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Food and Drug Administration

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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acid limits are placed on nutrient content claims, health claims, and disclosure and disqualifying levels are being withdrawn.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.

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

A. Nutrition Labeling

B. Nutrient Content and Health Claims

C. Comments

II. Highlights of the Final Rule

III. Legal Authority

A. Statutory Authority

B. The First Amendment

IV. Review of the Science

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

B. Published Studies

V. Nutrition Labeling of *Trans* Fat

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

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

of *Trans* Fat

C. Definition of *Trans* Fatty Acids

D. Methodology

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

VII. Other Issues

VIII. Effective Date

IX. Final Regulatory Impact Analysis

A. The Current Situation and the Need for This Regulation

B. Regulatory Alternatives

C. Changes Resulting From This Rule

X. Final Regulatory Flexibility Analysis

A. Introduction

B. Economic Effects on Small Entities

C. Regulatory Options

D. Recordkeeping and Reporting Requirements

E. Summary

XI. Unfunded Mandates

A. Future Costs

B. Particular Regions, Communities, or Industrial Sectors

C. National Productivity and Economic Growth

D. Full Employment and Job Creation

E. Exports

XII. Environmental Impact

XIII. Paperwork Reduction Act

XIV. Federalism

XV. References

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; eference 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 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 reproposed. 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 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 voluntary 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

[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 '01(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.

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 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

[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.

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, 484–85 (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 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 (*Glastetter* 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." *Glastetter*, 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, although not as much 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 incidence. (Ref. 89, p. V–15).

Based on these conclusions, the Expert Panel recommended for individuals at increased risk for CHD that:

Intakes of *trans* fatty acids should be kept low. The use of liquid vegetable oil, soft margarine, and *trans* fatty acid-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 persons at increased risk for CHD whose LDL–C is above goal levels (Ref. 89).

(Comment 1) Several comments on the November 1999 proposal questioned 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* fat have health benefits, at least in comparison to saturated fatty acids. Several other comments stated that *trans* fats displace saturated fats in the diet, thus implying that they are healthful alternatives to saturated fats.

FDA disagrees with the comments' conclusions that the recommendations of the AHA and other scientific bodies that margarine be substituted for butter provides a basis for concluding that *trans* fat has health benefits or is a healthier choice than saturated fats. The recently updated 2000 AHA Guidelines (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 fatty acids.

It should be noted that recommendations to consume margarine instead of butter are based on the fact that the combined amount of cholesterol-raising lipids (*trans* and saturated fats) are lower in margarines than in butter (Ref. 92). Additionally, butter, unlike margarine, contains dietary cholesterol which also has cholesterol-raising effects (Ref. 139).

B. Published Studies

To evaluate the evidence that dietary *trans* fat increases the risk of CHD, 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 62799–62821).

In the November 1999 proposal, FDA also reviewed nine publications that examined associations between *trans* fatty acids, serum lipids and CHD

endpoints: Four publications describing three prospective cohort studies (Refs. 19 through 21 and 38), one publication describing an inter-cohort study (Ref. 22), three publications describing case control studies (Refs. 16 through 18), and one publication describing a cross-sectional study (Ref. 23). FDA stated that these epidemiological investigations of associations 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. 18) and 3.4 g/day for men in another (Ref. 23). Some studies presented mean or median intakes for quintiles of the population studied. Median intakes 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. 18). 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. FDA has addressed this study in Comment 4 of this document.

(Comment 3) Many comments discussed the strength of 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 strong and supportive of *trans* fatty acid 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 observational studies) consistently show that *trans* fat intakes adversely affect CHD risk under both controlled trial conditions and in free-living populations following their usual dietary patterns. This consistency was seen across studies done: (1) In the United

States and several European countries, (2) using a variety of test and control products and study designs, (3) using a range of intake levels for *trans* fatty acids (less than (<) 1 percent to 7 percent of calories), (4) by different investigators and research groups, (5) with different populations and selection/exclusion criteria, 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 diary 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. In response to the 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 only information that the IOM/NAS relied on to conclude that *trans* fatty acid consumption should be as low as possible relative to CHD risk. Moreover, FDA did not find the LDL/HDL cholesterol ratio used in the Ascherio et al. analysis to be a useful endpoint for purposes of the *trans* fatty acid rule-making (see Comment 10). Additionally, 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 serum 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 support of this conclusion to be sufficiently compelling to now warrant *trans* fatty acid labeling.

(Comment 4) Several comments stated that a new observational study by van de Vijver et al., "Association between *trans* fatty acid intake and cardiovascular risk factors in Europe: The *trans*FAIR Study" (Ref. 93) showed 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 *trans*FAIR 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 *trans*FAIR 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 *trans*FAIR 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 *trans*FAIR study indicates that average *trans* fat intake in the United States is probably not detrimental to human health.

(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 current data are insufficient in regard to the *trans* fatty acid content

of foods. One comment noted that USDA's data for the *trans* fatty acid content of foods are limited to a few foods with a small number of samples. Thus, the comment concluded that extrapolation of *trans* fatty acid content from a few foods must be used to estimate the content of *trans* fat in the large number of foods that make up the total 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 also approximately 265 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 data are likely significantly under-reported, particularly when expressed on a gram per day basis.

The second type of *trans* fatty acid intake estimate considered in the November 1999 proposal was derived from estimates of *trans* fatty acids available in the U.S. food supply calculated from USDA-Economic 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 trials. It is important to note, however, that the agency's determination of the scientific basis for 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 trials most heavily. The intervention trials clearly demonstrate, 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 that contained 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 had *trans* fat intakes that ranged from very low levels (less than 1 percent of calories) to intakes up to 6 to

7 percent of calories and on findings from observational studies that showed an adverse relationship between *trans* fat intakes and CHD risk among U.S. population groups 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 of 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 (88 percent) had mean HDL–C levels in the range of 41 to 59 mg/dL. Also, 73 percent of the population was in the age group where the CHD risk is lower, e.g., men <45 years of age and women <55 years of age. The study populations were described as participants who had normal cardiac, 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 through 13, and 34). The study designs also varied significantly in how they identified controls for the comparisons of interest. Despite these differences in objectives and study design, the general consistency across studies in finding that *trans* intakes are adversely related to CHD risk provides evidence 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 comparison diet. In the dietary intervention research reviewed, the study investigators used a variety of 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. The best study 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 the same percent of calories from *cis*-monounsaturated fatty acids, was predicted to increase 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 within a moderate fat intake to implement dietary guidelines for healthful diets. These conclusions 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 surrogate biomarker for CHD risk must be done

with caution and clear recognition of 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, regardless of whether results are expressed as increased levels of LDL–C or as increases in LDL/HDL ratios, 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 declaration of 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 as 2.91 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 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 stated that market incentives and 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 adequate diet" (Ref. 90). It is clear that 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 guidance.

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, 1g 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 section IV of this document. Because 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 or 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 would be inconsistent 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 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 certain. Before the 1990 amendments 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 footnote.

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 physiologically different. Comments 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 prospective studies, *trans* fat should be 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 the product would remain the same.

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. Accordingly, the agency concludes that 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 calculated by combining the amount of 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 saturated and *trans* fats are substituted 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 and *trans* fats represent two different 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 need to be reviewed by both countries. 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 acids should be listed only as a part of 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 utting 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 (Ref. 89).

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 established with the 1993 mandatory 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., without a % DV, until such time as 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* at 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 event 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 to warrant *trans* fat labeling, the agency 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 ules 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 DRVs. However, the recent IOM/NAS 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 below.

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 (c)(2)(iv).

(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 correctly chose food 2 (69 percent) as 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 consumers would be confused about the 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