that is specifically authorized by regulation governing a particular food, or unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for dietary use other than regulating body weight, e.g., "for low-sodium diets."

(f) *"Sugars free", and "no added sugars"*. Criteria for the use of the terms "sugars free" and "no added sugars" are provided for in § 101.60(c) of this chapter.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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21 CFR Part 101

[Docket No. 84N-0153]

RIN 0905-AB68

Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the food labeling regulations to define, and to provide for the proper use of, the terms "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol" in the labeling of foods and to provide for the use of other truthful and nonmisleading statements about a food's fat, fatty acid, and cholesterol content in food labeling. This proposed rule is intended to permit meaningful declarations about fat, fatty acid, and cholesterol content, while preventing misleading claims about these food components. In this document, FDA is responding to comments received in response to the tentative final rule on cholesterol claims (55 FR 29456, July 19, 1990) and to the provisions of the Nutrition Labeling and Education Act of 1990 regarding fat, fatty acid, and cholesterol content claims. In addition, this document sets forth related agency policies.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 6 months following its publication in accordance with the provisions of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1561.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Regulatory History of Fat, Fatty Acid, and Cholesterol Labeling

The agency has had a long interest in the proper labeling of foods with information on fat, fatty acid, and cholesterol content. FDA's policies have reflected contemporary knowledge on the relationship between these dietary components and chronic disease conditions.

1. The 1959 Policy Statement

In the **Federal Register** of December 10, 1959 (24 FR 9990), the agency published a statement of policy concerning the status of food offered to the general public for the control or reduction of blood cholesterol levels and for the prevention and treatment of heart and artery disease. The policy statement acknowledged the public interest in the effect of various fatty foods on blood cholesterol and the relationship between blood cholesterol levels and diseases of the heart and arteries. However, the statement noted that the role of dietary cholesterol in heart and artery diseases had not been established. Therefore, FDA took the position that any labeling claim for fats and oils that indicated or implied that a food would prevent, mitigate, or cure diseases of the heart or arteries would be considered false or misleading and would misbrand the food under the Federal Food, Drug, and Cosmetic Act of 1938 (the act). FDA pointed out that the policy statement was not intended to interfere with clinical research on the possible role of dietary unsaturated fats in lowering blood cholesterol. The policy statement was, the agency stated, intended to prevent the promotion of foods for use by the public without medical supervision.

2. Quantitative Labeling of Fatty Acid and Cholesterol Content

In the **Federal Register** of May 25, 1965 (30 FR 6984), the agency proposed to establish requirements for label statements relating to oils, fats, and fatty foods used as a means of reducing the dietary intake of fatty acids. FDA received a number of comments on this proposal. After considering the comments and other available information, FDA terminated the rulemaking (31 FR 3301, March 2, 1966) because comments convinced the agency that the role of fats in the diet had not been sufficiently studied to make a definitive decision.

In the 5 years that followed, the terms "saturated," "monounsaturated," and "polyunsaturated," as applied to food fats or fatty acids, received considerable publicity, which led to consumer demand for more information about fat-containing foods. In 1970, the White House Conference on Food, Nutrition, and Health recommended that regulatory agencies permit and encourage the food industry, on a voluntary basis, to label the fat and fatty acid content of foods that constitute the major sources of fats in typical diets (Ref. 1).

Accordingly, in response to the consumer requests and to a report of the American Medical Association's Council on Foods and Nutrition, which contained a number of recommendations regarding the labeling of fat and fatty acids, FDA proposed in the **Federal Register** of June 15, 1971 (36 FR 11521) to adopt a regulation (21 CFR 125.12) on the requirements for label statements intended to provide guidance for regulating intake of fatty acids. This proposal would have established labeling requirements for foods represented for special dietary use containing 10 percent or more fat on a dry weight basis and no less than 3 grams (g) of fat in an average serving.

In the same issue of the **Federal Register** (36 FR 11521), FDA also proposed to amend the agency's policy statement on labeling foods for the prevention and treatment of heart and artery disease to make it clear that claims such as "lower cholesterol" were deemed to be false or misleading. However, the agency also proposed to provide that labeling statements would be acceptable if they set out only the fat content of the food, the source of the fat and the content of saturated, monounsaturated, and polyunsaturated fatty acids in accordance with proposed § 125.12.

After considering the comments on these proposals and other available information, FDA concluded that information associated with the cholesterol and fatty acid content of foods should be combined into a single regulation. Accordingly, in the **Federal Register** of January 19, 1973 (38 FR 2132)

(amended March 14, 1973, 38 FR 6951) FDA removed the 1959 policy statement and established a new § 1.18 *Labeling of foods in relation to the fat and fatty acid and cholesterol content* (21 CFR 1.18; recodified as 21 CFR 101.25 in the **Federal Register** of March 15, 1977 (42 FR 14302)), which established requirements for labeling the cholesterol and fatty acid composition of food products. (Requirements for labeling the fat content of food were included in the rulemaking for general nutrition labeling (38 FR 2132) (amended March 14, 1973, 38 FR 6951).)

Section 101.25 provides for the voluntary listing of the cholesterol and fatty acid content of the food as part of the food's nutrition labeling (21 CFR 101.9). This regulation provides that cholesterol be declared (to the nearest 5-milligram (mg) increment) in mg per serving and in mg per 100 g of food, and that fatty acid content be declared (to the nearest g) in g per serving in two categories: "Polyunsaturated fatty acids" and "saturated fatty acids." It limits fatty acid declarations to foods containing not less than 2 g of fat per serving and 10 percent or more fat on a dry weight basis. FDA said that any food that contains less than these levels was deemed "not suitable for use by man as a means of regulating the intake of fatty acids" (§ 101.25(c)(1)). In other words, FDA believed that foods that contained less than these levels were so low in fat as to not be a significant source of fatty acids, and, thus, that lowering the levels at which these foods were eaten would not affect blood cholesterol levels. Therefore, FDA decided that such foods should not be permitted to bear claims about the relative amounts of polyunsaturated fatty acids in such small amounts of fat. Since FDA promulgated this provision (currently codified as § 101.25(c)(1)), the agency has advised those who have requested guidance on the use of the term "low fat" that "a definition for the term 'low fat' can be inferred from § 101.25(c)(1)" (Ref. 2). The definition that FDA is proposing in this document for "low fat" differs from these criteria.

3. Food Standards

In addition to issuing 21 CFR 101.25, the agency, in response to recommendations in the 1970 report of the White House Conference on Food, Nutrition, and Health (Ref. 1), issued a limited number of food standard regulations that describe nonfat and lowfat food products. Food standards specifically prescribe the composition and name of particular products to protect the public from economic fraud. Presently, the agency has food standards of identity for various types of nonfat and lowfat milk products (21 CFR part 131), lowfat cottage cheese (21 CFR part 133), nonfat and lowfat yogurt (21 CFR part 131), macaroni products containing nonfat milk (21 CFR part 139), and low-fat cocoa (21 CFR 163.114).

4. The 1978 Food Labeling Initiative

In the **Federal Register** of June 9, 1978 (43 FR 25296), FDA, the U.S. Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection published a notice requesting the public's views on numerous food labeling issues and announcing public hearings across the nation to elicit comments on improving food labeling.

The results of the joint hearings were published in a notice in the **Federal Register** of December 21, 1979 (44 FR 75990). In that notice, FDA announced its plans to undertake a major food labeling initiative, including its plans to propose regulations to define cholesterol claims in food labeling and to consider proposing regulations to define fatty acid claims in food labeling.

5. The 1986 Proposed Cholesterol Nutrient Content Claims

In the **Federal Register** of November 25 1986 (51 FR 42584), FDA published a proposal to define terms that describe the cholesterol content of foods and to provide for their proper use in food labeling. FDA proposed to amend § 101.25 to define the terms "cholesterol free," "low cholesterol," and "reduced cholesterol" and to provide for truthful comparative statements that describe significant reductions in cholesterol content. Specifically, FDA proposed that "cholesterol free" be defined as less than 2 mg of cholesterol per serving, "low cholesterol" as less than 20 mg of cholesterol per serving, and "reduced cholesterol" as a 75 percent reduction. FDA proposed to require that whenever these terms or statements about cholesterol content appear on labels, the amount of cholesterol be declared in the nutrition label. FDA also proposed to amend § 101.9, the nutrition labeling regulation, to require that when cholesterol content is declared on the nutrition label, fatty acid content also be declared, and that when fatty acid content is declared, cholesterol content also be declared. FDA received over 1,000 comments in response to this proposal.

B. Current Food Labeling Initiative

1. The 1969 ANPRM

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative of the Department of Health and Human Services (DHHS) to take a new look at food labeling as a tool for promoting sound nutrition for the nation's consumers. FDA asked for public comment on five areas of food labeling, including the use of nutrient content claims such as "cholesterol free" to characterize foods.

In response to the ANPRM, FDA received over 2,000 written comments, plus over 5,000 copies of a questionnaire that had been distributed by a consumer organization. Over 500 of the written comments addressed issues related to specific nutrient content claims. These comments made clear that both consumers and food manufacturers are strongly in favor of improving food labels and, in particular, that FDA should define additional food nutrient content claims. In addition, approximately 3,500 of the over 5,000 questionnaires supported the need for additional descriptor definitions. Many comments stated that the proliferation of undefined terms has resulted in confusion for consumers and unfair competition for manufacturers. One comment stated that terms are "meaningless the way they are used now and are primarily used as marketing tools rather than guides for the health conscious consumer." Many comments suggested that commonly used nutrient content claims should either be defined by FDA or not permitted.

As part of this DHHS initiative, FDA announced in the **Federal Register** of September 20, 1989 (54 FR 38806) a series of four public hearings to discuss nutrition labeling and other issues related to food labeling, including the use of nutrient content claims. Representing a cross-section of interested parties, some 200 people including consumers, health professionals, trade associations, other industry representatives, and State and local health officials, testified at these hearings. In addition, 1,500 more persons participated in 50 local "consumer exchange" meetings conducted by FDA. Comments received as a result of the ANPRM and testimony from people at the hearings approved of FDA's past efforts to define terms relating to the content of calories, sodium, and cholesterol. The comments supported FDA's basic approach of defining terms such as "no ____," "low ____," and "reduced ____." They urged FDA to proceed immediately to define the other terms that are commonly used, giving priority to terms with the greatest

impact on public health. There was general agreement that top priority should be given to the terms that describe the fat content of foods.

On March 7, 1990, Secretary of Health and Human Services, Louis W. Sullivan, announced that FDA would undertake a comprehensive, phased response to the comments on the ANPRM. Subsequently, FDA prepared and published, in the **Federal Register** of July 19, 1990, three proposed rules that would: (1) Make nutrition labeling mandatory on foods that are a meaningful source of nutrients and revise the content of the nutrition label (55 FR 29487); (2) establish standard serving sizes (55 FR 29517); and (3) establish reference values for declaring nutrient and other food component content in nutrition labeling (55 FR 29476). In the same issue of the **Federal Register**, FDA published a tentative final rule defining terms that may be used in food labeling to describe the cholesterol content of foods.

2. Tentative Final Rule on Cholesterol Nutrient Content Claims

In the tentative final rule that published in the **Federal Register** on July 19, 1990 (55 FR 29456), FDA addressed the comments received in response to the proposed rule on cholesterol nutrient content claims (51 FR 42584, November 25, 1986) as well as the comments received in response to the 1989 ANPRM and the public hearings. Many of the comments requested that FDA limit the amount of fat and of saturated fatty acids in foods claiming to be "cholesterol free" or "low in cholesterol." FDA agreed with these comments and in the tentative final rule (55 FR 29456) proposed to limit the content of fat and saturated fatty acids in foods bearing these claims. FDA proposed to limit the use of the terms "cholesterol free" and "low cholesterol" to foods that contain not more than 5 g of fat and not more than 2 g of saturated fatty acids per serving, as well as the requisite cholesterol levels. On a dry weight basis, these foods could contain not more than 20 percent fat and not more than 6 percent saturated fatty acids.

The requisite cholesterol levels remained the same as proposed in the 1986 proposal, except that FDA proposed: (1) To define "low cholesterol" as "20 mg or less of cholesterol per serving" rather than as "less than 20 mg per serving," and (2) to add a second criterion based on density to the definition of "low cholesterol," namely that the food contain 0.2 mg or less cholesterol per g of food. The first change was made to be consistent with FDA's other definitions for "low," for calories (§ 105.66(c)(1)(i)) and for sodium (§ 101.13(a)(3)), that include the integer in the definition.

FDA made the second change to prevent "low cholesterol" label claims from conveying a misleading impression about the cholesterol content of certain foods. Comments pointed out that a single criterion based on serving size could result in widely recognized "high cholesterol" foods with small serving sizes (e.g., butter, lard, and some processed cheese foods) being labeled as "low cholesterol". These comments stressed that despite their small serving sizes, such foods actually may be consumed frequently and in large amounts, resulting in a substantial total daily intake of cholesterol. In addition, the comments were concerned that a "low cholesterol" claim on such foods could encourage increased consumption of the food, significantly adding to an individual's total cholesterol intake.

Additionally, in the tentative final rule FDA proposed to limit comparative statements about cholesterol content to products with at least a 25 percent reduction in cholesterol content. This requirement was added to prevent deceptive comparative claims and to help ensure that consumers are not misled into believing that an inconsequential reduction in cholesterol content will provide significant health benefits.

FDA advised that it considered the tentative final rule to contain the agency's final determination on all substantive issues other than on the threshold levels of fat and saturated fatty acids, and that a comment would have to be very significant to make any changes in the rule other than to the threshold levels.

3. Nutrition Labeling

On July 19, 1990, FDA also published a proposed rule (55 FR 29487) (the mandatory nutrition labeling proposal) to require nutrition labeling on most foods that are meaningful sources of nutrients and to revise the list of nutrients required to be declared. The agency proposed to require that nutrition labeling include fat, saturated fat (which could also be declared as "saturated"), and cholesterol content of the food, as well as the amount of calories from fat. In addition, the following items could be included voluntarily: unsaturated fat (which the proposal said could also be stated as "unsaturated" or, alternatively, as "monounsaturated" and "polyunsaturated"), calories from unsaturated fat, and calories from saturated fat.

The agency proposed that the listing of unsaturated fatty acid content would be mandatory when a claim is made about fatty acids or cholesterol, or when calories from unsaturated fatty acids are voluntarily declared. Moreover, under the proposal, the specific listing of the monounsaturated and polyunsaturated fatty acid content would become mandatory when a claim is made about a particular type of unsaturated fatty acid. Finally, the agency proposed to prohibit any claim that a food is nutritionally superior to another food in fat or saturated fatty acid content unless the level of these substances is at least 25 percent less than in the food to which the comparison is being made.

4. Reference Daily Intake (RDI) and Daily Reference Values (DRV)

In a proposed rule related to nutrition labeling (55 FR 29476, July 19, 1990) (the RDI/DRV proposal), FDA updated the U.S. Recommended Daily Allowances (U.S. RDA's) used in food labeling and proposed to replace the term "U.S. RDA" with "Reference Daily Intake". In the same proposal, the agency also introduced the term "Daily Reference Value" and proposed DRV's for seven food components, including total fat (75 g), saturated fatty acids (25 g), unsaturated fatty acids (50 g), and cholesterol (300 mg). These DRV's are based upon a diet of 2,350 calories, which is the population-adjusted mean of the recommended energy allowances for persons 4 or more years of age, as indicated in the 10th edition of the "Recommended Dietary Allowances" (Ref. 3). The DRV for cholesterol is, however, independent of calories.

5. Serving Size

FDA proposed standardized serving sizes for the major categories of foods in a third proposed rule (55 FR 29517, July 19, 1990) to assure reasonable serving sizes and to provide for comparison among similar products. FDA said that these serving sizes, if adopted, would ensure that claims, such as "low cholesterol," were the result of the characteristics of the food and not manipulation of the serving size. The agency stated that these standardized serving sizes would help to ensure that food label claims are not misleading to consumers.

6. Institute of Medicine Report

On September 26, 1990, the National Academy of Sciences (NAS's) Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling: Issues and Directions for the 1990's" (the IOM report) (Ref. 4). The IOM report was

written under contract to the Public Health Service, DHHS, and the Food Safety and Inspection Service, USDA. This report makes recommendations for changes in food labeling that will assist consumers in implementing the recommendations of "The Surgeon General's Report on Nutrition and Health" (Ref. 5) (the Surgeon General's Report) and NAS's recent report, "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) (the NAS report). The IOM report recommends, among other things, that FDA define nutrient content claims for fat, fatty acid, and cholesterol content.

7. Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). The 1990 amendments make the most significant changes in food labeling law since passage of the act. They strengthen DHHS's food labeling initiative by clarifying FDA's legal authority to require nutrition labeling on foods and by defining the circumstances under which claims may be made about the nutrients in foods. Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, states that a food is misbranded if a claim is made in its label or labeling that characterizes the levels of any nutrient of the type required in nutrition labeling under section 403(q) of the act, including fat, fatty acids, and cholesterol, unless the claim is made in a manner that conforms to the requirements of the act. These requirements, and the agency's proposed regulations implementing these requirements, are generally discussed in a companion proposed rule entitled "Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register** (hereinafter referred to as the "companion document on nutrient content claims"). However, the requirements that specifically apply to nutrient content claims (synonymously referred to as "nutrient content claims") with respect to fat, fatty acids, and cholesterol are the subject of this document.

The 1990 amendments directly affect FDA's tentative final rule on cholesterol claims of July 19, 1990. Because a number of changes in the tentative final rule are necessary to bring it into conformity with the requirements of the 1990 amendments, the agency is issuing this new proposed rule on cholesterol nutrient content claims. In doing so, the agency is including proposed definitions for fat and fatty acid nutrient content claims in this document because of the interrelationship among these components and cholesterol in the etiology of cardiovascular disease. The agency is also providing for the use of other truthful and nonmisleading comparative statements about the levels of fat, fatty acids, and cholesterol in foods.

8. Supplementary Nutrition Labeling Proposal

Elsewhere in this issue of the **Federal Register**, FDA is publishing a reproposal entitled "Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as the "supplementary nutrition labeling proposal") to bring its earlier mandatory nutrition labeling and RDI/DRV proposals into conformity with the 1990 amendments. In addition to the changes required by the legislation, FDA is proposing some changes to assist the implementation of the final regulations and to help clarify the earlier proposals. With respect to fat and fatty acids, the agency is proposing that they be declared in increments of ½ g rather than 1 g.

II. Scientific Background to Proposed Action

A. Overview

The Surgeon General's Report (Ref. 5) and the NAS report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 6) considered the evidence on the effect of diet on an individual's health. One of the main conclusions from these reports is that consumption of diets high in fat, saturated fat, and cholesterol is associated with increased risks of developing certain chronic diseases. These reports recommend that Americans reduce their consumption of these substances in their diets.

Given the significance of dietary intake of fat, saturated fatty acids, and cholesterol, FDA is seeking ways to assist consumers in modifying their diets to reduce their intake of these food components. One way to do so is to ensure that the food label provides information on the fat, fatty acid, and cholesterol content of the food. To this end, FDA is issuing proposed nutrition labeling regulations that will require that most foods bear nutrition labeling that discloses the quantitative amounts per serving of total fat, saturated fat, and cholesterol as well as the number of calories derived from fat.

In this document, FDA is proposing to provide for the use of descriptor (nutrient content) claims on food labels or labeling to describe the fat, fatty acid, and cholesterol content of the food. This document does not, however, address whether it is possible to use the food label to communicate explicit health-related information, nor does it address what type of health information, if any, on dietary fat, fatty acids, and cholesterol would be appropriate for food labeling. FDA is addressing these issues in the ongoing rulemaking proceeding on "Health Messages and Label Statements" (see proposed rule, 55 FR 5176, February 13, 1990).

The following discussion describes dietary fats and the scientific background for this proposal to define fat and fatty acid nutrient content claims. Similar information on cholesterol can be found in the 1990 proposed rule (51 FR 42584).

B. Description of Dietary Fats

Fats provide the most concentrated source of energy in the diet. Each gram of fat furnishes approximately nine calories, while carbohydrates and protein furnish approximately four calories per gram. (FDA is using the term "calories" throughout this document rather than the more precise "kilocalories" or "energy" because the term "calories" is more readily understood by consumers.) The major sources of fat in the American diet are meat, poultry, and fish; dairy products; and the category of foods referred to as ("fats and oils" Ref. 5, p. 10).

Most fats occur in food as triglycerides, which, upon hydrolysis (which occurs during the digestion of fats), yield fatty acids and glycerol. A fatty acid is composed of a carboxylic acid group attached to a chain of carbon atoms. Most carbon atoms in the chain have two hydrogen atoms attached to them. However, sometimes two adjacent carbon atoms each have only one hydrogen atom attached to them instead of two and are joined together by what is called "a double bond."

The number of carbon atoms joined by double bonds determines the degree of unsaturation of a fatty acid. Fatty acids with no double bonds are saturated, those with one double bond are monounsaturated, and those with two or more double bonds are polyunsaturated. The fatty acids commonly found in foods are usually composed of an even number of carbon atoms, usually 12 to 22, and contain from 0 to 6 double bonds.

The fatty acid composition of fats and oils may be modified through a process

known as "hydrogenation," in which double bonds gain hydrogen atoms and become single bonds. Fats and oils are hydrogenated to reduce their susceptibility to rancidity and to change the fat from a liquid to a solid form. The degree of hydrogenation can vary considerably. The composition of the original fat or oil and the degree of hydrogenation affect the fatty acid composition of the final product.

Complete hydrogenation of a fat or oil results in a solid fat containing only saturated fatty acids. More commonly, a fat or oil is partially hydrogenated. Hydrogenation reduces the content of polyunsaturated fatty acids and increases the content of monounsaturated and saturated fatty acids. Partial hydrogenation of fats or oils may produce additional changes in the chemical structure of the fatty acids, such as changes in the location of double bonds along the carbon chain and in the formation of "trans" double bonds, which have a geometric configuration different from that which occurs predominately in nature.

All dietary fats consist of a mixture of saturated, monounsaturated, and polyunsaturated fatty acids. In general, animal-derived fats contain a higher proportion of saturated fatty acids than fats or oils derived from plants. The latter generally contain more monounsaturated and polyunsaturated fatty acids. There are some exceptions to this generalization. Coconut oil and palm kernel oil, for example, contain a high proportion of saturated fatty acids even though they are derived from plants, and some fish oils are good sources of polyunsaturated fatty acids (Ref. 5, p. 57). Furthermore, some hydrogenated vegetable oils that are used in processed foods as alternatives to animal fat or coconut or palm kernel oil may contain high levels of saturated fatty acids.

In regard to the effect of dietary fats on serum cholesterol levels, the amount of saturated fatty acids present in the final food product is more important health information than the source of the fat or oil (Ref. 7).

C. Diet and Chronic Diseases

Although much remains to be learned about the impact of diet on chronic disease risk, the overall evidence supports a relationship between certain dietary patterns and chronic diseases. As stated in the Surgeon General's Report:

High intake of total dietary fat is associated with increased risk for obesity, some types of cancer, and possibly gall bladder disease. Epidemiologic, clinical, and animal studies provide strong and consistent evidence for the relationship between saturated fat intake, high blood cholesterol, and increased risk for coronary heart disease * * *. Excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels. Dietary cholesterol raises blood cholesterol levels, but the effect is less pronounced than that of saturated fat * * *.

Dietary fat contributes more than twice as many calories as equal quantities (by weight) of either protein or carbohydrate, and some studies indicate that diets high in total fat are associated with higher obesity rates. In addition, there is substantial, although not yet conclusive, epidemiologic and animal evidence in support of an association between dietary fat intake and increased risk for cancer, especially breast and colon cancer. Similarly, epidemiologic studies suggest an association between gallbladder disease, excess caloric intake, high dietary fat and obesity. (Ref. 5, p. 10).

The NAS report similarly stated the general conclusion that "total amounts and types of fats and other lipids in the diet influence the risk of atherosclerotic cardiovascular diseases and, to a less well-established extent, certain forms of cancer and possibly obesity." The report went on to state that, "Intake of total fat per se, independent of the relative content of the different types of fatty acids, is not associated with high blood cholesterol levels and coronary heart disease," but rather that, "saturated fatty acid intake is the major dietary determinant of the serum total cholesterol and LDL cholesterol levels in populations and thereby of coronary heart disease risk in populations." (Ref. 6). On the basis of the current scientific evidence, both reports recommend that individuals reduce their consumption of fat (especially saturated fat) and cholesterol.

Coronary heart disease (CHD) remains the leading cause of death in the United States today. The causes of CHD are multifactorial. Evidence from animal and human studies and from epidemiologic surveys continues to accumulate, implicating among other factors high blood cholesterol, high blood pressure, and cigarette smoking as causative agents in the development of atherosclerosis. Atherosclerosis, in turn, leads to narrowing of the arteries and development of CHD. The scientific evidence supporting these conclusions has been extensively reviewed in the Surgeon General's Report (Ref. 5) and the NAS report (Ref. 6). In regard to blood cholesterol levels, the Surgeon General's Report states:

> An extensive body of clinical evidence supported by animal, epidemiologic, and metabolic studies has established the relationship between high blood cholesterol and increased CHD risk. The relationship is strong, continuous, and graded. (Ref. 5, p. 86.)

The Surgeon General's Report also states:

> Numerous expert bodies have examined the evidence relating diet to CHD and its implications for public health. Although there are many determinants of blood cholesterol levels, no modifiable factor has been shown to influence cholesterol and low-density lipoproteins more than diet.

Accordingly, many expert health organizations have made recommendations for modifying dietary intake of fat, fatty acids, and cholesterol for the purpose of improving the public health. These recommendations are summarized as follows:

1. *The Surgeon General's Report:* Reduce consumption of fat (especially saturated fat) and cholesterol. Choose foods relatively low in these substances, such as vegetables, fruits, whole grain foods, fish, poultry, lean meats, and low-fat dairy products. Use food preparation methods that add little or no fat (Ref. 5).

2. *The NAS Report:* Reduce total fat intake to 30 percent or less of calories, reduce saturated fatty acid intake to less than 10 percent of calories, and the intake of cholesterol to less than 300 mg daily (Ref. 6).

3. *U.S. Department of Health and Human Services and U.S. Department of Agriculture in "Nutrition and Your Health, Dietary Guidelines for Americans":* Choose a diet low in fat, saturated fat, and cholesterol (Ref. 8).

4. *The National Cholesterol Education Program (NCEP) Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel):* Healthy Americans should consume less than 10 percent of total calories from saturated fatty acids, an average of 30 percent of total calories or less from all fat, less than 300 mg of cholesterol per day, and energy (calorie) levels needed to reach or maintain a desirable body weight (Ref. 9).

5. *Report of the NCEP Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults:* For adults with borderline to high blood cholesterol, the NCEP recommended two diets to assist in lowering high blood cholesterol levels. In the step-one diet, less than 30 percent of total calories are to come from dietary fat, with less than 10 percent coming from saturated fatty acids, up to 10 percent

from polyunsaturated fatty acids, and 10 to 15 percent from monounsaturated fatty acids. In addition, cholesterol intake is to be less than 300 mg per day. The step-two diet (for persons requiring greater dietary modifications to lower serum cholesterol) differs in that saturated fatty acid intake is to be less than 7 percent of total calories and cholesterol less than 200 mg per day (Ref. 10).

6. *American Heart Association:* Calories derived from fat should be less than 30 percent of total caloric intake, calories derived from saturated fat should be less than 10 percent of calories, and the daily cholesterol intake should be less than 300 mg (Ref. 11).

7. *American Medical Association (AMA):* Persons with hypercholesterolemia (high serum cholesterol) and hypertriglyceridemia (high serum triglycerides) should consume a diet in which no more than 30 to 35 percent of calories are derived from fat, in which less than 10 percent of calories are from sources of saturated fat, and in which there is less than 300 mg of cholesterol per day (Ref. 12). While these recommendations were originally made in 1983, the AMA currently supports the NCEP recommendations.

8. *Inter-Society Commission on Heart Disease Resources:* Reduce dietary cholesterol to no more than 250 mg per day, reduce total fat intake to less than 30 percent of calories, and adjust fat intake to provide no more than 8 percent of calories from saturated fat (Ref. 13).

9. *World Health Organization Expert Committee on Prevention of Coronary Heart Disease:* In countries with a high incidence of CHD, such as the United States, blood cholesterol levels should be lowered through progressive changes in eating patterns, including consumption of under 300 mg of cholesterol per day and less than 10 percent of energy intake as saturated fat (Ref. 14).

III. Provisions of the Proposed Regulation—Use of Defined Terms and Comparative Statements

A. Introduction

1. Legal Basis

FDA is proposing to define terms that describe the fat, fatty acid, and cholesterol content of food, to provide for the proper use of these terms, and to provide for the use of comparative claims regarding the level of these substances in food labeling. FDA has authority to take these actions under sections 201(n), 403(a), 403(r), and 701(a) of the act (21 U.S.C. 321(n), 343(a), 343(r), and 371(a)). Those sections authorize the agency to adopt regulations that prohibit labeling that is false or misleading in that it fails to reveal material facts with respect to consequences that may result from use of the food and that uses terms to characterize the level of any nutrient in a food that have not been defined by regulation by FDA.

Because the consensus reports cited above suggest that consumers limit their dietary intake of fat, fatty acids, and cholesterol, and because comments to the 1989 ANPRM and testimony at FDA's public hearings on labeling show that consumers are concerned about, and wish to reduce their dietary intake of these substances, it is important that label statements not convey a misleading impression about the fat, fatty acid, or cholesterol content of a food. Without clear definitions of the terms that describe the levels of these nutrients in food, manufacturers could use a term like "low fat" on products that vary widely in fat content. Inconsistent use of the same term on various products could only lead to consumer confusion and nonuniformity in the marketplace. To ensure that consumers are not misled and are given reliable information, Congress found, and FDA agrees, that it is appropriate for the agency to establish specific definitions to standardize the terms used by manufacturers to describe the fat, saturated fatty acid, and cholesterol content of foods. FDA is proposing to do so in this document.

2. Organization of Regulations

As discussed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, FDA is proposing to reorganize part 101 of its regulations to add Subpart D—Specific Requirements for Nutrient Content Claims. In doing so, FDA is proposing to redesignate current § 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* as § 101.62 *Nutrient content claims for fat, fatty acid, and cholesterol content of foods.* This change will allow this section on fat, fatty acid, and cholesterol content claims to be grouped with the other descriptor definitions in new subpart D.

The companion document on nutrient content claims also proposes to add a new section, § 101.13 *Nutrient content claims—general principles*, which sets forth general rules for all nutrient content claims. FDA is proposing in § 101.62(a)(2) to require that fat, fatty acid, and cholesterol content claims comply with the provisions of § 101.13 as well as § 101.62.

Among the most significant of the proposed general provisions are §§ 101.13(g) and (h), which set forth the requirements for the statement that, under the act, must accompany any nutrient content claim. Pursuant to section 403(r)(2)(B) of the act, the labels or labeling of foods that bear nutrient content claims must contain the following statement that refers the consumer to the nutrition label: "See _____ for nutrition information." Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel of the package on which the nutrition label is located. Proposed § 101.13(g) reflects this requirement.

Proposed § 101.13(h) provides, in accordance with section 403(r)(2)(B)(ii) of the act, that the statement must also identify any nutrient that is present in the food at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet-related. The section also proposes to define specific levels of fat, saturated fat, cholesterol, and sodium that present such a risk.

Thus, some foods that meet the definition for "low fat," for example, contain cholesterol at levels that require identification of this nutrient (proposed in § 101.13(h) as levels of more than 45 mg of cholesterol per serving or per 100 g of food). Many species of fish and shellfish are examples of such foods. To refer consumers to the cholesterol content of these foods, the agency is proposing in § 101.13(h) that the label of such foods bear, in immediate proximity to the "low fat" claim, the following statement: "See _____ for information on cholesterol and other nutrients," with the blank filled in with the identity of the panel of the label where the nutrition information is located.

For other general provisions, the reader is referred to the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. Consistent with the discussion in that document, to ensure that foods that bear fat, saturated fat, and cholesterol claims bear nutrition labeling, FDA is proposing to require such labeling as a general requirement in proposed § 101.62(a)(3).

3. Serving Size to Evaluate Nutrient Content Claims

FDA proposed in § 101.12(f) of the 1990 serving size proposal (55 FR 29517) that for any container with more than one serving the proposed standard serving size would be used to determine the appropriateness of a nutrient content claim, such as "cholesterol free." For single-serving containers containing 100 percent or less of the standard serving, the agency proposed to evaluate the

label claim based on the standard serving size. However, for single-serving containers containing more than 100 percent, but 150 percent or less of the standard serving, the agency proposed to evaluate the claim on the basis of the entire content of the package.

A majority of comments on FDA's proposal supported the proposed basis for evaluation of nutrient content claims. However, many food industry and trade organization comments objected to the proposed evaluation criteria. Such comments generally stated that the standard serving size, not the package content, should be used to evaluate descriptor claims on all types and sizes of packages. Manufacturers pointed out that under the 1990 proposal on serving size, the same food product that could be labeled as "low sodium" on the basis of the standard serving size might not qualify for a "low sodium" claim when packaged in a single-serving container containing between 100 percent and 150 percent of the standard serving. For example, an 8 fluid ounce container of skim milk containing 126 mg of sodium would meet the criteria for a "low sodium" claim, but a 10 fluid ounce container of the same milk containing 158 mg of sodium would not.

Because of the complexity of the issues with respect to serving size and the need to obtain further public comment on the impact of the 1990 amendments and the IOM report (Ref. 4) on this subject, FDA announced a public meeting to discuss issues related to serving size determination (56 FR 8084, February 26, 1991). In the notice of the public meeting, FDA raised the question of whether the discrepancies in the use of nutrient content claims on food products would be confusing and asked for data to support any views presented. The public meeting was held on April 4, 1991, and provided opportunity for both oral and written comments.

In comments, a manufacturer suggested that FDA establish reference serving sizes, and that both the reference serving size and the serving size declared on the label be required to be used to evaluate the compliance with FDA criteria for the nutrient content claims. The agency believes that this suggestion is a reasonable approach to regulating the use of nutrient content claims not only on single-serving containers but also on all other products when the serving size declared on the label differs from the reference standard (e.g., products in discrete units such as muffins). Therefore, in proposed § 101.12(b) in the agency's reproposal on serving sizes published elsewhere in this issue of the **Federal Register**, FDA has set forth reference amounts customarily consumed per eating occasion (reference amounts) for 131 food product categories. In accordance with provisions of the 1990 amendments that require label serving sizes to be expressed in common household measures, proposed § 101.9(b)(2) in the same document provides procedures for manufacturers to use in converting the reference amounts, which generally are in metric measures, to label serving sizes most appropriate for their specific products.

In proposed § 101.12(g), FDA is proposing that, if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), both the reference amount and the serving size declared on the product label must be used to determine whether the product meets the FDA criteria for nutrient content claims as set forth in 21 CFR part 101, subpart D.

Consistent with proposed § 101.12(g), FDA is proposing for the subject fat, fatty acid, and cholesterol claims (as well as for all other nutrient content claims discussed in the companion document on nutrient content claims) that all per serving criteria (e.g., less than 2 mg of cholesterol per serving for "cholesterol free" claims) will apply to the serving size declared on the product label and, where the labeled serving size and the reference amount differ, to the reference amount as well. Therefore, taking the preceding example of skim milk, the proposed reference amount customarily consumed for all beverages is 240 milliliters which is equivalent to 8 fluid ounces. When considering the 8 fluid ounce container, the reference amount and the labeled serving size are the same. Therefore, because 8 fluid ounces of skim milk contain 126 mg of sodium and the definition for "low sodium" is an amount of 140 mg or less, the container could bear a "low sodium" claim.

However, when considering the 10 fluid ounce container, the labeled serving size is larger than the reference amount. Ten fluid ounces of skim milk contain 158 mg of sodium, an amount exceeding the definition for "low sodium." Therefore, while the amount of sodium in the reference amount of skim milk is within the definition, the amount of sodium in the labeled serving size is not. Hence, if this proposed rule is adopted, the 10 fluid ounce container could not bear a "low sodium" claim. While acknowledging the apparent contradiction this difference in treatment causes, FDA tentatively concludes that it would be misleading to allow claims based only on the reference amount because, particularly with single-serving containers, the consumer is expected to consume the entire labeled serving size. Likewise, it could also be misleading to allow claims based only on the labeled serving size, because this could cause manufacturers to attempt to manipulate serving sizes, even within the proposed constraints.

In the regulations in subpart D of 21 CFR part 101, the agency will describe the applicability of these dual criteria to the quantitative amounts in the proposed regulations as per reference amount customarily consumed and "per labeled serving size." Rather than complicating the discussions concerning proposed quantitative amounts in this preamble, however, FDA will abbreviate "per reference amount customarily consumed and per labeled serving size" as "per serving."

B. Total Fat Claims

1. "Fat free"

a. *Definition.* In response to the 1989 ANPRM, FDA received a few comments on the definition of the term "fat free." Most of these comments recommended that "fat free" be defined as 0.5 g or less per serving.

The agency finds merit in these comments and is proposing in § 101.62(b)(1)(i) to define the term "fat free" ("free of fat," "no fat," "zero fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat") to include foods that contain less than 0.5 g of fat per serving.

FDA has discussed in the companion document on nutrient content claims, published elsewhere in this issue of the **Federal Register**, its general approach to defining "free" levels of nutrients. This approach is that the level of a nutrient that is described as "free" should be at or near the reliable limit of detection for the nutrient in foods and should be dietetically trivial or physiologically inconsequential.

In the case of analytical methodologies for fat, 0.5 g of fat per serving defines a level of fat in food that is at or near the reliable limit of detection of fat in food. The actual limit of detection of fat in food varies with different food products. However, 0.5 g represents the limit of quantitation in essentially all foods (i.e., analytical precision and accuracy below this amount is difficult). In proposed § 101.9(c)(4) of the supplementary nutrition labeling proposal, the agency is proposing that less than 0.5 g of fat

could be declared as "0" in nutrition labeling.

In addition, the agency has selected 0.5 g per serving as the definition for "fat free" because it believes that a cutoff of 0.5 g is low enough compared to the DRV for fat, which is 75 g, to be considered dietetically trivial or physiologically inconsequential. For example, a person consuming 16 to 20 servings per day (Refs. 15 through 17) of food containing 0.5 g of fat per serving would consume only 8 to 10 g of total fat per day, or no more than 90 calories from fat per day and (for a diet of 2,350 calories) less than 4 percent of calories from fat. This level of fat is insignificant compared to the recommended level of 30 percent or less of calories from fat in the diet (Refs. 6, 9 through 11, and 13).

FDA established a policy of using "free" as a descriptor of physiologically insignificant levels of a food component when it adopted the regulation for sodium nutrient content claims (49 FR 15510, April 18, 1984). The agency has received comments that contend that the term "fat free" will mislead consumers into believing that food so labeled is completely without fat. However, the agency believes that no harm will result from any misunderstanding caused by the use of this term on foods that meet the definition because, as discussed above, foods containing less than 0.5 g of fat per serving contain a trivial amount of fat compared to the total dietary intake of fat for any particular individual. FDA is proposing to express this requirement on a per serving basis because it believes that consumers are most familiar with nutrient content claims being defined in this manner. The agency has used this basis in defining terms that describe the calorie, sodium, and cholesterol content of foods and is therefore proposing an approach that is consistent with that used by the agency in the past. Comments that the agency has received in response to the 1989 ANPRM and public hearings also supported continued use of serving sizes in the definition of nutrient content claims, as did the IOM report (Ref. 4).

The agency is not proposing a second criterion based on the amount of fat per 100 g for the definition of "free" because the first proposed criterion for this nutrient requires that the food contain such a trivial level of fat from a public health perspective that even frequent consumption in large amounts of foods that bear a "fat free" descriptor would not affect in any meaningful way the overall fat level in the diet.

b. *Use of "fat free" on products with added fat.* The agency is aware that the claim "fat free" appears on the labels of certain products to which small amounts of fat have been deliberately added as an ingredient. For example, some products that declare a fat content of "zero" and that bear the claim "fat free" list soybean oil as an ingredient. The agency has received letters expressing confusion about this type of labeling. The Minnesota State Attorney General, writing on behalf of eight other State attorneys general, has written to the agency to express their view that such labeling would be misleading to consumers (Ref. 18).

In response to these concerns, the agency is proposing in § 101.62(b)(1)(ii) to add a second criterion to the definition of "fat free" to disallow the use of the term on the labels of products to which fats or oils have been added as ingredients. Without this criterion, it would be possible for a food that meets the quantitative criterion for the "fat free" descriptor (i.e., contains less than 0.5 g of fat per serving) to have a small amount of fat or oil added as an ingredient.

The claim "fat free" is a representation that the food is free of fat. The agency believes that this representation can be made in good faith if the food inherently contains very small amounts of fat (i.e., less than 0.5 g per serving) because the food does not contain a dietarily significant amount of fat. Such a representation cannot be made in good faith, however, if the manufacturer intentionally adds a fat or oil to the food. In such circumstances, even though the fat might not be dietarily significant, it is obvious from reading the ingredient statement that it has been added, and, thus, FDA tentatively concludes that representing the food as free of fat would cause confusion and be false and misleading under sections 201(n) and 403(a) of the act. The agency solicits comments on this tentative conclusion.

As an alternative approach, it would be possible to allow "free" claims even though the nutrient is added, if the label includes a disclosure statement in association with the claim acknowledging the addition of the nutrient. In order for the claim to not be misleading, such a disclosure statement would need to be prominent and immediately adjacent to the claim each time it is made. Such a disclosure might state, "An insignificant amount of fat has been added to this product as an ingredient." This approach was suggested by the Minnesota Attorney General as an alternative if FDA determined that it was not feasible to prohibit nutrient free claims on products that contained a very small amount of a nutrient added as an ingredient (Ref. 18). The agency solicits comments on whether nutrient free claims should be allowed on products that contain a very small amount of a the nutrient as an ingredient if such products provide an appropriate disclosure statement and, if so, what such a disclosure statement should be. The agency points out, however, that although, under this proposal, a product would not be allowed to call itself "free" of a nutrient if a manufacturer intentionally added the nutrient to the food as an ingredient, the label could make other positive, true, and nonmisleading statements about the product such as how little of the nutrient is actually in the product. For example, if a manufacturer found that it was necessary to add a very small amount of fat to a product to assure that the product was palatable to consumers, the label could make a statement reflecting the amount of fat in the product provided that that amount of that nutrient could meet the definition for "low fat." Such a statement might be "contains less that ½ gram of fat per serving," or if accurate, "99 percent fat free." This labeling is consistent with § 101.13(i) which states that, in addition to statements about the percent of a vitamin or mineral in a food relative to the RDI, the label or labeling of a product may contain a statement about the percent or amount of a nutrient that implies that the food is high or low in a nutrient if the food actually meets the definition for either "high" or "low" as defined for the nutrient that the label addresses.

In addition, the label or labeling of a product may bear a variety of other positive statements about the product such as the product is "low," or in the case of sodium, "very low," in the nutrient or that the amount of the nutrient in the food is reduced, if that is the case, or that there is less of the nutrient in the product than some in another product.

c. *Foods inherently fat free.* Section 403(r)(2)(A)(ii) states that absence (i.e., "free") claims may not be made for foods unless the nutrient for which the claim is made is usually found in the food, or in a food that substitutes for the food (see proposed § 101.13(d)), or the Secretary allows such a claim based on a finding that the claim would assist consumers to maintain a healthy diet. Thus the act gives the agency the authority to limit "free" claims on foods inherently free of a nutrient.

However, FDA believes that highlighting "fat free" foods can help consumers maintain healthy dietary practices whether the food is inherently free of fat or is processed to be that way. Many respondents to FDA's

consumer surveys have reported difficulty in understanding the quantitative information presented in nutrition labeling (Ref. 19). Furthermore, FDA surveys have shown that consumers want nutrient content claims and find them useful in making food selections. Supermarket studies by FDA have shown that shoppers are using descriptive terms that highlight positive nutritional attributes (such as "fat free") to make food purchase selections (Refs. 20 and 21). In addition, they help to educate consumers on the intrinsic properties of foods. FDA believes that the definitions established in this proposed rule respond to consumers' needs. Therefore, FDA has tentatively concluded that it is not necessary to limit "fat free" claims to foods in which fat is usually present or that substitute for foods that usually contain fat.

However, the agency believes that the unqualified use of the term "free" on foods that are inherently free of a nutrient can be misleading because such terminology would imply that the food has been altered to reduce the nutrient as compared to other foods of the same type. Accordingly, FDA is proposing in this document (§ 101.62(b)(1)(iii)) and in the companion document on nutrient content claims (§ 101.13(e)) to require that if a food is free of a nutrient without the benefit of special processing, alteration, formulation, or reformulation to lower the content of the nutrient, it must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. For example, many fruits and vegetables are foods that would meet the definition for the term "fat free." Therefore, if the agency adopts this policy, broccoli that bears a "fat free" descriptor would have to bear labeling such as "broccoli, a fat free food."

This requirement is consistent with the general policy on "free" and "low" claims discussed in the preamble to the final rule on sodium labeling in relation to sodium claims (49 FR 15510 at 15517) and proposed in § 101.25(a)(2)(i) and (a)(2)(ii) of the tentative final rule for both "free" and "low" cholesterol claims (55 FR 29456). The agency believes that this requirement is necessary to prevent the consumer from being misled by an implication that a particular food has been altered to lower its fat, when, in fact, all foods of that type are naturally free of, or low in, that nutrient.

FDA is aware that the effect of this proposed action will be to allow "free" claims on foods that do not usually contain the nutrient (e.g., "Brand A soft drink, a fat-free food"). However, because of the importance of highlighting "fat free" foods, the agency believes that this course is the appropriate one. FDA specifically requests comments on this aspect of its proposal.

Therefore, FDA is proposing in § 101.62(b)(1) to allow "fat free" claims on all foods that contain less than 0.5 g of fat per serving and contain no added fat or oil and, in § 101.62(b)(1)(iii), to require that "fat free" claims on foods that are inherently "fat free" disclose that fat is not usually present in the food.

2. "Low Fat"

a. *Definition.* Most of the comments on the 1989 ANPRM that dealt with fat nutrient content claims favored a single, uniform maximum cutoff ranging from 2 to 5 g of fat per serving for all food categories for defining the term "low fat."

The comments favoring 5 g of fat per serving for all food categories were primarily from representatives of the dairy industry, who suggested that the cutoff for "low fat" be consistent with the cutoff in the food standard for lowfat milk (21 CFR 131.135). This standard, which was promulgated in 1973, allows milk containing 0.5-, 1-, 1.5- or 2-percent milkfat to be named "lowfat milk." Two percent milkfat in an 8-fluid ounce serving equates to 5 g of fat.

The agency, however, has derived its proposed definition for "low fat" and the synonyms "low in fat," contains a small amount of fat, "low source of fat," or "little fat" from the proposed general principles for nutrient content claims that appear in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. Under these general principles, the agency is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. FDA has selected 2 percent as the starting point based on its historical use of 2 percent of the U.S. RDA as a measurable amount of a nutrient in a food (§ 101.3(e)(4)(ii)).

To arrive at a defined value for "low" when a nutrient is not ubiquitous, the agency is proposing to increase the 2 percent amount to adjust for the nutrient's uneven distribution in the food supply. This adjustment recognizes the practice of dietary planning in which a person consumes in a day a reasonable number of servings of foods labeled as "low," balanced with a number of servings of foods that do not contain the nutrient in question and a small number of servings of foods that contain the nutrient at levels above the "low" level, and is still able to stay comfortably within the guidelines of the various dietary recommendations. This adjustment to reflect the nutrient's distribution in the food supply has the effect of permitting a wider variety of foods to be labeled as "low" than would be possible if the 2 percent of the DRV standard was used generally to define "low."

With respect to fat, current dietary guidelines (Refs. 6, 8, and 9) recommend that a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,350 calories per day would allow for consumption of a maximum of 75 g of fat per day. This value has been proposed as the DRV for fat (55 FR 29476). Two percent of this proposed DRV is 1.5 g.

The agency is not proposing 1.5 g as the cutoff of a "low fat" claim, however, because fat is not ubiquitous in the food supply. For instance, very little fat is found in most fruits, vegetables, and grains. Because fat is not ubiquitous and yet is found in more than a few food categories, FDA tentatively concludes that an appropriate upper limit for a "low fat" claim should be set at two times 2 percent of the DRV, or 3 g per serving. The agency tentatively concludes that this amount is a reasonable definition for "low fat" because an average level of 3 g in 16 to 20 servings of food per day (balancing the number of foods that do not contain fat with those that contain higher levels of fat to yield an average of 3 g of fat per serving) would supply 48 to 60 g of fat daily, comfortably within the DRV of 75 g of total fat. Therefore, the agency is proposing in § 101.62(b)(2)(i) that a "low fat" food contain 3 g or less of fat per serving.

It should be noted that in deciding whether a food meets the criteria for "low fat" (and all other nutrient content claims except "free"), FDA considers the per serving criterion to pertain to the amount that is appropriately declared in nutrition labeling under § 101.9 rather than the amount that is actually present in the food product. Therefore, a food may meet the "low fat" criterion of "3 g or less fat per serving" even though it actually contains slightly more than 3 g of fat per serving. This anomaly occurs because of the rounding rules that FDA is proposing in the nutrition labeling regulations. Proposed § 101.9(c)(4) states that fat is to be expressed to the nearest 1/2 g. Accordingly, if FDA adopts that provision in the final nutrition labeling regulations, a food containing up to 3.24 g of fat would declare the level of fat as 3 g in nutrition labeling and would thus meet the criterion of "3 or less fat per serving."

This anomaly will not occur with "free" claims because FDA is proposing to define them as "less than X amount" rather than "X amount or less." Because the integer is not included in the definition, FDA is proposing not to allow rounding above that amount.

b. *Need for criterion based on weight.* The agency is proposing in § 101.62(b)(2)(i) that a "low fat" food would have to contain 3 g or less fat per 100 g as well as per serving. FDA has stated in the companion document on nutrient content claims that an additional criterion based on weight is needed in some cases to prevent claims from being misleading. For example, some nutrient-dense foods have small serving sizes. Although these foods would meet the "low fat" definition on a per serving basis, because they may be consumed frequently throughout the day, they could produce a substantial total daily intake of a nutrient like fat. Thus, the agency has tentatively concluded that a second density criterion is appropriate for "low fat" foods. A density criterion has been used in conjunction with "low calorie" claims since 1977 (see current § 105.66(c)(1)(ii)) and was proposed as part of the definition for "low cholesterol" in § 101.25(a)(2)(ii) of the tentative final rule for cholesterol nutrient content claims (55 FR 29456).

Examples of foods that do not meet the definition of "low fat" because they do not meet the serving and density criteria include semi-solid frozen desser toppings (2.3 g of fat per serving but 25 g of fat per 100 g of the food) and thick vanilla shakes (10.4 g of fat per serving although only 3 g of fat per 100 g of the food).

The agency notes that the proposed criteria for the definition of "low fat" differ from the criteria of 2 g or less of fat per serving and 10 percent or less of fat on a dry weight basis that the agency in the past has advised those interested to infer from § 101.25(c)(1) as a definition of "low fat" (Ref. 2). Although the first criterion (3 g per serving) of the proposed definition is more lenient than past agency advice (2 g per serving), the second criterion (3 g per 100 g of food) makes the total number of foods that meet the proposed definition essentially equivalent to the total number of foods that met the criteria of 2 g or less of fat per serving and 10 percent or less of fat on a dry weight basis. The assortment of foods varies somewhat however. For instance, some of the foods that meet the proposed criteria and not the previous criteria include 1 percent lowfat milk, and some soups. Foods that would meet either "low fat" definition include most fruit and vegetables, certain fish, shellfish, soups, and a few types of bread and cereal. Foods that do not meet the proposed criteria that had met the previous criteria include some breads, cookies, cereals (particularly presweetened cereals), and dehydrated soups. FDA tentatively finds it is appropriate to no longer permit these foods to make "low fat" claims because, if they are consumed frequently, they could result in a substantial total daily intake of fat.

c. *Foods inherently "low fat."* Consistent with the discussion above for foods inherently fat free, the agency believes that the use of the term "low fat" on foods that are inherently low in fat can be misleading. Accordingly, FDA is proposing in § 101.62(b)(2)(ii) to require that "low fat" claims on foods that inherently meet the definition for "low fat" refer to all foods of that type and not merely to the particular brand to which the labeling is applied.

For example, frozen perch would inherently meet the definition for the term "low fat." Therefore, if the agency adopts proposed § 101.62(b)(2)(ii), a package of frozen perch would be labeled "frozen perch, a low fat food." This requirement is consistent with the general policy on "free" and "low" nutrient content claims proposed in § 101.13(e)(2), which is published elsewhere in this issue of the **Federal Register.**

d. *"Low fat" meal-type products.* FDA has discussed in the companion document on nutrient content claims the requests that the agency has received for definitions for nutrient content claims that can be used on labels and in labeling of meal-type products. It is apparent that the per serving criteria in the agency's proposed definitions for claims for individual food products are too restrictive to apply to these products.

In 1986, in an effort to establish nutrient content claims that would help consumers identify positive nutritional characteristics of meal-type products, the agency proposed as a guideline that a meal containing less than 100 mg of cholesterol could be described as a "low cholesterol meal." However, in its tentative final rule on cholesterol nutrient content claims, the agency withdrew from this position because there was no clear definition of the term "meal" and asked for further comment.

To meet this need, and based on a letter submitted by the Grocery Manufacturers of America, Inc. (GMA) (Ref. 22), FDA is proposing in § 101.13(l) in its companion document on nutrient content claims to define a "meal-type product" as a food that: (1) Makes a significant contribution to the diet (a) by providing at least 200 calories or (b) weighing at least 6 ounces, and (2) contains ingredients from 2 or more of the following four food groups: bread, cereal, rice, and pasta group; fruit and vegetable group; milk, yogurt, and cheese group; and meat, poultry, fish, dry beans, eggs, and nuts group, and (3) is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza.

In its letter, GMA suggested that for meal-type products "low fat" be defined as 3.5 g or less fat per 100 g of food. FDA finds merit in setting nutrient content claims for meal-type products on the basis of the amount of the nutrient per 100 g rather than on the basis of the amount per serving and per 100 g as is done for individual foods. A review of meal-type products on the market (Ref. 23) shows that such a criterion would allow nutrient content claims on meal-type products that can be used in a diet that is consistent with dietary recommendations set forth in the Dietary Guidelines for Americans. However, FDA believes it would be beneficial and less confusing if it used the same quantitative amounts to qualify for nutrient content claims for meal-type products that it is proposing for individual foods. Such consistency would assist consumers and health professionals to be able to recall and to use these amounts. Accordingly, the agency is proposing in § 101.62(b)(3)(i) to provide that a "low fat" claim may be made for a meal-type product that contains 3 g or less total fat per 100 g of product. The agency is also proposing in § 101.62(b)(3)(ii) to provide for such claims on meal-type products that meet the criterion without special processing.

e. *Related issues.* The agency received a comment that urged the establishment of different cutoffs for "low fat" for different foods (i.e., varying the quantitative definition of "low fat" according to food category).

The agency rejects this comment. The use of different criteria for different food categories has several disadvantages that affect both consumers and the food industry. When different criteria are used for different categories of foods, consumers cannot use the nutrient content claims to compare products across categories and will likely find it difficult to use the descriptor in substituting one food for another in their diets.

Although an argument can be made that different criteria for different foods would permit consumers to identify the

products with the lowest fat levels in each category, the agency believes that such a system would have a high potential for misleading the consumer about the fat content of foods. To identify the product that has the lowest fat content in a category does not mean that the product is low in fat. Furthermore, by having different criteria for different food categories, it would be possible that some foods that did not qualify to use the descriptor would have a lower fat content than foods in other categories that did qualify. This situation would contribute to consumer confusion and misunderstanding.

FDA has received many comments asking for increased consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report recommended such consistency stating that "low sodium, for example, should have the same meaning, whether it is applied to soup, frozen peas, or meat" (Ref. 4, p. 251). Accordingly, the agency concludes that establishing different cutoffs for each descriptor according to food category would greatly increase the complexity of the task given to consumers who would use nutrient content claims to plan diets that meet dietary recommendations.

The agency wishes to emphasize that it is not necessary for persons to limit their diets solely to "low fat" and "fat free" foods. However, the agency believes that nutrient content claims identifying "low fat" and "fat free" foods will help the American public to attain the nutrition objective in "Healthy People 2000" to "reduce dietary fat intake to an average of 30 percent or less of calories and saturated fat intake to less than 10 percent of calories among people aged 2 and older" (Ref. 24). The current U.S. diet is reported, on average, to provide about 37 percent of calories from fat (Ref. 5).

The agency recognizes that the definition of "low fat" that it is proposing differs from the use of the term in certain standardized foods (e.g., 1% and 2 percent lowfat milk). In 1987, the Center for Science in the Public Interest petitioned FDA to prohibit the use of the term "lowfat" on 2 percent milk because it contains 5 g of fat per serving and is 18 percent fat on a dry weight basis. The agency is not, however, proposing any action to resolve the inconsistency between the proposed definition and this food standard use of the term at this time. FDA believes that it would be inappropriate to act before a definition for "low fat" is finalized.

In addition, section 403(r)(5)(C) of the act, which was added by the 1990 amendments, specifies that nutrient content claims required by a standard of identity do not have to be defined by regulation or to comply with the definitions that FDA does adopt and do not require the referral statement required in § 101.13(g). The use of nutrient content claims in conjunction with names of standardized foods is outside the scope of this document and is addressed in a separate document in this issue of the **Federal Register**.

3. "Reduced Fat"

a. *Percent reduction.* Most of the comments received in response to the 1989 ANPRM on the term "reduced fat" supported FDA's general policy of requiring reductions that are nutritionally significant. Fewer than 15 comments offered suggestions on how much of a reduction should be required for a "reduced fat" claim. Most of those comments favored a reduction of at least 25 or 33 percent. The comments favoring 33 percent were primarily from cheese manufacturers, who stated that a greater reduction is not feasible for cheese.

The agency has considered these comments. However, it is proposing in § 101.62(b)(4)(i) that the term "reduced fat" ("reduced in fat" or "fat reduced") be used to describe a food that has been specifically formulated or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 g per serving, from the food that it resembles and for which it substitutes (hereinafter referred to as "reference food").

The agency has tentatively selected the level of 50 percent for the minimum fat reduction to qualify for the "reduced fat" descriptor in accordance with general criteria for "reduced" nutrient content claims discussed in the preamble to the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. These general criteria take into consideration the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, and the technological feasibility of reducing levels of nutrients in foods. They also take into consideration the need for dietary changes relative to current intakes of nutrients.

FDA states in the companion document on nutrient content claims its belief that to make a reduced claim, there should be a substantial reduction in the amount of the nutrient present in the food. This belief is supported by comments that it received in response to the agency's 1989 ANPRM and public hearings. FDA believes that in defining the amount that constitutes a substantial reduction in a nutrient, it must take into consideration the distribution of the nutrient in the food supply. If a nutrient is ubiquitous, it will be consumed in a wide range of foods, and therefore, a dietary reduction in consumption of the nutrient can be spread out over all or most food categories. Thus, a smaller reduction on a food-by-food basis would be needed to achieve a substantial reduction in consumption of such a nutrient than would be needed if the nutrient were present in only some food categories. In the latter case, the nutrient would not be found in as many foods, and therefore, the reduction in the nutrient on a food-by-food basis would have to be greater to achieve a substantial dietary impact.

Fat is not ubiquitous throughout the food supply. Most fruit and vegetables and many grain products contain little or no fat. Reductions in the fat content of foods that are inherently low in fat are difficult and less cost effective than modifying foods that are high in fat. Therefore, to make substantial reductions in dietary fat intake, it is necessary to make significant reductions in foods containing high levels of fat.

Of the total number of foods on FDA's Regulatory Food Composition Data Base, approximately half are either fat-free or low-fat foods (Ref. 25). While this data base may not be representative of the entire food supply, it suggests that a large portion of the food supply is not amenable to a substantial reduction of fat content.

FDA notes that for calories, a nutrient that is ubiquitous in the food supply, the agency has determined that a percent reduction of 33 percent is necessary to justify a "reduced" claim. 21 CFR 105.66(d)(1)(i). Given this precedent, and the fact that at best only half the food supply is available to produce a substantial reduction in the fat content of the diet, FDA is proposing that a 50 percent reduction in the fat content of a food from the food that it is intended to resemble and to replace is necessary to justify a "reduced fat" claim. FDA notes that this level is consistent with the guidance that it has been giving the retail food industry for many years on "reduced fat" claims (Refs. 2 and 26).

The appropriateness of a 50 percent reduction is supported by calculations of the dietary changes needed to meet recommended intake levels. Dietary guidelines recommend reducing the intake of fat from foods from the current level in the average U.S. adult diet of approximately 37 percent of calories (Ref. 5) to 30 percent of calories (Refs. 6, 8, and 9). This change would require a

reduction in total fat intake of approximately 23 percent (Ref. 27). Since substantial reductions in fat can only be made in half of the foods in the food supply, it is reasonable to require that for foods making a "reduced fat" claim the fat content should be reduced by at least twice the reduction needed in the total diet in order to meet dietary recommendations (i.e., twice the 23 percent reduction, or 46 percent, which can be rounded to 50 percent).

As mentioned above, the agency's general criteria for "reduced" claims include consideration of the need for consistency of terms and the technological feasibility of achieving the specified levels of reduction. The continued use of the 50 percent criterion would allow not only for consistency with past guidelines but also with the values FDA is proposing for "reduced" claims for sodium, saturated fat, and cholesterol. In regard to technological feasibility, current technology has demonstrated that for many foods, including dairy products, a reduction in fat of 50 percent or more is readily achievable (Ref. 28).

The agency requests that interested persons submit comments on the proposed 50-percent reduction. Comments containing technical information supporting this or other suggested reduction levels will be particularly helpful.

b. *Absolute reduction.* Additionally, the agency is proposing, in § 101.62(b)(4)(i), a second criterion that would require a minimum absolute reduction of fat from the reference food that it replaces. As stated in the companion document on nutrient content claims, because the use of the term "reduced" is based on a percentage change rather than a specified amount per serving, the agency believes that an additional criterion specifying a minimum absolute amount of reduction for the nutrient is necessary to preclude manufacturers from making inconsequential changes in their products, which, given the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts. For instance, without the inclusion of an additional criterion, a food containing only 4 g of fat per serving could be reformulated to contain 2 g of fat per serving and thereby qualify to use the term "reduced" when, in fact, the reduction of 2 g of fat cannot be considered either substantial or of nutritional significance.

In its companion document on nutrient content claims, FDA has tentatively concluded that, if a food is to make a consequential as well as a measurable reduction in a nutrient, the absolute reduction should not be less than that amount which is considered to be "low" on a per serving basis. A measurable amount of a nutrient is an amount greater than 2 percent of the label reference value (the amount defined in current § 101.3(e)(4)(ii) as a measurable amount of a nutrient). Two percent of the proposed DRV for total fat is 1.5 g (0.02 times 75 g). However, this amount is less than the amount of the per serving criterion for "low fat" (i.e., 3 or less g of fat per serving). Therefore, to bear a "reduced fat" claim, a food would have to have a minimum reduction that exceeds the per serving criterion for "low fat" (i.e., the reduction must be more than 3 g of fat per serving).

Guidelines or definitions for determining amounts of nutrients in foods that can be considered consequential or nutritionally meaningful are not available. However, as described in the companion document on nutrient content claims, FDA is proposing to use the definition for a "low" claim as the minimum amount of reduction in a nutrient in a food that would justify a "reduced" claim because a diet made up of exclusively "low" foods would contain a small but not insignificant amount of the nutrient. Total intake of the nutrient would not exceed the recommended DRV level, but would be as much as 50 percent or more of that level. Therefore, in considering consequential reductions for "reduced" foods, FDA has tentatively concluded that the amount per serving specified for "low" is a consequential amount of a nutrient, and that it is appropriate to define a consequential or nutritionally meaningful reduction in a nutrient as an amount that is not less than that amount considered to be "low" for the nutrient. Accordingly, FDA is proposing in § 101.62(b)(4)(i) that a "reduced fat" claim may be used on the label of a food in which the fat content has been reduced by more than 3 g of fat per serving, in addition to a reduction of fat of 50 percent or more from the reference food.

c. *Reference food.* As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference point against which a food can be said to contain a reduced level of a nutrient is either an industry-wide norm or the manufacturer's regular product. FDA is proposing to define an "industry-wide norm" in § 101.13(j)(1)(i) as a composite value weighted on a unit or tonnage basis according to a national market share of all foods of the same type as the food for which the claim is made. The agency is proposing to define a manufacturer's regular product in proposed § 101.13(j)(1)(ii) as a food that has been offered for sale to the public by the same business (or a unit entitled to use its name) and in the same locale on a regular basis for a substantial period of time.

These reference points were initially identified in comments to the agency's proposed regulation defining cholesterol content claims (51 FR 42584). The comments and FDA's response were discussed in the tentative final rule on the subject (55 FR 29456 at 29460). In the cholesterol rulemaking, FDA also proposed to allow a third reference point for a reduced claim, that of a similar product or class of products as found in a current, valid, composite data base. The agency has reconsidered permitting the use of this third reference point with "reduced fat" claims and now tentatively concludes that for a "reduced" claim a manufacturer should be required to compare the fat content of a food product either with its own product or with an actual market average as represented by the "industry-wide" norm for two reasons.

Foremost, the agency believes that the term "reduced" is a specific claim that requires that the comparison be made to products that are most like the product bearing the claim. A data base for a class of products will most likely include a spectrum of products that is too broad to support such a claim. For example, if a product is labeled as "reduced fat imitation bacon bits," it is claiming that it contains reduced fat when compared to other imitation bacon bits. If such a claim could be made on the basis of a data base of products similar to imitation bacon bits, the data base would likely include a range of products, including bacon. The imitation bacon bits could have reduced fat when compared to the data base but no less fat than other imitation bacon bit products. In such circumstances, the claim would clearly be misleading. Thus, FDA believes that comparison to a data base of similar products is not an appropriate basis for a "reduced fat" claim.

Moreover, particularly as a data base ages, the values in the base may no longer represent the nutrient composition of foods that are on the market. If, for example, all manufacturers have reduced the fat in their products, it would not be appropriate for an individual manufacturer to make a "reduced" claim against the higher value represented by the older average value. By requiring that the comparison be made against an

"industry-wide norm" or the manufacturer's regular product, the agency believes that this problem is minimized.

The agency is proposing in § 101.62(b)(4)(ii) that a food that bears a "reduced fat" claim be labeled in compliance with § 101.13(j)(2) as proposed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**. Proposed § 101.62(b)(4)(ii) thus requires information in immediate proximity to the most prominent use of the claim of the extent (percent or fraction) that the fat is reduced, the identity of the reference food to which it is compared (e.g., "50 percent less fat than our regular brownie"), and quantitative information comparing the actual amount of fat in a serving of the food to the amount in the reference food (e.g., "Fat content has been reduced from 8 grams to 4 grams per serving").

The agency currently requires the comparative quantitative information and the identification of the reference food for reduced claims for sodium (§ 101.13(a)(4)) and calories (§ 105.66(d)(1)(ii)) to help prevent consumer misunderstanding. The agency believes that such information must be presented with a "reduced fat" claim for the same reason. The agency is proposing to add the requirement that the label or labeling declare the percent (or fraction) that fat and other nutrients have been reduced to give consumers additional information to evaluate the significance of the claim. This information will also allow consumers to more readily compare the levels of reduction in different foods making "reduced fat" claims. Thus, it is a material fact in light of the representations being made in the labeling.

In this and other situations where information is required to be in "immediate proximity" to a claim, the information must be immediately adjacent to the claim with no intervening material. This interpretation of "immediate proximity" is set forth in proposed § 101.13(g)(2) in the companion document on nutrient content claims and is required to prevent possible consumer misunderstanding.

Similarly, to identify the location in which the comparative information for relative claims is required, proposed § 101.13(j)(2)(ii) in the companion document defines "the most prominent location" as, in descending order: (1) A claim on the principal display panel (PDP) adjacent to the statement of identity, (2) a claim elsewhere on the PDP, (3) a claim on the information panel, or (4) a claim elsewhere on the label.

4. Comparative Claims

In proposed § 101.62(b)(5), the agency is providing for the use on food labels of comparative claims that use the term "less" to describe the fat content of the food expressed on a per serving basis. The agency recognizes that there are some foods that can achieve significant reductions in fat content but not reductions of 50 percent or greater. Because these foods do not attain a 50-percent reduction, they could not bear a "reduced fat" claim under this proposal. However, the agency believes that such foods should be able to be labeled with comparative statements using the term "less" that specify the extent of the fat reduction that has been made. For example, the label of a pound cake could bear the statement "40 percent less fat than our regular pound cake—fat lowered from 10 grams to 6 grams per serving."

To ensure that consumers are not misled by claims for reductions that are inconsequential, the agency is proposing in § 101.62(b)(5)(i) to permit a comparative statement on the label of a food only if the food has been formulated or processed to reduce its fat content by 25 percent or more, with a minimum reduction of more than 3 g of fat per serving. The requirement for a reduction of 25 percent or more is consistent with the agency's current policy for comparative claims for sodium (49 FR 15521, April 18, 1984) and proposed regulations for cholesterol (55 FR 29456). These positions were based on agency findings that products in which there has been a 25 percent or greater reduction will serve a useful role in the diet of those individuals who are attempting to limit their consumption of the nutrient. These criteria are also consistent with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent or more.

Improvements in food technology or other factors may make it practicable for manufacturers to measure reductions in nutrient content of less than 25 percent. The agency solicits comments, including data, on whether 25 percent is necessary as a minimum reduction requirement for all foods, or whether a lower level is possible.

However, FDA acknowledges that permitting comparative claims for foods with a percentage reduction of less than 25 percent may serve to facilitate consumers efforts to improve their diets if such claims are reliably made and the absolute reduction referred to by the comparative claim is nutritionally significant.

Consistent with "reduced fat" claims, the agency is also proposing to require an absolute reduction of more than 3 g of fat per serving from the reference food. While this criterion is new, FDA stated above its belief that an additional criterion specifying the absolute amount of reduction for the nutrient is necessary in order to preclude manufacturers from making inconsequential changes in a product, which, because of the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts.

In determining the absolute reduction to be required, FDA considers that the amount must be both measurable in foods and nutritionally consequential. To meet these criteria, the amount would have to be, as discussed above with respect to "reduced fat" claims, not less than that amount that is considered to be "low." The amount defined as "low fat" is proposed to be 3 g or less per serving and per 100 g of food. Accordingly, FDA is proposing in § 101.62(b)(5)(i) that to bear a comparative claim for fat, an absolute reduction of more than 3 g of fat per serving is required.

In regard to reference foods, the agency is proposing in § 101.13(j)(1) in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register** that for comparative claims, comparisons may be made to an industry-wide norm, to the manufacturer's regular product, or to a current, valid composite data base such as USDA's Handbook No. 8, "Composition of Foods, Raw, Processed, Prepared." The first two reference points are identical to those listed above for a "reduced" claim. The agency is proposing to permit the third reference point, as initially proposed in FDA's tentative final rule on cholesterol content claims (55 FR 29456 at 29463), for comparative claims because it believes that consumers will benefit from label statements that make legitimate, appropriate comparisons with similar classes of products, and that comparative claims do not necessarily need to imply a comparison to the product itself or a narrow range of similar products. For example, a label statement such as "My amaranth chips have 25 percent less fat than other chip snack foods" would be appropriate (if the amaranth chips also contain more than 3 g less of fat than the named class of products). In making this comparison, the manufacturer could rely on values from a current, valid data base for the

similar class of products. FDA specifically solicits comment on this point.

The agency is proposing in § 101.62(b)(5)(ii) that, as required in proposed § 101.13(j)(2), labels or labeling of a food for which a comparative claim is made must include a statement in immediate proximity to the most prominent such claim of the extent (percent or fraction) that the fat is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of fat in a serving of the food to the amount in the reference food that it resembles and for which it substitutes. This requirement is identical to that for "reduced fat" claims discussed above. An alternative approach to comparative nutrient content claims is discussed in the companion document on general principles for nutrient content claims published elsewhere in issue of the Federal Register.

5. "____ Percent Fat Free" Claims

The agency received many comments to the 1989 ANPRM stating that "____ percent fat free" claims on foods are confusing and misleading. These comments suggest that many consumers do not understand this type of claim. Additional comments suggested that the term be prohibited.

The agency is proposing to prohibit the use of this claim in those circumstances in which it would be misleading and thus would misbrand the product. Claims that a food is "____ percent fat free" emphasize how close the food is to being free of fat, that is, to containing no fat. They imply that the food has a very small amount of fat in it, and that the food is useful in structuring a diet that is low in fat. The impression that the claim makes is misleading, however, if the food, despite the percentage calculation, contains a significant amount of fat.

On June 6, 1991, in a speech given at the 20th Anniversary Conference sponsored by the Center for Science in the Public Interest, the Commissioner outlined the agency's concerns about "____ percent fat free" claims:

> The high number—often 90 percent, 93 percent, and even 97 percent—linked with a desirable characteristic—"fat free"—leads people to conclude that the food itself promotes good health. It can also lead people to conclude that they can eat as much of it as they want. * * * We believe that this kind of assertion confuses and misleads consumers. Foods that derive a high percentage of their calories from fat should not be making low-fat claims.
> (Ref. 29)

The Commissioner called on industry to remove these claims from their products.

To ensure that the consumer is not misled by the term "____ percent fat free," and that, as the claim implies, the food does in fact contain only a small amount of fat, FDA is proposing in § 101.62(b)(6)(i) to require that such claims can only be made in foods that meet the criteria: (1) For "low fat" foods as proposed in § 101.62(b)(2) of this document (i.e., such foods would contain 3 g or less of fat per serving and per 100 g of food) or (2) for "low fat" meal-type products as proposed in § 101.62(b)(3) (i.e., such meal-type products would contain 3 g or less of fat per 100 g of product). The agency believes the claim would be misleading on a food or meal-type product that contains more than this low level.

The agency advises that a "____ percent fat free" declaration would be misleading if the number of g of fat in a serving of the food were not presented in conjunction with the claim. Under section 201(n) of the act, a food label is misleading if it fails to reveal facts material in light of the representations that are made on the label. Clearly, the actual amount of fat in a food is a material fact when a "____ percent fat free" claim is made. Therefore, in § 101.62(b)(6)(ii), FDA is proposing to require that the disclosure of the amount of total fat in a serving of food appear in immediate proximity to the most prominent such claim. In addition, given the potentially misleading nature of the claim, FDA believes that the quantitative disclosure of the amount of fat in a serving of the food should be in no less than one-half the size of the type of the "____ percent fat free" statement.

Finally, FDA is proposing in § 101.62(b)(6)(ii) that if the food contains less than 0.5 g of fat per serving (i.e., meets the criteria for "fat free"), the amount of fat may be declared as "0." This proposal is consistent with the rules set forward in the supplementary nutrition labeling proposal for declaration of fat in the nutrition label.

FDA is proposing in § 101.62(b)(6)(iii) that the type size of all components of the "____ percent fat free" claim be uniform. FDA is concerned that claims that would give the numerical percentage in smaller type size than the words "fat free" would lead consumers to focus only on the "fat free" portion of the claim, misleading them into believing that the food was totally free of fat.

Finally, § 101.62(b)(6)(iv) proposes that a "100 percent fat free" claim must meet all of the criteria in § 101.62(b)(1) for "fat free" claims. This would require that, in addition to containing less than 0.5 g of fat per serving, the food will have to contain no added ingredient that is a fat or oil, and if the food is inherently free of fat, the label will have to so indicate by use of the term "a 100 percent fat free food."

The agency requests comments on these proposed provisions for the use of "____ percent fat free" claims. Specific comments on whether these provisions are sufficient to prevent such claims from being misleading, or whether such claims should be prohibited entirely, are requested.

C. Fatty Acid Claims

In response to the 1989 ANPRM, FDA received very few comments that addressed nutrient content claims regarding fatty acids. However, not only do the 1990 amendments require in section 403(r)(2)(A)(i) of the act that claims characterizing the level of nutrients required in nutrition labeling be made in accordance with definitions adopted by FDA, they add section 403(r)(2)(A)(iv) to the act. This section states that a claim "may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claims and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat."

In accordance with these provisions, the agency is proposing in § 101.62(c) to provide for the proper use of the terms "low in saturated fat" and "reduced in saturated fat" and of comparative statements about the content of saturates. As required in the 1990 amendments, proposed § 101.62(c) requires that labels of foods containing 2 mg or more of cholesterol per serving that bear any of the claims being proposed for saturated fat, disclose the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which must be no less than one-half of the size of the claim. FDA is proposing to exempt foods containing less than 2 mg of cholesterol per serving from this requirement because the agency is proposing in this rulemaking that such foods be considered "free" of cholesterol and the amount be declared as zero in nutrition labeling.

The agency is also proposing in § 101.62(c) to require that the amount of total fat be disclosed in immediate proximity to claims about saturated fat. The agency believes that disclosure of

total fat is needed because recent FDA research suggests that consumers often do not differentiate between total fat and saturated fat content (Ref. 30). This finding leads FDA to tentatively conclude that "low" or "reduced" saturated fat claims would often be interpreted as "low" or "reduced" total fat claims. Such an interpretation would be incorrect because not all foods that are low in saturates are low in total fat (e.g., some vegetable oils and nuts are low in saturates yet contain about 14 g of total fat per serving). Accordingly, the agency believes a saturated fat claim will be misleading under section 201(n) and 403(a) of the act if the total fat content is not disclosed in immediate proximity to such claim.

1. "Low in Saturated Fat"

a. *Definition.* The agency is defining the term "low in saturated fat" (or "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "little saturated fat") in proposed § 101.62(c)(1)(i) to describe foods that contain 1 g or less of saturated fatty acids per serving and not more than 15 percent of calories from saturated fatty acids.

The agency derived the first criterion (i.e., 1 g or less of saturated fatty acids per serving) of its proposed definition for "low in saturated fat" following the general approach to defining "low" claims that is discussed in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register** and summarized under the above discussion for "low fat" claims. As discussed above, this general approach suggests that the starting point for the definition of "low" for a nutrient is 2 percent of its DRV. If a nutrient is not ubiquitous in the food supply, the percent of the DRV used as the cutoff is increased to adjust for its uneven distribution.

With respect to saturated fatty acids, current dietary guidelines (Refs. 6, 8, and 9) recommend that a person consume less than 10 percent of calories from saturated fats, which for a diet of 2,350 calories per day would allow for consumption of about 25 g of saturated fat per day. This value has been proposed as the DRV for saturates (55 FR 29476). Two percent of this proposed DRV is 0.5 g.

However, the agency is not proposing 0.5 g as the cutoff of a "low in saturated fat" claim because saturated fat is not ubiquitous in the food supply. Very little saturated fat is found, for example, in most fruit, vegetables, and grains. Because of the uneven distribution of saturated fat, the agency tentatively concludes that an appropriate upper limit for a "low saturated fat" claim should be set at two times 2 percent of the DRV, or 1 g per serving. Doubling the 2 percent level is consistent with the agency's treatment of fat, and the distribution of saturated fat in the diet roughly parallels the distribution of total fat. Moreover, this amount appears to be a reasonable definition for "low saturated fat" because if a person consumed an average level of 1 g in 16 to 20 servings of food per day, he or she would consume 16 to 20 g of saturated fat daily, comfortably within the DRV of 25 g of saturated fat.

Therefore, the agency is proposing in § 101.62(c)(1)(i) that the first criterion for the definition of "low in saturated fat" be 1 g or less of saturated fat per serving. According to FDA's Regulatory Food Composition Data Base (Ref. 25), this criterion would allow a "low saturated fat" claim on foods such as most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; evaporated milk; a few nondairy cream substitutes and dessert toppings; egg substitutes; mayonnaise-style salad dressing; and many soups, breads, and low calorie salad dressings. Of the fats and oils food group, only a few oils, such as canola and safflower, and a few margarine spreads containing less than 40 percent fat meet the criterion of 1 g or less saturated fat. While FDA's Regulatory Food Composition Data Base is not representative of the entire food supply and does not contain foods that have recently been introduced in the marketplace, it gives an indication of the types of food categories that would meet the subject criterion.

b. *Need for second criterion.* A general discussion of the need for a second criterion in establishing definitions for nutrient content claims can be found in the companion document on nutrient content claims which is published elsewhere in this issue of the **Federal Register**. The agency has stated that it believes a second criterion is needed to control "low" claims on nutrient-dense foods with small serving sizes where such food items can be consumed frequently, resulting in a substantial intake of the nutrient. The agency then proposed using g of the nutrient per 100 g of food as the preferred second criterion.

In considering the appropriateness of using "per 100 g" as the second criterion for "low in saturated fat," two things become apparent. First, fats and oils that are commonly consumed generally contain only fat, and, second, 100 g of these foods would rarely, if ever, be consumed in a day. Furthermore, a review of FDA's Regulatory Food Composition Data Base (Ref. 25) revealed that of those fats and oils identified above as containing 1 g or less of saturated fat per serving, none would be able to make "low saturated fat" claims if a second criterion based on 100 g is included in that definition. Because all fats and oils contain more than 1 percent saturated fatty acids, they would exceed 1 g of saturated fat per 100 g.

The agency believes that it is important that consumers be able to easily identify fats and oils that contain especially low levels of saturated fats. While the information needed to make this assessment will be located on the nutrition label once the revised mandatory nutrition labeling regulations are finalized, comments have clearly shown that many consumers use nutrient content claims to make purchase decisions rather than relying on the more complete nutrient content information in the nutrition label. Accordingly, the agency tentatively concludes that a "low saturated fat" claim would be helpful to consumers in identifying such foods, and that the identification, and subsequent purchase, of such foods will help individuals to meet dietary recommendations. The agency also believes that it will assist in reaching population goals such as the "Healthy People 2000" national objective of reducing average saturated fat intake to less than 10 percent of calories (Ref. 24). Additionally, such claims will provide an incentive to the food industry to develop fats and oils with lower levels of saturated fatty acids.

Accordingly, FDA is not proposing to use a second criterion based on weight for "low saturated fat claims". However, the agency continues to be concerned about saturated fat content claims made on small servings of food that may be consumed frequently and thereby result in a substantial total daily intake of saturated fat. In addressing this issue, FDA looked at similar definitions used by other nations. Canada defines "low saturates" as foods containing no more than 2 g of saturated fatty acids per serving and not more than 15 percent calories from saturated fatty acids (Ref. 31). In the United Kingdom (UK), a food is considered to be low in saturated fat if it contains 3 g or less saturates per serving and per 100 g of food (Ref. 32). In setting their per serving criterion at 2 and 3 g, respectively, both countries are far less restrictive on that primary criterion than the subject proposal; however they both seem to share FDA's concern over the need for a second criterion. The British (UK) compensate

by setting a second criterion at 3 g per 100 g of food, a criterion what would eliminate many foods with small serving sizes.

FDA has studied and finds merit in Canada's approach of no more than 15 percent of calories coming from saturated fats. While dietary recommendations are for less than 10 percent of calories in the diet being provided by saturated fat, the fact that saturated fat is not ubiquitous in the food supply would allow higher amounts in those foods that contain saturated fats to balance off those that are lower, resulting in a total daily diet that meets dietary recommendations.

The use of a second criterion of no more than 15 percent of calories from saturated fat would continue to allow for "low saturated fat" claims on most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; a nondairy liquid cream substitute; egg substitutes; mayonnaise-style salad dressing; many soups, breads, and low calorie salad dressings; and canola and safflower oils. Those foods that would meet the first criterion but not a criterion of no more than 15 percent of calories from saturated fats include evaporated milk, nondairy dessert toppings, and the margarine spreads. The agency tentatively concludes that it is appropriate to prohibit these foods from bearing a "low saturated fat" claim because they all could be consumed frequently, resulting in a substantial daily intake of saturated fat.

Accordingly, FDA is proposing in § 101.62(c)(1)(i) that "low saturated fat" claims may be used to describe the level of saturated fat provided the food contains 15 percent or less of calories from saturated fat as well as 1 g or less of saturated fat per serving. Comments are specifically requested on the suitability of, and need for, the proposed second criterion for "low saturated fat" claims.

c. *Foods inherently "low in saturated fat."* As previously discussed for "low fat" claims, the agency believes that the use of the claim "low in saturated fat" on the labels of foods that are inherently low in saturated fat can be misleading. Accordingly, FDA is proposing in § 101.62(c)(1)(ii) to require that "low in saturated fat" claims on foods that inherently meet the criteria specified in § 101.62(c)(1)(i) refer to all foods of that type and not merely to the particular brand to which the labeling is attached. This is consistent with the general policy on "free" and "low" nutrient content claims proposed in § 101.13(e)(2), which is published elsewhere in this issue of the **Federal Register.**

For example, raspberries would meet the definition for the term "low in saturated fat." Therefore, if the agency adopts proposed § 101.62(c)(1)(ii), a package of raspberries bearing a saturated fat claim would be labeled "raspberries, a low saturated fat food."

d. *"Low in saturated fat" meal-type products.* FDA is proposing in § 101.62(c)(2)(i) that a "low in saturated fat" claim may be made for a meal-type product that contains 1 g or less of saturated fat per 100 g of product. The proposed policy of basing nutrient content claims on the amount of the nutrient per 100 g rather than on the amount per serving and per 100 g as is done for individual foods is explained above for "low fat" meal-type products.

In its submission (Ref. 22), GMA suggested that for meal-type products "low saturated fat" be defined as 1.2 g or less of saturated fat per 100 g. FDA believes that it would be beneficial and less confusing if it used the same quantitative amount for "low saturated fat" claims for meal-type products that it is proposing on a per serving basis for "low saturated fat" claims on individual foods, 1 g. The proposed value of 1 g of saturated fat per 100 g would permit a "low saturated fat" claim on a 10-ounce meal when the declaration of saturated fat on the nutrition label is 3 g or less. GMA's suggestion would allow it on the same meal when the declaration is 3.5 g or less. FDA does not believe the difference is significant enough to warrant the confusion that would be caused by using different quantitative amounts.

As with other foods, if a meal-type product inherently meets the "low saturated fat" definition, its label will have to reveal that fact if a claim is made. This requirement is set out in proposed § 101.62(c)(2)(ii).

2. "Reduced Saturated Fat"

In proposed § 101.62(c)(3)(i), the agency is defining the term "reduced in saturated fat" ("reduced saturated fat," or "saturated fat reduced") to describe a food that has been specifically formulated or processed to reduce its content of saturated fat by 50 percent or more, with a minimum reduction of more than 1 g per serving from the reference food that it resembles and for which it substitutes.

The agency selected the level of 50 percent for the minimum reduction in saturated fat to qualify for the "reduced in saturated fat" descriptor in accordance with the general provisions for "reduced" nutrient content claims described above for "reduced fat" foods. These general provisions consider the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, and the technological feasibility of reducing levels of nutrients in foods. The provisions also consider the need for dietary changes relative to current intakes of nutrients.

Comments from both consumers and health professionals to the 1989 ANPRM and at the public hearings urged consistency in the definitions of terms to assist consumers in understanding the meaning of terms. They suggested that unless there were compelling reasons to the contrary, the agency should revise the current definitions for "reduced" calories, fat, and sodium that were 33 percent, 50 percent, and 75 percent, respectively, because it was not reasonable to expect consumers to remember the definition for each. Such variability, they argued, defeated the purpose of the terms.

In response to these comments and because of the many similarities between saturated fat and total fat, FDA believes that it is appropriate to use the same percent reduction to define "reduced" for both food components. Being absent from most fruit, vegetables, and grain products, neither food component is ubiquitous in the food supply. Therefore, similar levels of reduction could be expected to have a significant impact on dietary intakes of both.

In support of this position, FDA compared the need for dietary changes in saturated fat relative to current intakes with that for total fat discussed above under "reduced fat" claims. Current guidelines recommend reducing saturated fat from the current level in the average U.S. adult diet of 13 percent of calories (Ref. 1) to less than 10 percent of calories (Refs. 6, 8, and 9). This will require a reduction in saturated fat intake of 29 percent (Ref. 27). The need for dietary changes in total fat relative to current intakes is 23 percent, a comparable value. This information, and the agency's desire to provide for consistent definitions for similar terms so that consumer education efforts can be more easily implemented, have led FDA to propose that the first criterion for "reduced saturated fat" claims be a reduction of saturated fat of 50 percent or more.

FDA is also proposing in § 101.62(c)(3)(i) a second criterion that the amount of saturated fat in a food bearing a "reduced saturated fat" claim be reduced as a minimum by more than 1 g per serving from the reference food to which it is being compared. This criterion is consistent with the agency's

position discussed above for "reduced fat" claims and is intended to preclude manufacturers from making inconsequential changes in their products that, because of the initial low level of the nutrient, result in considerable reductions in terms of percent but not in terms of absolute amounts.

As stated above, the agency has tentatively concluded that if a food is to make a consequential as well as measurable reduction in a nutrient, the absolute reduction should not be less than that amount that is defined as "low" on a per serving basis. For saturated fat, that amount would be "more than 1 g."

As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference foods against which "reduced" claims may be measured are either an industry-wide norm or the manufacturer's regular product. These reference points are defined and discussed above in the section on "reduced fat" claims.

The agency is proposing in § 101.62(c)(3)(ii) that a food that bears the claim "reduced in saturated fat" be labeled as required in proposed § 101.13(j)(2), which is included in the companion document on nutrient content claims. Thus, proposed § 101.62(c)(3)(ii) requires that in immediate proximity to the most prominent use of the claim, information be presented on the extent (percent or fraction) that the saturated fat has been reduced, the identity of the reference food to which it is compared, and the actual quantity of saturated fat in a serving of the food compared to the amount in the reference food. For example, a nondairy creamer that had been reformulated to reduce its saturated fat content from the industry-wide norm could make a "reduced saturated fat" claim when accompanied by the following information: "Contains 50 percent less saturated fat than the national average for nondairy creamers. Saturated fat reduced from 3 grams per serving to 1.5 grams per serving."

3. Comparative Claims

Consistent with the discussion of comparative claims describing the fat content of foods, FDA is proposing in § 101.62(c)(4) to allow the use of comparative claims using the term "less" for foods that have been formulated, reformulated, altered, or processed in a way that has resulted in at least a minimum reduction in their saturated fat content. Proposed § 101.62(c)(4)(i) requires a reduction of 25 percent or more in saturated fat and a minimum reduction of more than 1 g of saturated fat per serving from a reference food. The agency believes that a reduction of 25 percent or more is necessary to ensure that consumers are not misled by claims for reductions that are inconsequential, i.e., that the products will serve a useful role in the diet of those individuals who are attempting to limit their consumption of saturated fat.

Additionally, the requirement for an absolute reduction of more than 1 g is necessary to preclude manufacturers from making comparative claims for products that are relatively low in saturated fat and therefore in which even a high percentage reduction in saturated fat content would be inconsequential. For example, without the inclusion of an additional criterion, a food containing only 2 g of saturated fat per serving could be reformulated to contain 1.5 g of saturated fat per serving and thereby qualify to use a comparative claim. In fact, the reduction of 0.5 g of saturated fat cannot be considered either substantial or of nutritional significance.

As discussed under comparative claims for fat, FDA is proposing in § 101.13(j)(1) in the companion document on nutrient content claims that for comparative claims, the reference food may be an industry-wide norm, the manufacturer's regular product, or, when the comparison is to a class of similar foods, to a current, valid data base such as USDA's Handbook No. 8, "Composition of Foods, Raw, Processed, Prepared."

Additionally, the labeling requirements proposed in § 101.62(c)(4)(ii) are identical to those for "reduced saturated fat" claims in proposed § 101.62(c)(3)(ii). The information that must be presented in immediate proximity to the most prominent use of the comparative claim is the percent or fraction that the saturated fat is reduced, the identity of the reference food to which the comparison is made, and the quantitative information that compares the actual amount of saturated fat in a serving of the food to the amount in the reference food.

4. Need for Additional Definitions

The agency is requesting comments on whether there are any other definitions that are necessary to effectively inform consumers about fat and fatty acid content. The agency is not proposing definitions for terms that describe the content of monounsaturated or of polyunsaturated fatty acids. Although the supporting text in some consensus reports (Refs. 6 and 9) noted the likelihood of reducing the risk for CHD (Ref. 9) and atherosclerotic cardiovascular disease (Ref. 6) when specific unsaturated fatty acids are substituted for saturated fatty acids in the diet, the conclusions of these reports did not include quantitative recommendations with respect to intakes of these fatty acids. Therefore, the agency has tentatively concluded that, except for use of the comparative term "more," which is discussed in the companion document on nutrient content claims, the scientific evidence is not sufficiently clear to establish the need for nutrient content claims for unsaturated fatty acids. The agency invites comments on this view.

The agency also is not proposing to define the term "saturated fat free." The agency has proposed in § 101.62(c)(1)(i) to establish a per serving criterion for "low in saturated fat" claims at 1 g or less. This amount is approximately ⅓ the level of fat that it has proposed would qualify for the "low fat" descriptor (3 g or less per serving) and corresponds with dietary guidance that saturated fat should amount to no more than ⅓ of the total fat intake in the diet. The agency believes that the amount of saturated fat that would justify a "saturated fat free" claim should similarly be ⅓ of the maximum fat content permitted to make a "fat free" claim. This standard would result in a criterion of 0.17 g or less of saturated fat per serving. Analytical methodologies for assessing saturated fat content are not precise at such low levels, however. Also, from a food processing point of view, control at such a low level may be difficult. Therefore, the agency has concluded that a "saturated fat free" claim is not feasible.

5. Other Comments

Several comments to the tentative final rule argued that the declaration of fatty acid content ought to be mandatory within nutrition labeling and recommended breaking out additional subcomponents, such as omega-3, omega-6, and trans fatty acids.

At the time the tentative final rule was issued, the 1990 amendments had not been passed. As a result, including saturated fatty acids as a required element of nutrition labeling was only a proposal, and the agency could not assume that this proposal would be adopted. Hence, FDA included discussions on the type and form of fatty acid labeling in the tentative final rule. With the passage of the 1990 amendments, the inclusion of saturated fat within nutrition labeling has become more of a certainty.

The issue of exactly what should be included in nutrition labeling, including what type of breakdown of fatty acid content should be included, is being considered as a part of the agency's supplementary nutrition labeling proposal. Therefore, there is no need to consider that issue as part of this rulemaking.

D. Cholesterol Claims and Responses to Comments to the Tentative Final Rule

1. Thresholds and Other General Requirements for Cholesterol Claims

a. *Saturated fat thresholds.* Several comments to the tentative final rule on cholesterol nutrient content claims (55 FR 29456) objected to the saturated fat thresholds on cholesterol claims. Many of these comments asserted that FDA did not have the legal authority to prohibit truthful claims. They stressed the need for consumer education rather than prohibition of claims. One comment argued that scientific evidence does not show that following dietary guidelines to reduce fat and saturated fat intake will decrease the risk of CHD.

While the agency concluded that it had the authority under sections 403(a)(1), 201(n), and 701(a) of the act to propose threshold levels of fat and saturated fat in the tentative final rule (55 FR 29456), its authority was clarified by passage of the 1990 amendments, particularly section 403(r)(2)(A)(vi) of the act. This section states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food."

One of the main purposes of this rulemaking is, by defining cholesterol content claims, to provide consumers with information that they can use to reduce their risk of CHD. There is convincing evidence that dietary intake of saturated fatty acids is also a significant factor in the etiology of this disease. The Surgeon General's Report, for example, states that "excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels" (Ref. 5, p. 11), and the NAS's "Diet and Health" report found a strong relationship between blood cholesterol levels and the prevalence and incidence of atherosclerotic CHD (Ref. 6). Accordingly, the agency believes it would be misleading for a food that contains significant amounts of saturated fatty acids to make claims regarding cholesterol content and, thereby, to encourage consumers to buy the product for the purpose of reducing their risk of heart disease.

The agency agrees that consumer education programs are necessary to explain the relationship of cholesterol and saturated fat to the risk of cardiovascular disease. However, FDA is not persuaded that such programs can effectively reach and be understood by all consumers. A recent FDA consumer survey found that 40 percent of respondents thought that a "cholesterol free" food would also be low in saturated fat, and another 20 percent were not sure what the claim implies about saturated fat content (Ref. 33). The survey found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart disease (Ref. 33). These findings lead FDA to conclude that a significant number of consumers are likely to believe that a food that bears a cholesterol content claim will help to lower blood cholesterol levels and to reduce the risk of heart disease. In point of fact, foods containing little or no cholesterol can contain saturated fats at levels that can contribute to high blood cholesterol which, in turn, can contribute to atherosclerotic CHD (Ref. 6). Accordingly, FDA continues to believe that to ensure that cholesterol content claims do not mislead consumers, it is necessary to permit their use only when the foods also contain levels of saturated fats that are below a specified threshold level.

The agency, therefore, is proposing in § 101.62(d) to prohibit the use of cholesterol content claims, including, in a change from the tentative final rule, "reduced cholesterol" and comparative claims, on foods that contain more than 2 g of saturated fatty acids per serving.

b. *Appropriate threshold level for saturated fat.* Many comments suggested changing the threshold levels for saturated fatty acids. The agency had proposed levels of 2 g or less per serving and 6 percent or less saturated fat on a dry weight basis. Most of the comments were opposed to the percent dry weight criterion. They argued that a dry weight limit would discourage the development of new food products with lower fat and cholesterol contents, particularly those in which water is substituted, in part, for fat. Comments stated that the development of new food technologies to produce more healthful foods would be hampered, and that the dry weight criterion was unnecessary and would unfairly penalize foods that have a high moisture content. One comment also objected to the 2 g criterion and suggested lowering the threshold level to 1 g, related to suggested changes in the definition of "saturated fatty acids."

The agency is persuaded that the dry weight criterion is not necessary and is possibly counterproductive to the "Healthy People 2000" objective of increasing the availability of processed food products that are reduced in fat and saturated fat content (Ref. 24). Accordingly, FDA is deleting the dry weight criterion.

In regard to the definition for "saturated fatty acids," the agency noted in the tentative final rule on cholesterol nutrient content claims (55 FR 29459) that this definition was the subject of another rulemaking, namely the proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." The discussion of this definition has been carried forward in the agency's supplementary mandatory nutrition labeling proposal. FDA recognizes the relationship between the definition, that is, the particular fatty acids that are included in the definition, and the numerical value associated with this threshold level (as well as the values defining "low" and "reduced" saturated fat) and will make adjustments in the proposed threshold level as necessary if the definition is modified in the associated rulemaking on nutrition labeling. However, if the definition of "saturated fatty acids" is not modified, the agency does not find compelling reasons, given in the comments, to revise the per serving value of 2 g. Accordingly, FDA is proposing in § 101.62(d)(1)(i)(B) and (d)(1)(ii)(B), (d)(2)(i)(B) and (d)(2)(ii)(B), and (d)(4)(i)(B) and (d)(4)(ii)(B) that the terms "cholesterol free," "low cholesterol," and "reduced cholesterol," respectively, be allowed only when the food product contains 2 g or less of saturated fatty acids per serving. A similar requirement is proposed for comparative cholesterol claims in § 101.62(d)(5)(i)(B) and (d)(5)(ii)(B).

As a result of this 2 g saturated fat threshold above which cholesterol claims may not be used, FDA tentatively concludes that it is not necessary to propose a requirement, based on section 403(r)(2)(A)(iii)(II) of the act, that the saturated fat content be disclosed adjacent to a cholesterol claim whenever the amount of saturated fat exceeds a set value. As discussed in the companion document on descriptor claims published elsewhere in this issue of the **Federal Register**, FDA is proposing in § 101.13(h) that the disclosure level for saturated fat be 4 g per serving or per 100 g. This value is 15

percent of the proposed DRV for saturated fat and is proposed as the level of saturated fat "that increases to persons in the general population the risk of disease or a health related condition which is diet related" as required by section 403(r)(2)(A)(iii) of the act. Because the agency is proposing that it would be misleading to make a cholesterol claim on a food exceeding 2 g of saturated fat, disclosure of levels of 4 g and above have no application to cholesterol claims.

c. *Fat thresholds.* Many comments to the tentative final rule (55 FR 29456) were opposed to the use of a total fat threshold that would prohibit cholesterol claims on foods that contain more than 5 g fat per serving and more than 20 percent fat on a dry weight basis. Some of these comments argued that current scientific knowledge does not support an association between the intake of total fat and high blood cholesterol as it does with saturated fatty acid intake, and therefore that a limit on total fat does not pass scientific scrutiny. Comments also asserted that such a threshold would condone the "good food/bad food" concept by requiring individual foods (and even ingredients of foods), rather than the total diet, to meet dietary guidelines of less than 30 percent of calories from fat.

A few comments pointed out that FDA surveys show that many consumers believe that cholesterol is found in all fats and oils, and that this finding demonstrates that there is a need for consumer education (which could include declarative statements adjacent to claims informing consumers of the total fat content of the product) rather than removal of truthful claims. Comments also stated that a total fat threshold would be a disincentive to the food industry to formulate low cholesterol and low fat foods, which would hinder the achievement of the "Healthy People 2000" objectives (Ref. 24). Comments also pointed out that such a threshold would interfere with harmonization between the U.S. and Canada, because Canada only restricts the saturated fatty acid content of foods making cholesterol claims.

FDA does not agree that a threshold for disallowing a descriptor supports a "good food/bad food" concept. The agency believes that such a threshold merely restricts the use of nutrient content claims to those foods on which they will not be misleading. However, FDA is persuaded by the comments that a cholesterol claim is not inherently misleading on a food that is high in total fat but contains 2 g or less of saturated fatty acids per serving.

The agency notes that Congress in the 1990 amendments appears to have considered that, in appropriate circumstances, cholesterol claims could be made on foods that contain significant levels of fat (see 21 U.S.C. 343(r)(2)(A)(iii)). For example, House Report 101–538 (Ref. 34, p. 20) states that a "no cholesterol" claim may be allowed on margarine, a food that is largely fat, under certain conditions. Accordingly, the agency is deleting the total fat thresholds.

d. *Conditions for use of cholesterol claims on foods exceeding disclosure levels of fat.* A cholesterol claim represents and suggests that the product provides a health benefit, and the level of fat in the food has a material bearing on this claim. This position is supported by section 403(r)(2)(A)(iii) of the act, which states that if a food contains fat or saturated fat in an amount that increases the risk for persons in the general population of developing a diet-related disease or health condition, it may not make a claim with respect to cholesterol unless it meets certain requirements and discloses the amount of total fat or saturated fat in immediate proximity to such claims.

Section 403(r)(2)(B)(ii) of the act provides similar language for nutrient content claims with the requirement that any nutrient in a food at a level that increases risk of diet related disease or health condition shall prominently disclose that nutrient on the label or in labeling in immediate proximity to the claim. FDA is referring to this level as a "disclosure level." The act goes even further with respect to health claims. In section 403(r)(3)(A)(ii), the act prohibits, except in special circumstances, health claims for a food if any nutrient is present in the food in an amount that increases the risk of diet-related disease or health condition. FDA will refer to this level as a "disqualifying level." The statutory language defining a disclosure level for a nutrient in conjunction with a nutrient content claim is the same as that for a disqualifying level for the nutrient for a health claim. Consequently, FDA is proposing the same levels for the individual nutrients for both types of claims.

The disclosure level for fat is proposed in § 101.13(h) of the companion document on nutrient content claims as an amount that is more than 11.5 g per serving or per 100 g of food. The identical amount is proposed in § 101.14(a)(5) of the proposed rule on health claims published elsewhere in this issue of the **Federal Register** as the disqualifying level for fat for health claims. In the proposed rule on health claims, the agency discusses how it arrived at the proposed disclosure and disqualifying levels.

Briefly, in setting such levels, FDA considered that there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease. Therefore, if FDA were to attempt to set these levels on an individual food basis, it would not be possible to do so. However, sections 403(r)(2)(B)(ii) and 403(r)(3)(A)(ii) of the act require that the agency take into account the significance of the food in the total daily diet. The intake of nutrients such as fat, saturated fat, and cholesterol in the total day's diet in excess of dietary recommendations increases the risk of diet-related disease. Therefore, because the agency's proposed DRV's for total fat, saturated fat, cholesterol, and sodium are based on recommended dietary intake levels, the agency tentatively decided to tie the disclosure and disqualifying levels to the DRV's.

To determine the appropriate disclosure/disqualifier levels, FDA used an approach based on the number of servings of food in a day and available information on food composition. As described in the health claims proposal, the agency has tentatively found that an appropriate disclosure/disqualifying level for individual foods is between 10 and 20 percent of the DRV. The agency made this tentative finding by looking at the food supply. It noted that the nutrients fat, saturated fat, cholesterol, and sodium are present in roughly one-half of the general USDA food categories. Therefore, if approximately 20 foods/beverages are consumed in a day and half of the foods consumed contain the nutrient at a level of 10 percent of the DRV (on average), then the total daily intake of the nutrient would be 100 percent of the DRV. This level of intake would not constitute a risk for chronic disease. On the other hand, if the same number of foods are consumed and half the foods contain on average 20 percent of the DRV, then the total daily intake of the nutrient would be 200 percent of the DRV, a level of intake that would increase the risk for diet-related disease. The agency then used food composition data to evaluate the effect of establishing various disclosure/disqualifying levels between 10 and 20 percent and tentatively concluded that a level of 15 percent of the DRV was most appropriate. If one-half of the foods consumed during the day contains on average this amount, the total daily intake of the nutrient

would exceed the DRV but without the risks inherent at higher levels. Yet, if this criterion is used, a significant number of foods would not be disqualified. Thus, FDA is proposing to establish disclosure/disqualifying levels for total fat, saturated fat, cholesterol, and sodium, and that these levels be 15 percent of the DRV per serving and per 100-g of food. These levels are 11.5 g for total fat, 4.0 g for saturated fat, 45 mg for cholesterol, and 360 mg for sodium. FDA is proposing that the disclosure/disqualifying levels apply on a 100–g basis as well as on a serving size basis to prevent nutrient-dense foods (i.e., those foods that contain relatively high concentrations on a caloric basis of one or more of the subject nutrients) that are consumed in small servings from being promoted for increased use in a diet through the use of health claims or nutrient content claims.

Accordingly, to implement section 403(r)(2)(A)(iii) of the act, FDA is proposing in § 101.62(d)(1)(ii)(C), (d)(2)(ii)(C), (d)(4)(ii)(C), and (d)(5)(ii)(C) that a "cholesterol free," "low cholesterol," "reduced cholesterol," or a comparative claim, respectively, may be made on foods containing more than 11.5 g of fat per serving or per 100 g of food only if, in addition to meeting the requisite cholesterol and saturated fat levels, the food label or labeling discloses the level of total fat in a serving of the food as labeled. The agency believes this requirement, if adopted, will prevent consumers from being misled about the health benefits of the product by the cholesterol claim.

In accordance with section 403(r)(2)(A)(iii)(II) of the act, FDA is also proposing in these paragraphs that the disclosure of fat must appear in immediate proximity to such claim and with appropriate prominence, that is in type that is no less than 1/2 the size of the type used for such claim. Because the level of fat has a material bearing on the claim, FDA is proposing that the disclosure of fat come immediately after the claim and before the referral statement required by § 101.13(g) (i.e., "See [*appropriate panel*] for nutrition information"). To limit unnecessary duplication of information, FDA is also proposing that if the claim appears on more than one panel, the requirement of the act will be met if the fat content is disclosed adjacent to the claim on each panel except for the panel that bears nutrition labeling, where it will not be required. Likewise, if the claim appears more than once on a panel, the requirement of the act will be met if the fat content is disclosed adjacent to the claim that is printed in the largest type on that panel. This proposal is similar to that proposed in § 101.13(g) of the companion document on nutrient content claims regarding the referral statement.

In addition to requiring that total fat levels be disclosed in immediate proximity to any cholesterol claims made on labels of foods that have more than 11.5 g of fat, section 403(r)(2)(A)(iii) of the act identifies two other conditions for use of cholesterol claims on such foods. These conditions are: (1) "the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share," or (2) "the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food" (21 U.S.C. 343(r)(2)(A)(iii)(I)).

i. *Substantially less.* In regard to the first condition, FDA is proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) to permit "free" and "low" cholesterol claims to be made on foods that contain more than 11.5 g of total fat if the foods meet the required cholesterol levels for the claim as a result of special processing, alteration, formulation, or reformulation that caused them to contain "substantially less" cholesterol than the reference foods.

The agency is proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) to define "substantially less" in a way that is consistent with the requirements of § 101.62(d)(5)(i)(A) for a comparative claim using the term "less." Proposed § 101.62(d)(5)(i)(A) provides that to make a comparative claim, a food must contain at least 25 percent less cholesterol, with a minimum reduction of more than 20 mg of cholesterol per serving, than the reference food. The 25 percent reduction is consistent with the agency's position that a 25 percent or greater reduction in a nutrient for which excess consumption is a public health concern is consequential (that is, substantial) because it will assist persons attempting to limit their consumption of the nutrient to meet dietary recommendations. This position is the basis for comparative claims for sodium (49 FR 15510 at 15521, April 18, 1984) and for cholesterol as proposed in § 101.25(a)(2)(iv) of the tentative final rule. It also corresponds with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent.

FDA is proposing, as the second criterion for "substantially less," a minimum reduction of more than 20 mg of cholesterol per serving to preclude manufacturers from making inconsequential changes in a product, which, because of the initial low level of the nutrient, results in considerable reductions in terms of percent but not in terms of absolute amounts. The level of more than 20 mg cholesterol is that amount which exceeds the level proposed for a "low cholesterol" claim. FDA has tentatively concluded in its companion document on nutrient content claims that if a food is to make a consequential as well as a measurable reduction in a nutrient, the absolute reduction should not be less than that amount which is considered to be "low."

In reference to the requirement in section 403(r)(2)(A)(iii)(I) of the act that the level of cholesterol be less than the level usually present in the food "or in a food which substitutes for the food," the agency is proposing in § 101.62(d)(1)(ii)(E), (d)(2)(ii)(E), (d)(4)(ii)(A), and (d)(5)(ii)(A) for "cholesterol free," "low cholesterol," "reduced cholesterol," and comparative cholesterol claims, respectively, that the substitute food meet the requirements for a substitute food proposed in § 101.13(d) of the companion document on nutrient content claims. Proposed § 101.13(d) states that a substitute food is a food that organoleptically, physically, and functionally resembles the food for which it substitutes, that may be used interchangeably with such food, and that is not nutritionally inferior (as defined in current § 101.3(e)(4)). For example, vegetable oil margarine resembles butter in its performance characteristics (i.e., organoleptic properties, physical attributes, and functional properties), is used interchangeably with butter, and is not nutritionally inferior to butter. Therefore, a "cholesterol free" claim would be allowed for vegetable oil margarine on the basis that it substitutes for butter and contains substantially less cholesterol than butter.

Section 403(r)(2)(A)(iii)(I) of the act also requires that the substitute food discussed in the preceding paragraph have a "significant market share." FDA is proposing to find that a food has a significant market share if it has a market share of 5 percent or more of the sales of that category of foods according to an authoritative marketing data base. Examples of national data bases of food sales include those developed by The A.C. Nielsen Co. and Information

Resources, Inc. The agency is proposing to define "significant market share" as 5 percent or more because, for most categories of foods, products with less than this amount are not likely to remain on the market. Many retailers will not carry products with less than 5 percent of the market, and manufacturers find it uneconomical to continue to produce and market such products (Ref. 35). Therefore, in proposed § 101.62(d)(1)(ii)(E), (d)(2)(ii)(E), (d)(4)(ii)(A), and (d)(5)(ii)(A) for "cholesterol free," "low cholesterol," "reduced cholesterol," and comparative cholesterol claims, respectively, FDA is proposing to parenthetically define "significant market share" as a market share of 5 percent or more.

The agency is also proposing in § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) that foods containing more than 11.5 g of fat per serving or per 100 g of food that make "free" and "low" cholesterol claims on the basis of containing "substantially less" amounts than another food be labeled in accordance with proposed § 101.13(j)(2) for all relative claims. Similar requirements exist in § 101.62(d)(4)(i)(C) and (d)(4)(ii)(D) for foods making "reduced cholesterol" claims and in § 101.62(d)(5)(i)(C) and (d)(5)(ii)(D) for foods making comparative cholesterol claims. Thus, if the agency adopts these requirements, the label or labeling would have to bear, in immediate proximity to the claim, a statement of the percent of reduction, identification of the reference food, and quantitative information comparing the product's per serving cholesterol content with that of the reference food (e.g., "Cholesterol free margarine, contains 100 percent less cholesterol than butter (0 mg of cholesterol compared with 30 mg in one serving of butter). Contains 11 grams of fat per serving."). (Note: Even though margarine contains less than 11.5 g per serving, it contains more than 11.5 g per 100 g, and therefore a "cholesterol free" claim on this food must disclose the amount of total fat.)

ii. *Absence claims.* The second condition in section 403(r)(2)(A)(iii) of the act for allowing cholesterol claims on foods that have more than 11.5 g of fat is that absence (i.e., "free") claims may be permitted on the basis of a finding that while cholesterol is not usually present in the food, such a claim would assist consumers in maintaining healthy dietary practices, and the claim discloses that cholesterol is not usually present in the food.

Consistent with the discussion on claims for foods that are inherently free of fat, FDA believes it is helpful to consumers to highlight "cholesterol free" foods useful in maintaining healthy dietary practices whether the food is inherently free of cholesterol or is processed to be that way. Several FDA surveys have shown that consumers want and use descriptor claims to identify foods having positive nutritional attributes (Refs. 19 through 21). These survey results, in conjunction with comments to the 1989 ANPRM, have persuaded FDA that the definitions established in this proposed rule respond to consumers' needs and help to educate consumers on the intrinsic properties of foods. Therefore, FDA has tentatively concluded that it is not necessary to limit "cholesterol free" claims to foods in which cholesterol is usually present or that substitute for foods that usually contain cholesterol.

However, the agency is concerned that unrestricted use of "free" claims on foods that are inherently free of cholesterol can be misleading since the claim could imply that the particular brand of food bearing the claim is different from other foods of the same type. Accordingly, FDA is proposing in § 101.62(d)(1)(ii)(D) to require that if a food is inherently free of cholesterol (i.e., it has not been processed, altered, formulated, or reformulated to remove cholesterol) it may make a cholesterol claim only if the claim refers to all foods of that type and not merely to the particular brand to which the labeling is attached (e.g., "Canola oil, a cholesterol-free food"). Such claims are subject to additional disclosure requirements in § 101.62 and § 101.13 (e.g., "Contains 14 g fat per serving" and "See [*appropriate panel*] for information on fat and other nutrients"). (Note: The agency does not consider margarines to be inherently free of cholesterol since the standard of identity for margarine allows for the use of animal fats.)

This requirement is consistent with the general policy on "free" and "low" nutrient content claims stated in rulemaking for sodium (49 FR 15510 at 15517) and cholesterol descriptor claims (51 FR 42584 at 42589 and 55 FR 29456 at 29465) and set forth in current § 105.66(c)(2) for "low calorie" claims. The agency has taken the position that foods inherently free of, or low in, a nutrient should not be labeled with a claim such as "cholesterol free," or "low cholesterol," immediately preceding the name of the food because such terminology would imply that the food has been altered to remove the nutrient as compared to other foods of the same type. Thus, FDA is proposing in § 101.62(d)(2)(i)(C) and (d)(2)(ii)(D) that foods that inherently contain 20 mg or less of cholesterol may be labeled as "low cholesterol" as long as the label makes clear that all foods of that type, and not merely the brand to which the label attaches, are low in cholesterol (e.g., "lowfat cottage cheese, a low cholesterol food").

For the same reasons, FDA is proposing in § 101.62(d)(1)(i)(C) to reflect the statutory language of section 403(r)(2)(A)(ii)(II) of the act by proposing to require that foods that contain less than the disclosure level of fat and that are inherently free of cholesterol must disclose that cholesterol is not usually present if they make a "cholesterol free" claim (e.g., applesauce, a cholesterol free food"). Foods that contain less than the disclosure level of fat and that have been processed to contain less than 2 mg of the cholesterol that is usually present in the food, or that have substitutes that contain cholesterol, can bear a "cholesterol free" claim under section 403(r)(2)(A)(ii)(I) of the act and proposed § 101.62(d)(1)(i)(A).

e. *Application of saturated fat thresholds to "reduced cholesterol" foods.* Comments were mixed on whether the fat and saturated fat thresholds should apply to "reduced cholesterol" claims. Several comments expressed the belief that reduced claims should adhere to the same thresholds as "free" or "low" cholesterol claims to be consistent and, thereby, to avoid consumer confusion and to provide "a level playing field." One such comment expressed the opinion that any cholesterol claim will convey to consumers the impression that a food is a healthy choice, and, therefore, a "reduced cholesterol" claim would be misleading if it did not have the same thresholds as "free" and "low" claims. Opposing comments supported the proposed position of not applying threshold levels to foods making "reduced" claims, stating that the use of thresholds would prevent some foods from making claims, thereby depriving consumers of useful information and the selection of foods with significant reductions in cholesterol.

The agency is convinced by the comments and the scientific evidence that cholesterol content claims can be misleading to consumers if the product contains amounts of saturated fat that contribute to high blood cholesterol levels. As stated above, a cholesterol claim represents and suggests that the product provides a health benefit, and that benefit is missing if the product contains high levels of saturated fat. Therefore, under section 403(r)(2)(A)(vi) of the act, which prohibits a claim if the claim is misleading in light of the level

of another nutrient, the agency is proposing to apply the saturated fat threshold to "reduced" as well as to free" and "low" cholesterol claims. Accordingly, FDA is modifying proposed § 101.25(a)(iii) in the tentative final rule (redesignated as § 101.62(d)(4) in this document) to require that "reduced cholesterol" claims only be used on labels or in labeling of foods that contain less than 2 g of saturated fat per serving. For these reasons, the agency is also including a similar requirement in proposed § 101.62(d)(5) for comparative claims.

2. "Cholesterol Free"

a. *Definition.* FDA first proposed that a "cholesterol free" food be defined as one containing less than 2 mg of cholesterol per serving in its proposed rule of November 25, 1986 (51 FR 42584). The agency selected a cutoff of less than 2 mg of cholesterol because that level is biologically and nutritionally insignificant. Moreover, analytical precision below that limit is not possible (51 FR 42584 at 42588). This quantitative amount was carried forward in the agency's tentative final rule on cholesterol nutrient content claims (55 FR 29456). In the tentative final rule, the agency rejected comments to the 1986 proposal that suggested that the level used in defining "cholesterol free" should be changed. Differing comments had recommended both lowering the defined amount to absolute zero and raising it to 5 mg per serving. FDA responded that a zero level could not be detected with analytical certainty, and that raising the level up to 5 mg could result in consumption of dietarily significant amounts of cholesterol when only "cholesterol free" foods were consumed.

A few comments on the 1990 tentative final rule reiterated comments received on the 1986 proposed rule on cholesterol nutrient content claims (51 FR 42584) that the level used in defining "cholesterol free" should be modified. Comments again recommended lowering the defined amount to zero and raising it to 5 mg per serving. However, none of these comments presented any information that the agency had not already received in response to the 1986 proposal and considered in drafting the tentative final rule.

In its tentative final rule, FDA advised that it considered that document to contain the final determination of the agency on all substantive issues other than on the threshold levels of fat and saturated fatty acids, and that a comment would have to be very significant to cause the agency to make any changes in the rule other than to the threshold levels. Therefore, not being presented with any new evidence, FDA has not revised the level of cholesterol in the definition for "cholesterol free" in proposed § 101.25(a)(2)(i), redesignated in this document as § 101.62(d)(1).

FDA is not proposing a second criterion based on the amount of cholesterol per 100 g for the definition of "free" because the first proposed criterion for "cholesterol free" requires that the food contain such a trivial level of cholesterol from a public health perspective that even frequent consumption in large amounts of food that bear a claim would not affect in any meaningful way the overall cholesterol level in the diet.

b. *Synonyms.* In accordance with the discussion on synonyms in the companion document on nutrient content claims, the agency is proposing in § 101.62(d)(1) to add the term "zero cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," and "dietary insignificant source of cholesterol" as a synonym for "cholesterol free," "free of cholesterol," and "no cholesterol." As suggested in the IOM report on nutrition labeling (Ref. 4), the use of consistent and targeted nutrient content claims increases consumers' confidence in the validity of the claim. The agency requests comments on whether consumers commonly understand the other synonyms to have the same meaning as "free."

3. "Low Cholesterol"

a. *Definition.* In its proposed rule of November 25, 1986 (51 FR 42584), FDA proposed to allow the term "low cholesterol" on the label or in labeling of foods that contain less than 20 mg of cholesterol per serving. The agency found that foods containing less than 20 mg of cholesterol per serving were generally those that had been identified as useful to persons who want to control or moderate their cholesterol intakes or to maintain their cholesterol intakes at relatively low levels.

Comments submitted to the proposed rule persuaded FDA to modify the proposed definition in its tentative final rule: (1) To change the definition from "less than 20 mg per serving" to "20 mg or less per serving," and (2) to add a second criterion based on density, namely that the food contain 0.2 mg or less of cholesterol per g of food. FDA made the first change to be consistent with the agency's other definitions for "low," for calories (§ 105.66(c)(1)(i)) and for sodium (§ 101.13(a)(3)), that include the integer in the definition.

FDA made the second change to prevent "low cholesterol" label claims from conveying a misleading impression about the cholesterol content of certain foods. Comments pointed out that a single criterion based on serving size could result in widely recognized "high cholesterol" foods with small serving sizes (e.g., butter, lard, and some processed cheese foods) being labeled as "low cholesterol." These comments stressed that despite their small serving sizes, such foods actually may be consumed frequently and in large amounts, resulting in a substantial total daily intake of cholesterol. In addition, the comments were concerned that a "low cholesterol" claim on such foods could encourage increased consumption of the food, significantly adding to an individual's total cholesterol intake.

The comments to the tentative final rule fully supported the first criterion for "low cholesterol" claims (i.e., that the food should contain 20 mg or less cholesterol per serving). However, several comments requested the second criterion based on cholesterol density (i.e., 0.2 mg per g) be eliminated. These comments argued that promulgation of a regulation specifying serving sizes would negate the need for the second criterion.

As explained in the companion document on nutrient content claims, the agency has determined that, for the reasons discussed above, there continues to be a need for a second criterion for "low" claims even when FDA's rulemaking on serving sizes is completed (Ref. 36). The agency is proposing in that document to base the second criterion on the amount of the nutrient per 100 g of food.

Accordingly, FDA is proposing to keep the second criterion for the definition of "low cholesterol." However, the agency is modifying proposed § 101.25(a)(ii), redesignated as § 101.62(d)(2), to specify the second criterion as 20 mg per 100 g of food rather than 0.2 mg per g, an identical amount.

This definition is in accordance with the general approach described in the companion document on nutrient content claims for arriving at a definition for "low." This approach is described above in the discussions of the definitions of "low fat" and "low in saturated fat." Under that approach, the definition of "low" for a nutrient that is ubiquitous in the food supply, such as calories, is 2 percent of the DRV. If the nutrient is not ubiquitous but is found in more than a few food categories, such as fat, FDA has proposed to define "low" as two times the level that is 2 percent of the DRV. If the nutrient is found at measurable levels in the foods in only a few food categories, the agency has

proposed to define "low" as three times 2 percent of the DRV. Cholesterol, which is found only in foods of animal origin, is in the latter group. The DRV for cholesterol is 300 mg, 2 percent of which is 6 mg. Therefore, the definition of "low" is 18 mg (three times 6 mg). Rounded to the nearest 5 mg increment as is required in current and proposed nutrition labeling regulations, the proposed level is 20 mg per 100 g of food.

FDA is also proposing in § 101.62(d)(2) to allow the use of the synonymous terms, "contains a small amount of cholesterol" in accordance with the discussion on synonyms in the proposed rule on nutrient content claims.

b. *Definition of "low cholesterol" meal-type product.* As discussed in the companion document on nutrient content claims and above for "low fat" claims for meal type products, the agency has received many comments requesting that FDA provide for the use of nutrient content claims on these products. In recognition of the increasing role that meal-type products have in the marketplace, the agency believes that it is important to establish nutrient content claims that will help consumers to identify positive nutritional characteristics of such products. Accordingly, FDA is proposing in § 101.62(d)(3) that a "low cholesterol" claim may be made for a meal-type product that contains 20 mg or less of cholesterol per 100 g of the product. This value is the same as that suggested by GMA (Ref. 22) and uses the same quantitative amount of cholesterol used to define "low cholesterol" for individual foods. As noted above, FDA finds merit in setting nutrient content claims for meal type products on the basis of the amount of a nutrient per 100 g rather than on the basis of the amount per serving and per 100 g as is done for most "low" claims for individual foods. FDA anticipates that people will not consume more than one or two meal-type products per day, rather than the average of 16 to 20 servings of individual foods (Refs. 15 through 17). Therefore, FDA tentatively concludes that it is not reasonable to expect meal-type products to meet the same per serving criteria as individual foods.

For the same reason, FDA is proposing that the saturated fat threshold in § 101.62(d)(2)(i)(B) and (d)(2)(ii)(B) be modified from 2 g or less per serving to 2 g or less per 100 g. This proposed level would allow a 10 ounce meal that meets the requisite cholesterol levels to make a "low cholesterol" claim if it contained less than 5.5 g of saturated fat, a value that is approximately ⅓ of the DRV for saturated fat. FDA is proposing to make a similar modification in the fat level in § 101.62(d)(2)(i) and (d)(2)(ii). Thus, under proposed § 101.62(d)(3), the determination as to whether § 101.62(d)(2)(i) or (d)(2)(ii) applies will be made on the basis of whether the product contains 11.5 g or less of fat per 100 g of food.

4. "Reduced Cholesterol"

In its proposal of November 25, 1986 (51 FR 42584), FDA proposed to allow a "reduced cholesterol" claim on a food that had been specially formulated or processed to reduce its cholesterol content by 75 percent. The 75 percent criterion reflected FDA's concern about the many foods that contain relatively large amounts of cholesterol, and the possibility that products with relatively high levels of cholesterol could easily claim to have reduced cholesterol content if the agency permitted a lesser reduction.

Comments on the proposed rule requested that the percent reduction be lowered to 30 or 50 percent because the 75 percent requirement was unrealistic and technologically infeasible. FDA was not persuaded that cholesterol levels could not be reduced by 75 percent in many foods, and, in accordance with the agency's intent that the "reduced cholesterol" claim be reserved for those products that accomplished a very substantial reduction in the level of cholesterol, it did not change the requirement in the tentative final rule (55 FR 29456).

Comments to the tentative final rule requested that the agency reevaluate its position on the definition of "reduced cholesterol," suggesting that the definition be lowered from 75 percent to 25 or 33 percent. The comments pointed out that consumption surveys reflect a decrease in consumption of cholesterol over the past two decades, and these comments argued that too stringent a requirement for "reduced cholesterol" would limit the incentive for industry to develop "reduced cholesterol" foods to further this trend.

The agency has reviewed the use of "reduced" claims for cholesterol in light of the general criteria for "reduced" nutrient content claims set out in the companion document on nutrient content claims. These general criteria take into consideration the level of reduction that would result in substantial reductions in the nutrient content of foods, the need for consistency of terms, the technological feasibility of reducing levels of nutrients in foods, and the need for dietary changes relative to current intakes of nutrients.

The basis for defining a substantial reduction of a nutrient in food should include consideration of the distribution of the nutrient within the food supply and the amount of reduction that is necessary to produce a substantial reduction in the amount of the nutrient in the diets of individuals. Dietary cholesterol is not ubiquitous in the food supply. It is found only in foods of animal origin. Accordingly, if dietary intake levels of cholesterol are to be reduced substantially, it is important to make substantial reductions in individual foods that are major sources of cholesterol. FDA has reevaluated what level of reduction constitutes a substantial reduction in cholesterol content for several reasons.

First, FDA's 1988 Food Labeling and Package Survey (FLAPS) did not encounter any foods that made "reduced cholesterol" claims (Ref. 37). A few foods that had removed all of their cholesterol content (i.e., egg substitutes) properly bore "cholesterol free" rather than "reduced cholesterol" claims. These results of the FLAPS survey, in addition to earlier comments about the technological unfeasibility of a 75 percent reduction, are significant.

Moreover, comments indicate that lowering the defined level of reduction for "reduced cholesterol" claims from 75 percent to 50 percent would give industry greater incentive to develop new foods that meet the criterion through special processing or reformulation. In addition, this change would allow for greater consistency in the definitions of "reduced" foods because the agency is proposing that "reduced" claims for sodium, fat, and saturated fat be defined as a 50 percent reduction. The importance of such consistency of terms for consumer education purposes was emphasized at the 1989 public hearings and in comments to the ANPRM.

FDA has also examined the need for dietary change in light of dietary recommendations. In the case of dietary cholesterol, NAS's "Diet and Health" report (Ref. 6) and the NCEP report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Ref. 9) recommend consumption of less than 300 mg of cholesterol per day. The agency compared these values to current intake levels reported in a recent food consumption survey and estimates that a reduction in cholesterol intake of 20 percent is needed to lower the cholesterol content of the American diet to amounts recommended in dietary

guidance (Ref. 27). Since substantial reductions in cholesterol can only be made in a few food categories, it is reasonable to triple this value, as was done in calculations above for defining "low cholesterol" foods, to bring the percent change needed to 60 percent, a value that could appropriately be rounded down to 50 percent to maintain consistency with the proposed definitions for "reduced fat," "reduced saturated fat," and "reduced sodium." FDA is persuaded by the comments that a 75 percent reduction, as originally proposed for "reduced cholesterol" claims in 1988 (51 FR 42584) and carried forward in the tentative final rule (55 FR 29456), is not necessary. The factors discussed above, in addition to recent food consumption survey data showing a decrease in cholesterol intake levels, have convinced the agency that the earlier proposed requirement for a 75 percent reduction is not necessary to evoke a sufficient change in the food supply to allow the public to meet current dietary recommendations. Accordingly, the agency is proposing in § 101.62(d)(4)(i)(A) and (d)(4)(ii)(A) that the term "reduced cholesterol" may be used on foods that have been formulated or processed to reduce their cholesterol content by 50 percent.

However, to ensure that a 50 percent reduction amounts to more than an inconsequential reduction in cholesterol content, the agency is also proposing in § 101.62(d)(4)(i)(A) and (d)(4)(ii)(A) to add a second criterion that there be a minimum reduction of more than 20 mg per serving from the reference food. This criterion is consistent with the second criterion for other "reduced" nutrient content claims discussed above and represents an absolute reduction that is no less than the amount which is considered "low."

As proposed in § 101.13(j)(1) of the companion document on nutrient content claims, the reference foods against which "reduced cholesterol" claims are to be measured are either an industry-wide norm or the manufacturer's regular product. These reference points are defined and discussed above in the section on "reduced fat" claims.

The agency is proposing in § 101.62(d)(4)(i)(C) and (d)(4)(ii)(D) that the food that bears a "reduced cholesterol" claim be labeled in compliance with § 101.13(j)(2) as proposed in the companion document on nutrient content claims. This proposed section requires information in immediate proximity to the most prominent use of the claim of the extent (percent or fraction) that the cholesterol is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of cholesterol in a serving of the food to the amount in the reference food.

5. Comparative Claims

Consistent with the earlier discussion of comparative claims describing the fat content of foods, FDA is proposing in § 101.62(d)(5) to allow the use of comparative claims using the term "less" for foods that have been reformulated, altered, or processed in a way that has resulted in a reduction of cholesterol. Proposed § 101.62(d)(5)(i)(A) and (d)(5)(ii)(A) would require a reduction of 25 percent or more in cholesterol and a minimum reduction of more than 20 mg of cholesterol per serving from a reference food. The agency believes that a reduction of 25 percent or more is necessary to ensure that consumers are not misled by claims for reductions that are inconsequential, i.e., that the products will serve a useful role in the diet of those individuals who are attempting to limit their consumption of cholesterol. Additionally, consistent with other relative claims, FDA believes it is important to provide for an absolute reduction that is not less than the amount that is defined as "low" (i.e., more than 20 mg of cholesterol per serving).

As discussed with respect to comparative claims for fat, FDA is proposing in § 101.13(j)(1) in the companion document on nutrient content claims that for comparative claims, the reference food may be an industry-wide norm, the manufacturer's regular product, or, if the comparison is to a class of similar foods, a current, valid data base such as USDA's Handbook No. 8, "Composition of Foods. Raw, Processed, Prepared."

Additionally, the labeling requirements proposed in § 101.62(d)(5)(i)(C) and (d)(5)(ii)(D) are identical to those in proposed § 101.13(j)(2) for all other relative claims. They require, in immediate proximity to the most prominent use of the claim, the percent or fraction that the cholesterol is reduced, the identity of the reference food to which it is compared, and the quantitative information comparing the actual amount of cholesterol in a serving of the food to the amount in the reference food.

IV. Conditions of Use of Defined Terms

A. Foods for Children

In § 101.13(a) of the companion document on nutrient content claims, the agency is proposing to prohibit the use of nutrient content claims, including claims about the fat, fatty acid, or cholesterol content on foods that are specifically intended for infants and toddlers less than 2 years of age. This provision is consistent with the agency's proposed exclusion of the use of claims about cholesterol and fatty acid content in such foods in proposed § 101.25(a)(1)(ii) and (b)(2), respectively, of the tentative final rule on cholesterol nutrient content claims (55 FR 29456).

The agency proposed this provision (55 FR 29456) based on comments to its 1988 proposal on cholesterol nutrient content claims (51 FR 42584). These comments stated that changing the diet of these children toward a more restrictive dietary pattern should await demonstration that such dietary restriction is needed and would support adequate growth and development. The agency agreed with these comments and proposed to exclude the use of nutrient content claims and quantitative cholesterol and fatty acid labeling on foods specifically intended for use by infants and toddlers. The agency tentatively concludes that this exclusion should also apply to fat nutrient content claims because the issue of a suitable dietary pattern for infants and toddlers includes the issue of the total fat content of their diet. There is agreement among the American Academy of Pediatrics, the American Heart Association, the National Institutes of Health's Consensus Conference on Lowering Blood Cholesterol, and the NCEP that fat and cholesterol should not be restricted in the diets of infants (Ref. 38).

Until the agency has information that a more restrictive dietary pattern (as might be encouraged by the use of these nutrient content claims) is appropriate for these children and would support adequate growth and development, the agency is proposing to bar the use of these nutrient content claims on food products that are specifically intended for infants and toddlers.

B. Use of Defined Terms in Conjunction with Statement of Identity

Comments on the 1989 ANPRM addressed the issue of how claims that describe the fat content of foods should be used with the names of standardized foods. Some of the comments suggested that these terms be allowed in conjunction with the names of standardized foods, even when the resulting food no longer complies with the standard.

This is an important issue that has ramifications for all nutrient content claims. Accordingly, FDA has prepared

a separate document on this issue. It is published elsewhere in this issue of the Federal Register.

C. Misbranding

Proposed § 101.25(g), which was numbered as § 101.25(d) in the cholesterol tentative final rule (55 FR 29456), states that any label or labeling that is not in conformity with this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act. The agency is proposing to retain this provision, redesignated as § 101.62(e) and modified to include authority under section 403(r) of the act.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

The food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA has developed one comprehensive regulatory impact analysis (RIA) that presents the costs and benefits of all of the food labeling provisions taken together. The RIA is published elsewhere in this issue of the **Federal Register**. The agency requests comments on the RIA.

VII. Effective Date

FDA notes, however, that in section 10(a)(3)(B) of the 1990 amendments, Congress provides that if the Secretary of Health and Human Services (the Secretary), and by delegation FDA, finds that requiring compliance with section 403(q) of the act, on mandatory nutrition labeling, or with section 403(r)(2) of the act, on nutrient content claims, 6 months after publication of the final rules in the **Federal Register** would cause undue economic hardship, the Secretary may delay the application of these sections for no more than 1 year. In light of the agency's tentative findings in its regulatory impact analysis that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6 month and 1 year extensions of that compliance date will result in savings that arguably outweigh the lost benefits, FDA believes that the question of whether it can and should provide for an extension of the effective date of sections 403(q) and (r)(2) of the act is squarely raised

FDA has carefully studied the language of section 10(a)(3)(B) of the 1990 amendments and sees a number of questions that need to be addressed. The first question is the meaning of "undue economic hardship." FDA recognizes that the costs of compliance with the new law are high, but those costs derive in large measure from the great number of labels and firms involved. The agency questions whether the costs reflected in the aggregate number represent "undue economic hardship." Therefore, FDA requests comments on how it should assess "undue economic hardship." Should it assess this question on a firm-by-firm basis, as was provided in the bill that passed the House Committee on Energy and Commerce (H. Rept. 101–538, 101st Cong., 2d sess., 24 (1990)), an industry-by-industry basis, or should it assess this question on an aggregate basis? If the agency should take the latter approach, comments should provide evidence that would permit the agency to make a determination that there is "undue economic hardship" for most companies. FDA also points out that assessing hardship on a firm-by-firm basis would likely be extremely burdensome because of the likely number of requests.

FDA will consider the question of the meaning and appropriate application of section 10(a)(3)(B) of the 1990 amendments as soon as possible after the comment period closes. The agency intends to publish a notice in advance of any final rule announcing how it will implement this section to assist firms in planning how they will comply with the act. The early publication of this notice is to assist firms in avoiding any unnecessary expenses that could be incurred by trying to comply with a compliance date that may cause "undue economic hardship."

VIII. Comments

Interested persons may, on or before February 25, 1991, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with section 3(b)(1)(B) of the 1990 amendments, FDA must issue by November 8, 1992, final regulations permitting nutrient content claims for fat and cholesterol. If the agency does not promulgate final regulations by November 8, 1992, section 3(b)(2) of the 1990 amendments provides that the regulations proposed in this document shall be considered as the final regulations. The agency has determined that 90 days is the maximum time that it can provide for the submission of comments and still meet this statutory timeframe for the issuance of final regulations. Thus, the agency is advising that it will not consider any requests under 21 CFR 10.40(b) for extension of the comment period beyond February 25, 1992. The agency must limit the comment period to no more than 90 days to assure sufficient time to develop a final rule based on this proposal and the comments it receives.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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2. Vanderveen, J. E., letter to Stop and Shop Supermarket Co., October 11, 1985.

3. Subcommittee on the 10th Edition of the Recommended Daily Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th Ed.," Washington, DC, National Academy Press, 1989, pp. 32–33.

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5. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health," Publication No. 88–50210, Washington, DC, GPO Stock No. 017–001–00465–1), U.S. Government Printing Office, 1988.

6. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

7. American Medical Association, Report of the Board of Trustees, "Food Labeling and Advertising," Report C (A–90), Annual Meeting, June 19–24, 1990.

8. U.S. Department of Health and Human Services and U.S. Department of Agriculture in "Nutrition and Your Health, Dietary Guidelines for Americans," Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington, DC, 1990.

9. National Heart, Lung, and Blood Institute, "National Cholesterol Education

Progress Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel)," NIH Publication No. 90-3046, 1989.

10. The National Heart, Lung, and Blood Institute, "Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults," *Archives of Internal Medicine*, 148:36-69, 1988.

11. American Heart Association, Nutrition Committee, "Position Statement, Dietary Guidelines for Healthy American Adults," *Circulation*, 77:721A-724A, 1988.

12. American Medical Association, The Council on Scientific Affairs, "Dietary and Pharmacologic Therapy for the Lipid Risk Factors," *Journal of the American Medical Association*, 250:1873-1879, 1983.

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14. World Health Organization, Prevention of Coronary Heart Disease," World Health Organization Technical Report Series 678, Geneva, 1982.

15. Interagency memorandum from Connie Marie Dresser, National Center for Health Statistics, to Marilyn Stephenson, Food and Drug Administration, December 3, 1981.

16. Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86-3, U.S. Department of Agriculture, Hyattsville, MD, September 1988, p. 168.

17. Buzzard, I. M., Letter to Virginia Wilkening, February 12, 1991.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

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

PART 101—FOOD LABELING

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

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

§ 101.25 [Removed]

2. Section 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* is removed.

3. Section 101.62 is added to subpart D to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or, where applicable, § 101.30.

(b) *Fat content claims.* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "nonfat" "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of a food provided that:

(i) The food contains less than 0.5 gram of fat per reference amount customarily consumed and per labeled serving size;

(ii) The food contains no added ingredient that is a fat or oil; and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the food (e.g., "broccoli, a fat-free food").

(2) The terms "low fat," "low in fat," "contains a small amount of fat," "low source of fat," or "little fat" may be used on the label or in labeling of foods, except meal-type products as defined in § 101.13(l), provided that:

(i) The food contains 3 grams or less of fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "frozen perch, a low fat food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(l) that:

(i) The product contains 3 grams or less of fat per 100 grams; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat," "reduced in fat," or "fat reduced" may be used on the label or in labeling of a food, except meal-type products as defined in § 101.13(l), provided that:

(i) The food has been specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13 (j)(1)(i) and (j)(1)(ii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced; the identity of the reference food; and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Reduced fat—50 percent less fat than our regular brownie. Fat content has been reduced from 8 grams to 4 grams per serving").

(5) A comparative claim using the term "less" may be used on the label or in labeling of a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less fat, with a minimum reduction of more than 3 grams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13 (j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the fat has been reduced; the identity of the reference food; and quantitative information comparing the level of fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g. "This pound cake contains 40 percent less fat than our regular pound cake. Fat content has been lowered from 10 grams to 6 grams per serving.").

(6) The term "___ percent fat free" may be used on the label or in labeling of a food provided that:

(i) The food meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section.

(ii) The label or labeling discloses the amount of total fat per serving (as declared on the label) of the food expressed to the nearest 1/2 gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) and in type size that shall be no less than one half the size of the type used for such claim.

(iii) The percent of reduction and the words "fat free" are in uniform type size.

(iv) A claim for "100 percent fat free" meets all criteria for "fat free" in paragraph (b)(1) of this section.

(c) *Fatty acid content claims.* The label or labeling of foods that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams of cholesterol per labeled serving size.

(1) The terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "a little saturated fat" may be used on the label or in labeling of a food, except meal type products as defined in § 101.13(l), provided that:

(i) The food contains 1 gram or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size, and not more than 15 percent of calories from saturated fatty acids.

(ii) If a food meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "raspberries, a low saturated fat food").

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(l) provided that:

(i) The product contains 1 gram or less of saturated fatty acids per 100 grams of food; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(3) The terms "reduced saturated fat," "reduced in saturated fat," or "saturated fat reduced" may be used on the label or in labeling of a food, except meal-type products as defined in § 101.13(l), provided that:

(i) The food has been specifically formulated, altered, or processed to reduce its saturated fatty acid content by 50 percent or more, with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced; the identity of the reference food: and quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Reduced saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers. Saturated fat reduced from 3 grams to 1.5 grams per serving").

(4) A comparative claim using the term "less" may be used on the label or in labeling of a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 25 percent less saturated fat with a minimum reduction of more than 1 gram per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii); and

(ii) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the saturated fat was reduced; the identity of the reference food; and quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Brand Y crackers contains 40 percent less saturated fat than our regular Brand X crackers. Brand Y contains 6 grams saturated fat; Brand X contains 10 grams saturated fat.").

(d) *Cholesterol content claims.* (1) The terms "cholesterol free," "free of cholesterol," "zero cholesterol," "no cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," or "dietarily insignificant source of cholesterol" may be used on the label or in labeling of a food provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food:

(A) The food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The food contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) As required in § 101.13(e), if the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food").

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size;

(B) The food contains 2 grams or less of saturated fat per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e), if the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "Canola oil, a cholesterol-free food, contains 14 grams of fat/serving"); or

(E) If the food contains less than 2 milligrams of cholesterol per reference amount customarily consumed and per labeled serving size only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share. As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., Cholesterol free margarine, contains 100 percent less cholesterol than butter. Contains no cholesterol compared with 30 milligrams in one serving of butter. Contains 11 grams of fat per serving.")

(2) The terms "low in cholesterol," "low cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," or "little cholesterol" may be used on the label or in labeling of a food, except meal type products as defined in § 101.13(1), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams of food:

(A) The food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) As required in § 101.13(e), if the food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "lowfat cottage cheese, a low cholesterol food").

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), the food contains 20 milligrams or less of cholesterol per reference amount customarily consumed, per labeled serving size, and per 100 grams of food without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 milligrams or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(5)(i)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share. As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "Low cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers. Cholesterol lowered from 30 milligrams to 5 milligrams per serving, contains 13 grams of fat per serving.").

(3) The terms listed in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 101.13(1) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(ii) of this section applies to the product will be made only on the basis of whether the product contains 11.5 grams or less of fat per 100 grams of food, the

requirement in paragraphs (d)(2)(i)(A) and (d)(2)(ii)(A) of this section shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(ii)(B) of this section shall be modified to require that the food contain 2 grams or less of saturated fat per 100 grams rather than per reference amount customarily consumed and per labeled serving size.

(4) The terms "reduced cholesterol," "reduced in cholesterol" or "cholesterol reduced" may be used on the label or in labeling of a food or a food that substitutes for that food as specified in § 101.13(d), except meal type products as defined in § 101.13(l), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i) and (j)(1)(ii);

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 101.13(j)(2) for relative claims, the percent that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol content by 50 percent or more, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food (as defined in § 101.13(j)(1)(i) and (j)(1)(ii)) that it resembles and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol has been reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(5) A comparative claim using the term "less" may be used on the label or in labeling of a food or a food that substitutes for that food as specified in § 101.13(d), including meal-type products as defined in § 101.13(l), provided that:

(i) For foods that contain 11.5 grams or less of total fat per reference amount customarily consumed, per labeled serving size, and per 100 grams:

(A) The food contains at least 25 percent less cholesterol, with a minimum reduction of more than 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food that it resembles and for which it substitutes as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii);

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size; and

(C) As required in § 101.13(j)(2) for relative claims, the percent that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii).

(ii) For foods that contain more than 11.5 grams of total fat per reference amount customarily consumed, per labeled serving size, or per 100 grams of food:

(A) The food contains at least 25 percent less cholesterol, with a minimum reduction of 20 milligrams per reference amount customarily consumed and per labeled serving size, from the reference food as defined in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii) that it resembles and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share;

(B) The food contains 2 grams or less of saturated fatty acids per reference amount customarily consumed and per labeled serving size;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear each time the claim is made, in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims, the percent (or fraction) that the cholesterol was reduced; the identity of the reference food; and quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference food that it replaces are declared in immediate proximity to the most prominent such claim as defined in § 101.13(j)(2)(ii) (e.g., "This pound cake contains 30 percent less cholesterol than our regular pound cake. Cholesterol lowered from 45 milligrams to 30 milligrams per serving. Contains 12 grams of fat per serving.").

(e) *Misbranding.* Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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