effects because the model is neither able to take into account the exemption from nutrition labeling that is available to some small businesses, nor can it take into account the compliance period of over 2 years which allows small businesses to budget and plan ahead for the expense of the label change.

TABLE 16A.—ILLUSTRATIONS OF IMPACTS ON SMALL BUSINESS

Product Category	NAICS Code	Total Number of Small Businesses	Average Number SKUs Changed Early per Firm	Range of Cost per Firm	Standard Number of Small Businesses Lost Regardless of Regulation	Additional Small Businesses Lost Due to Compliance Costs of This Rule
Nonchocolate Confectionery Products	311340	590	6	\$8,700–\$18,100	30–80	0–30
Cheese	311513	520	6	\$7,500–\$16,300	40–90	0–20
Commercial Bakery Products	311812	2,760	4	\$4,200–\$9,800	560	10–60

C. Regulatory Options

The Regulatory Flexibility Act requires that FDA consider options for regulatory relief for small entities.

1. Exemption for Small Businesses

The exemption of small businesses from the provisions of the final rule would provide regulatory relief. Table 16 of this document shows that small businesses are expected to bear total costs of about \$130 million as a result of the final rule, an average of \$12,000 per small business. As a first approximation, then, exempting small businesses would reduce the burden by an average of \$12,000 per small business.

FDA believes that this option would not be desirable. On the one hand, because so many of the businesses in the food processing industry are classified as small by the Small Business Administration, if small businesses are exempted, most of the

would not be realized. On the other hand, exempt businesses may be forced by market pressures to adopt the final label in any case. In addition, under section 403(q)(5)(E) of the act and implementing regulations, very small producers (those with fewer than 100 full-time employees) that: (1) File a notice with the Office of Nutritional Products, Labeling, and Dietary Supplements; (2) make very low volume products (fewer than 100,000 units annually); and (3) place no claims or other nutrition information on product labels, labeling, or advertising would already be exempt from this final rule.

2. Longer Compliance Period for Small Businesses

Longer compliance periods provide regulatory relief for small businesses. Some comments requested that the compliance period be extended several years (e.g., 4 to 7 years) for small businesses. These comments stated that

be able to phase in the cost associated with the new label requirements so that they have extra time to absorb the costs of these changes. Some small manufacturers reported that they have significant inventories of labels. Also, smaller manufacturers indicated that they would incur costs, including, loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates. These small businesses believe that a longer compliance period would allow them to more easily manage their inventories and phase in the *trans* fat labeling requirements along with other scheduled labeling revisions. This will help minimize unnecessary labeling costs and costs passed on to consumers.

To minimize the need for multiple labeling changes and to provide additional time for compliance by small businesses to allow them to use current label inventories and phase in label changes, the agency is setting the

next uniform effective date following publication of this rule. This allows firms more than 2 years to implement this final rule providing some regulatory relief and economic savings for small businesses. This should be long enough for most small businesses to coordinate the label change for this rule with other label changes and reprinting. However, in this final rule, FDA has decided not to extend the compliance period for small businesses beyond what is given for all businesses. Because this final rule does not affect nutrient content or health claims, no small businesses will have to change the principal display panels or marketing of their products, which could be very costly.

With small businesses producing 85 percent of the products and 73 percent of the SKUs, extending the compliance period for small businesses to the uniform effective date after January 1, 2006, would leave most labels not listing *trans* fat for almost 5 years after publication. This could result in significant confusion for consumers looking for *trans* fat content on labels and would make the Nutrition Facts panel inconsistent across product categories. The new labeling would be contrary to the intent of the 1990 amendments. It also would undermine the policy goal of providing consistent nutrition information to consumers. Also, extending the effective date for products containing *trans* fat would delay the benefits of this rule to the public health.

3. Exemptions for Small Entities

FDA has chosen not to exempt small entities because consumption of *trans* fat results in consequences to the consumer. Consumers may increase or decrease their risk of CHD based on the level of *trans* fat in their diets. Thus, the presence or absence of *trans* fat in a food product is a material fact under section 201(n) of the act.

Consumers must know the amount of *trans* fat in food products that they select as part of their total daily diet to choose products that would allow them to reduce their intake of *trans* fat, and thus, reduce the risk of CHD. Section IV of this document discusses the scientific evidence for why *trans* fat consumption places consumers at risk for CHD. Absent mandatory labeling, consumers would not be able to understand the relative contribution that foods make to their total daily intake of *trans* fat. First, because polyunsaturated and monounsaturated fats are not subject to mandatory labeling, simply including *trans* fat as part of the total fat contribution would not allow

content by finding the difference between the sum total of all the mandatory fats listed on the label and the total fat content. Second, even if all component fats were required to be listed, it would not be realistic to expect consumers to do such calculations on each product to compare the relative *trans* fat contribution of each. Further, the fact that an individual food product may contain zero gram *trans* fat, and thus, not contain a level of *trans* fat that would contribute to CHD risk, does not prevent the absence of that fact on the label to no longer be considered a "material fact" for that food. In the context of mandatory labeling of nutrients in a nutrition facts panel, the relative contribution of various food products to the total day's consumption of a heart unhealthy fat is important for consumers "to readily observe and comprehend the information and to understand the relative significance of that information in the context of the total daily diet" (section 2(b)(1)(A) of Public Law 101-535).

Further, section 403(q)(2)(A) of the act provides that mandatory labeling would be appropriate when information about a nutrient would assist consumers to maintain healthy dietary practices. Information on the *trans* fat content of food would assist consumers in this way. Consumers need the information on *trans* fat content of all foods that they consume so that they can reduce their intake of *trans* fat. The fact that a food may have no *trans* fat or a small amount of *trans* fat is useful information to the consumer so that food choices can be made and the consumer can put that product, along with many other products consumed as part of the daily diet, into the context of the total daily diet to maintain healthy dietary practices. There is ample discussion in section IV of this document about the heart unhealthy effects of consuming *trans* fat and strong consensus among the scientific community for reducing *trans* fat intake.

Survey data show that consumers rely on the Nutrition Facts label as a guide to choosing foods that meet their dietary objectives. As consumers learn more about the dietary significance of *trans* fat and the dietary advice to limit its consumption, the Nutrition Facts panel is where label users will expect to find this information. If they cannot find information on *trans* fat content there or if it is only there when claims are made about fatty acids or cholesterol, they will be hampered in their ability to implement the most recent dietary guidance, and are likely to be misled

Consumers need the *trans* fat information on products in order to determine how each product fits into their individual health goal for reducing *trans* fat intake in the context of their total daily diet. Thus, the agency is requiring *trans* fat labeling, regardless of whether claims are made or the levels of other fats are declared, to prevent products from being misleading under sections 403(a)(1) and 201(n) of the act. Therefore, as described in section III of this document, in this rulemaking FDA is relying on its authority under those sections as well as its authority under section 403(q)(2)(A) of the act to require that information on *trans* fat be included in nutrition labeling to assist consumers in maintaining healthy dietary practices. Not requiring such information on labels, whether or not voluntary nutrients are listed or claims are made about fatty acids or cholesterol, would be inconsistent with statutory directives for nutrition labeling in section 403(q) of the act.

Furthermore, the benefits of covering products made by small businesses exceed the costs that would be saved by exempting them. The medium estimated benefit to small businesses is a one time cost of \$129 million dollars (table 16). If we assume no benefits from small businesses reformulating, then the benefits associated only with changing labels on all food products is \$48 million per year using Method 1 (\$99 million using Method 2). If small businesses produce at least 22 percent of food consumed annually, then benefits of covering products made by small businesses will exceed the costs that would be saved by exempting them after 20 years discounted at 3 percent. Using Method 2 for calculating benefits, small businesses would only need to account for production of at least 11 percent of food consumed. Since the Small Business Administration definition of small business includes the vast majority of food firms, products, and SKUs, even the 22 percent amount is quite plausible.

D. Recordkeeping and Reporting Requirements

The Regulatory Flexibility Act requires FDA to include a description of the recordkeeping and reporting required for compliance with this final rule. This final rule does not require the preparation of a report or a record.

E. Summary

FDA finds that under the Regulatory Flexibility Act (5 U.S.C. 605(b)) this final rule will have a significant economic impact on a substantial

10,300 small businesses could be affected by the rule. The total burden on small entities is estimated to be between \$96 and \$184 million, or about \$9,300 to \$17,900 per entity.

XI. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses for rules that would cost more than \$100 million in 1 single year. The final rule qualifies as a significant rule under the statute. FDA has carried out the cost-benefit analysis in sections IX.C and IX.D of this document. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following:

1. Future costs;
2. Particular regions, communities, or industrial sectors;
3. National productivity and economic growth;
4. Full employment and job creation; and,
5. Exports.

A. Future Costs

Most of the costs of this rule will be incurred during the compliance period. Future costs beyond that period would likely be small, because the food industry would have adjusted to the new requirements by that time.

B. Particular Regions, Communities, or Industrial Sectors

The final rule applies to the food industry and would, therefore, affect that industry disproportionately. Any long run increase in the costs of food production would largely be passed on to the entire population of consumers.

C. National Productivity and Economic Growth

The final rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the food industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, FDA anticipates that, because the health benefits are estimated to be significant, both productivity and economic growth would be higher than in the absence of

the rule. In section IX.C.3 of this document, FDA estimated benefits from the reduction in functional disability associated with a reduction in nonfatal CHD. A reduction of functional disability would result in an increase in productivity. The increased health of the population and the reduction in direct and indirect health costs could increase both productivity and economic growth.

D. Full Employment and Job Creation

The human resources devoted to producing certain foods would be redirected by the final rule. The final rule could lead to some short-run unemployment as a result of the structural changes within the food industry, the rise of some product lines and decline of others. The growth of employment (job creation) could also be temporarily slower.

E. Exports

Because the final rule does not mandate any changes in products, current export products will not be required to change in any way. Food processors, however, do not necessarily distinguish between production for export and production for the domestic market. The effect of the final rule on U.S. food exports depends on how foreign consumers react to information about *trans* fats and to product formulations that contain lower amounts of partially hydrogenated oils. The new label and possible new formulations could either increase or decrease exports. Products in Germany and certain other European countries, for example, currently use partially hydrogenated oils to a lesser degree than in the United States, so the final rule could make U.S. exports of margarine more attractive to consumers in those countries than they have been. However, it could also make U.S. exports of unrefined products that reveal the presence of *trans* fat less attractive to consumers in those countries than they have been.

XII. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 62746, November 17, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no

significant impact on the human environment and that an environmental impact statement is not required.

XIII. Paperwork Reduction Act

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling; *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims and Health Claims.

Description: Section 403(q)(1)(A) and (q)(1)(B) of the act requires that the label or labeling of a food bear nutrition information on the amount of nutrients present in the product. Under these provisions of the act and section 2(b) of the 1990 amendments, FDA has issued regulations in § 101.9(c)(2) that require that the Nutrition Facts panel disclose information on the amounts of fat and certain fatty acids in the food product. This final rule establishes § 101.9(c)(2)(ii) to require that the Nutrition Facts panel disclose information on the amount of *trans* fat in the food product. Similarly, under the provisions of section 403(q)(5)(F) of the act, FDA has issued regulations in § 101.36(b)(2) that specify the nutrition information that must be on the label or labeling of dietary supplements. This final rule establishes § 101.36(b)(2) (21 CFR 101.36(b)(2)) to specify that when nutrition information is declared on the label and in labeling, it must include the amount of *trans* fat.

The regulations set forth in this final rule 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 fat.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 17.—ESTIMATED REPORTING BURDEN¹

21 CFR Section	No of Respondents	Responses per Respondent	Total No of Responses	Hours per Response	Total Hours	Operating Costs (in thousands)
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	\$155,200
101.36(b)(2)	910	32	29,500	2	59,000	\$16,500
Totals					615,200	\$171,700

¹ There are no capital costs and or maintenance costs associated with this collection of information

The impact of these requirements concerning *trans* fatty acids would be largely a one-time burden created by the need for firms to revise food and dietary supplement labels. FDA used data from the 1999 County Business Patterns to estimate the number of respondents. The total number of responses is equal to the total number of SKUs being changed (table 3 of this document). Based upon its knowledge of food and dietary supplement labeling, FDA estimates that firms would require less than 2 hours per SKU (hours per response) to comply with the nutrition labeling requirements in this final rule. The 2 hours per SKU estimate is based on assumptions about the amount of time required per SKU to test a product for *trans* fat, to redesign the label as needed, and to order the change for the label. FDA received no comments objecting to this estimate.

Multiplying the total number of responses by the hours per response gives the total hours. FDA has estimated operating costs by combining the medium testing and relabeling costs from table 7 of this document (\$44.9 million + \$126.8 million for relabeling) to get the total operating cost. This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expects that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by this final rule with other planned labeling changes for their products.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

XIV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Section 403A of the act (21 U.S.C. 343-1) is an express preemption provision. That section provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce * * * certain food labeling requirements, unless an exemption is provided by the Secretary (and, by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is "any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * * " (act section 403A(a)(4), 21 U.S.C. 343-1(a)(4)). Prior to the effective date of this rule, this provision operated to preempt States from imposing nutrition labeling requirements concerning *trans* fat because no such requirements had been imposed by FDA under section 403(q) of the act. Once this rule becomes effective, States will be preempted from imposing any nutritional labeling requirements for *trans* fat that are not identical to those required by this rule.

Section 403A(a)(4) of the act (21 U.S.C. 343-1(a)(4)) displaces both state legislative requirements and state common-law duties. *Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cippollone v. Liggett*

(plurality opinion); *id.* at 548-49 (Scalia, J., joined by Thomas, J., concurring in part in the judgment and dissenting in part). Although this rule has preemptive effect in that it would preclude States from adopting statutes, issuing regulations, or adopting or enforcing any requirements that are not identical to the *trans* fat labeling required by this final rule, including State tort-law imposed requirements, this preemptive effect is consistent with what Congress set forth in section 403(A) of the act.

Section 4(c) of the Executive order further requires that any "regulatory preemption of State Law shall be restricted to the minimum level necessary" to achieve the regulatory objective. The agency is exercising its discretion under section 403(q)(2)(A) of the act, in a manner that is consistent with such section, to require that the amount of *trans* fat be listed in the label or labeling of food. This action is the minimum level necessary to achieve the agency regulatory objective. Further, section 4(e) of the Executive order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." FDA sought input from all stakeholders through publication of the proposed rule in the **Federal Register**. Eight comments from State and local governmental entities were received; all supported the proposal. In addition, one supportive comment was received from a municipal health agency in response to the reopening of the comment period relating to the proposed footnote.

In conclusion, FDA has determined that the preemptive effects of the final rule are consistent with Executive Order 13132.

XV. References

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List of Subjects in 21 CFR 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.9 is amended by:
 a. Redesignating paragraphs (c)(2)(ii) and (c)(2)(iii) as (c)(2)(iii) and (c)(2)(iv),
 b. Adding new paragraph (c)(2)(ii),

c. Revising paragraphs (c)(2)(i), (d)(1)(ii)(A), the first sentence of paragraph (f), the first sentence of paragraph (g)(5), the second sentence of paragraph (g)(6), and the sample labels in paragraphs (d)(11)(iii), (d)(12), (d)(13)(ii), (e)(5), (j)(13)(ii)(A)(1), and (j)(13)(ii)(A)(2).

The revisions and additions are to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(2) * * *

(i) "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid, or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a significant source of saturated fat is

declared, the statement "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 gram (1/2) gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) "*Trans* fat" or "*Trans*": A statement of the number of grams of *trans* fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration, except that label declaration of *trans* fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat, fatty acid or cholesterol content. The word "*trans*" may be italicized to indicate its Latin origin. *Trans* fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero. Except as provided for in paragraph (f) of this section, if a statement of the *trans* fat content is not required and, as a result, not declared, the product shall not be considered a

of *trans* fat" shall be placed at the bottom of the table of nutrient values.

(d)(1) * * *
(ii) * * *

(A) Except as provided for in paragraph (c)(2)(ii) of this section, a single easy-to-read type style,

* * * * *

(11) * * *
(iii) * * *

Nutrition Facts	Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
	Total Fat 1.5g		2%	Total Carbohydrate 26g
Saturated Fat 0.5g		3%	Dietary Fiber 2g	8%
Trans Fat 0.5g			Sugars 1g	
Cholesterol 0mg		0%	Protein 4g	
Sodium 280mg		12%		
Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 6%				
Thiamin 15% • Riboflavin 8% • Niacin 10%				

Serving Size 2 slices (56g)
Servings Per Container 10

Calories 140
Calories from Fat 15

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

(12) * * *

Nutrition Facts	
Serving Size 1 cup (228g)	
Servings Per Container 2	
Amount Per Serving	
Calories 260	Calories from Fat 120
% Daily Value*	
Trans Fat 2g	
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A 4% • Vitamin C 2%	
Calcium 15% • Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

(13) * * *
(ii) * * *

Nutrition Facts	Wheat Squares Sweetened	Corn Flakes Not Sweetened	Mixed Grain Flakes Sweetened
	Serving Size 1 Box Servings Per Container	(35g) 1	(19g) 1
Amount Per Serving			
Calories	130	70	100
Calories from Fat	0	0	0
	% Daily Value*	% Daily Value*	% Daily Value*
Total Fat	0g 0%	0g 0%	0g 0%
Saturated Fat	0g 0%	0g 0%	0g 0%
Trans Fat	0g	0g	0g
Cholesterol	0mg 0%	0mg 0%	0mg 0%
Sodium	0mg 0%	200mg 8%	120mg 5%
Potassium	125mg 4%	25mg 1%	30mg 1%
Total Carbohydrate	29g 10%	17g 6%	24g 8%
Dietary Fiber	3g 12%	1g 4%	1g 4%
Sugars	8g	6g	13g
Protein	4g	1g	1g
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.	Vitamin A 0%	10%	10%
	Vitamin C 0%	15%	90%
	Calcium 0%	0%	0%
	Iron 10%	6%	20%
	Thiamin 30%	15%	20%
	Riboflavin 30%	15%	20%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Total Fat	Less than 65g	65g
Saturated Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Potassium	3,500mg	3,500mg

* * * * *
 (e) * * *
 (5) * * *

Nutrition Facts		
Serving Size 1/12 package (44g, about 1/4 cup dry mix) Servings Per Container 12		
Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
% Daily Value**		
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Trans Fat 1g		
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

**Percent Daily Values are based on a diet of other people's misdeeds.

	2,000	2,500
Total Fat	65g	80g
Sat Fat	20g	25g
Cholesterol	300mg	300mg
Sodium	2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron: * * *

* * * * *
 (g) * * *

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. * * *

(6) * * * Reasonable deficiencies of calories, sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

* * * * *
 (i)
 (13) * * *
 (ii) * * *
 (A) * * *
 (I) * * *

Nutrition Facts			
Amount/serving	%DV*	Amount/serving	%DV*
Total Fat 2g	3%	Total Carb. 0g	0%
Sat. Fat 1g	5%	Fiber 0g	0%
Trans Fat 0.5g		Sugars 0g	
Cholest. 10mg	3%	Protein 17g	
Sodium 200mg	8%		
Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%			

Serving Size 1/3 cup (56g)
 Servings about 3
Calories 90
 Fat Cal. 20

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

(2) * * *

Nutrition Facts	
Serv. Size: 1 package, Amount Per Serving:	
Calories 45, Fat Cal. 10, Total Fat 1g (2% DV), Sat. Fat 0.5g (3% DV), <i>Trans</i> Fat 0.5g, Cholest. 0mg (0% DV), Sodium 50mg (2% DV), Total Carb. 8g (3% DV), Fiber 1g (4% DV), Sugars 4g, Protein 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium (0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet.	

* * * * *

■ 3. Section 101.36 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * * * *
 (h) * * *

(2) * * *

(i) The (b)(2)-dietary ingredients to be declared, that is total calories, calories from fat, total fat, saturated fat, *trans* fat,

cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in

nutrition labeling of foods in accordance with § 101.9(c) of this part. * * *

Appendix B to Part 101—Graphic Enhancements Used by the FDA

■ 4. Appendix B to Part 101 is amended by revising the sample label following the list of examples to read as follows:

Examples of Graphic Enhancements used by the FDA

Helvetica Regular 8 point with 1 point of leading

3 point rule

8 point Helvetica Black with 4 points of leading

1/4 point rule centered between nutrients (2 points leading above and 2 points below)

8 point Helvetica Regular with 4 points of leading

8 point Helvetica Regular, 4 points of leading with 10 point bullets.

Nutrition Facts	
Serving Size 1 cup (228g) Serving Per Container 2	
Amount Per Serving	
Calories 260	Calories from Fat 120
% Daily Values	
Total Fat 13g	20%
Saturated Fat 5g	25%
Trans Fat 2g	
Cholesterol 30mg	10%
Sodium 660mg	28%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A 4%	Vitamin C 2%
Calcium 15%	Iron 4%
*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:	
	Calories: 2,000 2,500
Total Fat	Less than 65g 80g
Sat Fat	Less than 20g 25g
Cholesterol	Less than 300mg 300mg
Sodium	Less than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g

Franklin Gothic Heavy or Helvetica Black, flush left & flush right, no smaller than 13 point

7 point rule

6 point Helvetica Black

All labels enclosed by 1/2 point box rule within 3 points of text measure

1/4 point rule

Type below vitamins and minerals (footnotes) is 6 point with 1 point of leading

Dated: May 7, 2003.
Mark B. McClellan,
Commissioner of Food and Drugs.

Dated: July 2, 2003.
Tommy G. Thompson,
Secretary of Health and Human Services.
[FR Doc. 03-17525 Filed 7-9-03; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 03N-0076]

RIN 0910-AC50

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* fatty acids (*trans* fat); to establish qualifying criteria for *trans* fat in current nutrient content claims for saturated fatty acids (saturated fat) and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria 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* fat be declared in the nutrition label of conventional foods and dietary supplements on a separate line under the line for the declaration of saturated fat.

DATES: Submit written or electronic comments by October 9, 2003.

ADDRESSES: Submit written or electronic comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 Pkwy., 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* fat present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fat 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 (l) 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* fat, like saturated fat, has 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/NAS 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 fat, there is "a positive linear trend" between *trans* fat intake and low density lipoprotein-cholesterol (LDL-C) concentration, and therefore increased risk of CHD (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 ed.) (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* fat 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 document 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 "zero" *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 consumer surveys that suggest the proposed footnote statement may lead 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* fat is unavoidable in ordinary diets. Moreover, the report states that eliminating them from an ordinary 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 exclusion of the other(s).

Comments also raised concerns about the absence of consumer studies to determine how the proposed footnote would be perceived. As noted previously, 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 fat 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 concluded 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 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 support the establishment of a DRV for *trans* fat. 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 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 Institutes of Health) (Ref. 5) that stated that saturated fat 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., 2,000 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* fat is unavoidable in ordinary, nonvegan 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, 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 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. If a company wants to make a statement about the fat content of a product that is demonstrably true, balanced, adequately substantiated, and not misleading, FDA would have to consider the exercise of its enforcement discretion.

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 lipids, 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 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 lipids. 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 *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; and
- Nutritionally adequate diets include diets low in saturated fat, *trans* fat, and cholesterol.

Other footnote statements may also be considered.

In particular, we are interested in 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 and whether they are: (1) Seen as credible, (2) understood as statements of dietary guidance or as product warning statements, or (3) 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 information, other than claims or a footnote or disclosure statement, that FDA should consider requiring 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 a potentially unhealthful substitution where a product lists fewer grams of *trans* fat, but lists more grams of saturated fat and reports 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 encourage more 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 references have been placed on display in the Division of

Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday, except on Federal government holidays. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

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: <http://www.health.gov>).

3. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management 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: June 26, 2003.

Mark B. McClellan,
Commissioner of Food and Drugs.

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