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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[Docket No. 91N-0384]

RIN 0905-AD08

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing: (1) To amend its food labeling regulations to define nutrient content claims and to provide for their use on food labels; (2) to provide definitions for specific nutrient content claims that include the terms "low," "free," "reduced," "light" or "lite," "source," and "high;" (3) to provide for comparative claims using the terms "less," "fewer," and "more;" (4) to set forth specific requirements for sodium and calorie claims; (5) to establish procedures for the submission and review of petitions regarding nutrient content claims; (6) to revise 21 CFR 105.66, which covers special dietary foods with usefulness in reducing or maintaining caloric intake or body weight; (7) to establish criteria for the appropriate use of the term "fresh;" and (8) to address the use of the term "natural". FDA is addressing claims for cholesterol, fat, and fatty acid content in a separate proposal published elsewhere in this issue of the **Federal Register**. This action is part of the food labeling initiative of the Secretary of the Department of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may be issued based on 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: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

FDA has a long history of interest in prescribing label statements concerning the dietary properties of food. As early as 1940 (5 FR 1199, March 28, 1940), FDA held a hearing to discuss what label statements might be used to inform purchasers of the value that a particular food purports to have. Initially, these label statements were concerned with foods that purported or were represented to be for special dietary use by humans. While these statements focused to a large extent, but not exclusively, on vitamins and minerals, the early rulemaking also dealt with control of body weight and the value of food for use in dietary management of disease through controlling the intake of various nutrients.

By 1953 (18 FR 7249, November 14, 1953), FDA had begun to focus on specific nutrients such as sodium. The 1953 notice, for example, announced a hearing on label statements relating to certain foods used as a means of regulating the intake of sodium for the purposes of dietary management with respect to disease. On July 1, 1954 (19 FR 3999), FDA issued a final regulation recognizing that sodium restricted diets were widely used for dietary management of edema associated with some types of heart, liver, and kidney diseases; and that food purporting to be, or represented for, special dietary use in regulating the intake of sodium in dietary management should bear information concerning its sodium content.

In 1973 (38 FR 20708, August 2, 1973), FDA issued a final regulation, which was temporarily stayed and later revised, in part, as § 105.3 (21 CFR 105.3), stating that the term "special dietary use" applied to a food supplying a special dietary need that exists by reason of a physical, physiological, or other condition including convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium. In 1978, FDA adopted regulations that defined the terms "low" and "reduced" for describing calorie content and set conditions for other label statements on special dietary foods used to reduce or maintain weight or in diabetic diets (43 FR 43278, September 22, 1978).

In the 1980s, FDA changed the focus of nutrient claims from providing guidance for the dietary management of certain diseases to providing information that is useful to the general population. In 1984, the agency adopted regulations (49 FR 15510, April 18, 1984) that defined how the terms "very low," "low," "free," or "reduced" may be used to describe the sodium content of food. In addition, in 1986, the agency proposed to define terms to describe the cholesterol content of foods (51 FR 42584, November 25, 1986).

This change in focus towards defining descriptors is in large part the result of recent scientific developments and recommendations that have emphasized the role of diet in the maintenance of health. For example, the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS) have jointly developed a set of recommendations known as "Dietary Guidelines for Americans" (Ref. 1). These recommendations, which were published in 1980 and revised in 1985 and 1990, are based on the view that the judicious selection of foods containing low or high levels of certain nutrients as part of an overall diet is prudent on the part of all consumers, not just those with special dietary needs.

In addition, two scientific consensus reports, "The Surgeon General's Report on Nutrition and Health" (1988) (Ref. 2) and the National Academy of Sciences' report "Diet and Health: Implications for Reducing Chronic Disease Risk" (1989) (Ref. 3), concluded that changes in current dietary patterns, namely reducing consumption of fat, saturated fatty acids, cholesterol, and sodium and increasing consumption of complex carbohydrates and fiber, could lead to reduced incidence of certain chronic diseases.

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 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 descriptors such as "low" or "free" to characterize foods.

FDA received over 2,000 written comments in response to this notice, plus over 5,000 responses to a questionnaire that had been distributed by a consumer organization. Over 500 comments addressed issues related to specific descriptors. Four hundred and

fifty addressed the terms "light," "fresh," and "natural." Among those commenting, there was nearly universal agreement that these descriptors should be defined, and that FDA needed to proceed as quickly as possible to develop regulatory definitions for all descriptors that lacked definitions. Approximately 3,500 of the over 5,000 questionnaire responses also supported the need for additional descriptor definitions.

As part of this DHHS food labeling initiative, FDA also held four national public hearings, announced in the **Federal Register** of September 20, 1989 (54 FR 38806), to discuss nutrition labeling and other issues related to food labeling, such as descriptors. Some 200 people, including consumers, health professionals, trade associations and 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.

The comments revealed a common concern about the unregulated use of descriptors. Many comments stated that the proliferation of undefined terms had resulted in confusion for consumers and unfair competition for manufacturers. One comment stated that the terms were "meaningless in the way they are now used and are primarily used as marketing tools rather than as guides for the health conscious consumer." Food industry representatives requested flexibility in the use of descriptors, not only to allow simple content statements ("Contains X amount of sodium") but also to allow statements of nutrient reductions brought about by technological advances.

Comments also generally supported expanding existing definitions for descriptors to include a number of food components of public health significance such as fats and cholesterol. Although some comments addressed specific descriptive terms to be used on the label, few comments recommended nutrient or food component levels to qualify for descriptors. Some food industry representatives did, however, suggest criteria for "high" and "reduced" claims.

Comments from health professional organizations also supported the need for content claims to take into account the negative aspects of food in addition to the positive aspects, in order to not mislead consumers. Finally, several comments emphasized the need for FDA and USDA to be consistent in their definitions of descriptive terms.

On March 7, 1990, the Secretary, Dr. Louis W. Sullivan, announced that FDA would undertake a comprehensive, phased response to the comments on the ANPRM. In the **Federal Register** of July 19, 1990, FDA published its first set of proposals, including a tentative final rule that defined terms for use to describe the cholesterol content of foods (55 FR 29456) and a proposed rule (55 FR 29487, July 19, 1990) to require nutrition labeling on most foods that are meaningful sources of nutrients (hereinafter referred to as the mandatory nutrition labeling proposal). At the same time, FDA published a proposed rule (55 FR 29476, July 19, 1990) in which the agency updated the U.S. Recommended Daily Allowances (U.S. RDAs) used in food labeling and replaced the term "U.S. RDA" with "Reference Daily Intake" (RDI) (the RDI/DRV proposal). In the same proposal, the agency also introduced the term "Daily Reference Value" (DRV) and proposed DRVs for eight food components: total fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrate, fiber, sodium, and potassium. These DRVs are based upon a reference diet of 2,350 calories, which is the population adjusted mean of the recommended energy allowances for persons 4 or more years of age (Ref. 4). Together the RDIs and DRVs are referred to as Daily Values. FDA also proposed (55 FR 29517, July 19, 1990) standardized serving sizes for categories of foods 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 of manipulation of the serving size. The agency stated that these standardized serving sizes will help to ensure that food label claims are not misleading to consumers.

In the fall of 1990, the Institute of Medicine (IOM) of the National Academy of Sciences, issued a report entitled "Nutrition Labeling Issues and Directions for the 1990s" (the IOM report) (Ref. 5). This report addressed, among other things, the use of descriptors on the principal display panel of food labels. The IOM report expressed concern that the unregulated use of these descriptors would nullify the efforts of consumers to make intelligent use of the factual information required on the nutrition label. The IOM report also stated that the absence of definitions for many descriptors would work to the disadvantage of manufacturers who are reluctant to use terms that distort or exaggerate nutritionally unimportant differences.

B. 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 the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act). They strengthen the Secretary's food labeling initiative by clarifying the Secretary's (and by delegation, 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 3 of the 1990 amendments among other things, added section 403(r)(1)(A) to the act. This provision states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim has been specifically defined (or otherwise exempted) by regulation.

In this document, FDA is proposing general principles and procedures to govern the use of nutrient content claims. The agency is also proposing definitions for descriptors except as they apply specifically to cholesterol, saturated fat, and total fat content. The use of descriptive terms for these nutrients, and the use of descriptive terms on standardized foods and on butter, is addressed in separate documents published elsewhere in this issue of the **Federal Register.**

In this document, the agency is also proposing procedures by which a person may petition FDA to revise these regulations, to provide for the use of new or similar descriptive terms, or to provide for the use of implied claims in brand names. It is also proposing to address certain descriptive terms that are used for purposes other than making nutrient content claims, namely "fresh," "natural," and "organic." The agency is proposing to define and provide for the proper use of "fresh," "freshly prepared," and "fresh frozen."

C. Organization of Regulations

To facilitate use of its regulations and to provide for the possibility of additional claims regulations, FDA is proposing to add Subpart D—Specific Requirements for Nutrient Content Claims to 21 CFR part 101. In so doing, FDA is proposing to redesignate current § 101.13 *Sodium labeling* as § 101.61 *Nutrient content claims for sodium content of foods* and to add a new

§ 101.13 *Nutrient content claims—general provisions.* This change will result in a more logical organization to the food labeling regulations. In addition, FDA is proposing to redesignate Subpart F as Subpart G and to add a new Subpart F—Specific Requirements for Descriptor Claims that are Neither Nutrient Content Claims nor Health Claims.

In response to section 3(b)(1)(A)(iii) of the 1990 amendments, the agency is organizing this preamble by descriptive term. However, to the extent that existing regulations are already in place or have been previously proposed, the agency is proposing to organize these regulations by nutrient. Claims for "light" or "lite" are codified separately.

II. General Principles for Nutrient Content Claims

A. Legal Basis

FDA is proposing to establish the conditions under which claims may be made about the level of a nutrient in a food (a nutrient content claim). FDA is also proposing to define various terms that may be used to make these claims. FDA, however, does not consider all terms used to describe a food as nutrient content claims. A term may describe some other attribute of a food such as freshness. Such claims would not be subject to requirements for § 101.13 *Nutrient content claims—general provisions.* FDA has authority to take these actions regarding nutrient content claims 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: (1) 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 (2) 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 adhere to certain dietary recommendations, and because comments to the 1989 ANPRM and testimony at FDA's public hearings on labeling show that consumers are concerned about, and want to adjust, their dietary intake of certain nutrients but are concerned with confusing and misleading label statements, it is important that these label statements not convey a misleading impression about the content of various nutrients in a food. Without clear definitions of the terms that describe the levels of these nutrients in food, manufacturers could use a term like "high in fiber" on products that vary widely in fiber content.

Inconsistent use of the same term on various products could 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 nutrient content of foods. FDA is proposing to do so in this document.

B. Scope

Under section 403(r)(1)(A) of the act, a claim that characterizes the level of a nutrient of the type required by nutrition labeling that is in a food may only be made in accordance with the regulations that FDA adopts under section 403(r)(2) of the act. FDA is incorporating this provision in proposed § 101.13(b). Among other things, such claims may only be made using terms that FDA has defined by regulation (21 U.S.C. 343(r)(2)(A)(i)) and must be made in conjunction with the appropriate labeling statements (21 U.S.C. 343(r)(2)(B)), unless they are subject to one of the exemptions in the act (21 U.S.C. 343(r)(2)(C), (D), and (E)). The remainder of this preamble and the accompanying proposed regulations fill in the details of these basic statutory requirements.

FDA is proposing in § 101.13 to prescribe the circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling (see 21 U.S.C. 343(r)(1)(A) and (r)(2)) In proposed § 101.13(a), FDA, reflecting the introductory language of section 403(r)(1) of the act, states that § 101.13 and the regulations in subpart D of part 101 apply to all foods that are intended for human consumption and that are offered for sale.

The regulation also states the types of claims that are covered. Proposed § 101.13(b), following section 403(r)(1)(A) of the act, limits the use of both express and implied nutrient content claims. The 1990 amendments do not elaborate about what constitutes an expressed or an implied claim. The legislative history, however, specifically the House report on the 1990 amendments (H. Rept. 101–538, 101st Cong., 2d sess. 19 (June 13, 1990)), states that an example of "an expressed claim covered by section 403(r)(1)(A) would be the statement 'low sodium'." Such an expressed claim makes a direct statement about the level of a nutrient, in this case sodium, in a food. Consequently, FDA is proposing in § 101.13(b)(1) that an expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food.

The House report also states that an example of an implied claim would be a statement that "implies that the product is low [or high] in some nutrient * * * but does not say so expressly." (*Id.*) The report cites two examples of implied claims: "lite," which according to the report implies that the food is low in some nutrient but does not say so expressly, and " 'high oat bran' which conveys an implied high fiber message." (*Id.*)

Although FDA is proposing a definition of "light" (or "lite") that is somewhat different than that portrayed in the House report, the agency considers that Congress' choice of the "high oat bran" claim as an example of an implied claim is significant. FDA notes that, based on this example, several other claims being used on the food label would constitute implied nutrient claims. For example, such claims as "contains no tropical oils," "contains no palm oil," and "made with 100 percent vegetable oil," convey an implied message that the product is low in, or free of, saturated fat. Therefore, FDA is proposing in § 101.13(b)(2) to define an implied nutrient content claim as any claim that describes the food, or an ingredient therein, in a manner that implies that a nutrient is absent or present in a certain amount or that may be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy"). Significantly, if FDA adopts this definition, under the provisions of the statute, such implied claims would be prohibited until such time as they are defined by FDA by regulation.

FDA recognizes, however, that an argument can be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers that oat bran is used as a significant ingredient in the product. Furthermore, a similar argument can be made that a statement that a particular ingredient constitutes 100 percent of the food (e.g., "100 percent corn oil" or "100 percent Columbian coffee) should not be considered an implied nutrient content claim when that statement is the statement of identity for the food. Moreover, FDA recognizes that this provision may raise questions about similar claims such as "contains no preservatives" or "contains no artificial flavors or colors." The agency believes that the latter claims cannot be

characterized as nutrient content claims because they do not relate in any way to nutrients of the type that are addressed in section 403(q) of the act. These claims are more appropriately characterized as ingredient claims. FDA requests comments on how to draw an appropriate line between implied nutrient content claims and ingredient claims.

In addition, because of the large variety of statements that can be considered to make implied claims about the level of a nutrient in a food or the usefulness of a food in achieving a diet that conforms to current dietary recommendations, and because of the resource constraints and strict timeframes under which this rulemaking is proceeding, FDA is not proposing to adopt regulations that authorize any implied claims at this time. However, the agency solicits comments concerning criteria for evaluating whether implied claims are appropriate and not misleading as well as information on specific implied claims.

If FDA receives sufficient information in comments, it will consider providing for specific implied claims in the final regulation. Alternatively, the agency may defer action on implied claims until after the rulemakings required by the 1990 amendments are complete. The agency would then consider individual implied claims through the petition process on a case-by-case basis. In this document, the agency is proposing procedural regulations for petitions on nutrient content claims, including those requesting definition of acceptable implied claims.

In § 101.13(b)(3), FDA is proposing to prohibit the use of nutrient content claims on food products that are specifically intended for infants and toddlers less than 2 years of age. The agency is proposing this prohibition for several reasons. Comments received in response to the 1986 proposal on cholesterol descriptors (51 FR 42584, November 25, 1986) 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 in the tentative final rule on cholesterol descriptors (55 FR 29456, July 19, 1990) to exclude the use of descriptors and quantitative cholesterol and fatty acid labeling on foods specifically intended for use by infants and toddlers. Furthermore, there is agreement among the American Academy of Pediatrics, the American Heart Association, the National Institutes of Health's Consensus Conference on Lower Blood Cholesterol and the National Cholesterol Education Program that fat and cholesterol should not be restricted in the diets of infants (Ref. 57). Relatively little attention has been given to the role of the pediatric diet in modifying the risk of other chronic diseases found in adults such as hypertension and obesity (Ref. 3). Thus, the agency lacks evidence that a more restrictive dietary pattern for other nutrients such as sodium or an increased intake for nutrients such as fiber are appropriate and recommended for infants and toddlers. Therefore, until the agency has information that such dietary patterns are appropriate for children and support adequate growth and development, FDA is proposing in § 101.13(a) that nutrient content claims may not be made on foods intended specifically for use by infants and toddlers less then 2 years of age.

The act specifically excludes statements that appear as part of nutrition information from the coverage of section 403(r)(1) of the act. This exclusion was included in the 1990 amendments to make it clear that the information required on the nutrition label, and the optional statements that are permitted as a part of nutrition labeling, are not claims under section 403(r)(1) of the act and are not subject to the disclosure requirements in section 403(r)(2) of the act (Congressional Record H5841 (July 30, 1990)). However, the legislative history of this provision specifically states that the identical information will be subject to the descriptor requirements if it is included in a statement in another portion of the label. (*Id.*) Consequently, FDA is proposing in § 101.13(c) that information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. Proposed § 101.13(c) also states, however, that if such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

C. Labeling Mechanics

The 1990 amendments do not include specific limits on the prominence of nutrient content claims. Although FDA recognizes the importance that certain nutrient content claims can have in encouraging sound dietary practices, it also recognizes that individual foods must be evaluated in the context of the total diet. Consequently, it is important not to overemphasize any one aspect of a single food. Therefore, FDA is proposing to require in § 101.13(f) that a nutrient content claim be, in type size and style, no larger than that of the statement of identity. The agency believes that this proposed requirement will ensure that descriptors are not given undue prominence. Under proposed § 101.13(f), descriptors that are a part of a statement of identity can be in the same type size and style as the other words in the statement of identity.

FDA is proposing this requirement under section 403(f) of the act as well as section 403(r) of the act. Section 403(f) of the act states that a food is misbranded if any statement required by or under the authority of the act is not placed on the label with such conspicuousness, as compared to other words, statements, designs, or devices, as to render it likely to be understood by the ordinary consumer. FDA believes that the requirement in proposed § 101.13(f) is necessary to ensure that importance of the information provided by the nutrient content claim, as well as that provided by the statement of identity, is fully understood by consumers. Because these two items will have at least equal prominence on the label or in labeling, the consumer will be able to judge that they both present important information that must be considered in structuring the total diet.

Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, the following statement: "See _____ for nutrition information" (hereinafter referred to as the referral statement). Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel on which the information described in the statement may be found. FDA is incorporating this requirement in proposed § 101.13(g).

Section 403(r)(2)(B) of the act requires that the referral statement must appear prominently, but it does not contain specific prominence requirements such as type size or style. However, section 403(r)(2)(A)(iii) through (v) of the act requires that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, "have appropriate prominence which shall be no less than one-half the size of the claim." The agency believes that for consistency, and because the referral statement and the statement disclosing the level of another nutrient must both be in immediate proximity to the claim, and therefore must be adjacent to one another, the type size of these statements should be the same. In

addition, FDA has long held that accompanying information should be in a size reasonably related to that of the information it modifies. This relative prominence, when codified, has been one-half the type size of the information modified (e.g., §§ 101.22(i)(2) and 102.5(b)(2)(ii)).

The agency is proposing one-sixteenth of an inch as the minimum type size for the referral statement. One-sixteenth of an inch is specified in § 101.2(c) as the minimum type size for most other mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, nutrition information, and warning and notice statements. Further, one-sixteenth of an inch is the minimum size required in § 101.105(i) for net quantity of contents statements. Consequently, the agency believes that the minimum type size for such information should be one-sixteenth of an inch.

In addition, the agency is proposing that the referral statement be "in easily legible boldface print or type in distinct contrast to other printed or graphic matter." Section 403(r)(2)(B) of the act states that the referral statement for nutrient content claims should be "prominent." In other instances where the act has suggested that information be prominent, FDA has proposed a similar requirement (see, e.g., proposed on percentage labeling of foods purporting to be beverages containing vegetable or fruit juice (56 FR 30452, July 2, 1991)). Therefore, to be consistent with previous actions and to ensure under section 403(f), that the referral statement is presented in a way that makes it likely to be read, FDA is proposing in § 101.13(a)(1) that the referral statement be presented in easily legible boldface print or type.

As stated above, the 1990 amendments require that the referral statement be in immediate proximity to the nutrient content claim. In addition, the related statements required by section 403(r)(2)(A)(iii) through (v) of the act are required to be in immediate proximity to such claims, and no distinction is made as to which statement must be closer to the actual claim. Because the related statements provide more specific information, FDA is proposing that they be presented before the referral statement.

Although there is no specific guidance given as to what constitutes immediate proximity, FDA has traditionally defined immediate proximity as immediately adjacent to, with no intervening material present. Section 101.2(e) of 21 CFR, for example, requires that there be no intervening material among the information that is required to appear on the information panel. By no intervening material, FDA means that there may be no printed matter, either pictorial or character between the two pieces of information. However, a claim may be made immediately preceding, or as part of, the statement of identity. Thus, for purposes of proposed § 101.13(g)(2), when the nutrient content claim immediately precedes or is part of the statement of identity, the statement of identity, or the non-claim part of the statement of identity, will not be considered intervening material. For example, if a product were labeled "Light cupcakes—contain ⅓ fewer calories than our regular cupcakes; see side panel for nutrition information," and no pictorial or written material intervened, the agency would consider that the related statements and the referral statement were in immediate proximity to the nutrient content claim of "light." The term "cupcakes" in this example would not be considered to be intervening material.

Section 3(b)(1)(A)(v) of the 1990 amendments states that the Secretary shall provide that if multiple claims subject to the nutrient content claim regulations are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy the requirements for referral statements. To ensure that this referral statement is adequately prominent, the agency is proposing in § 101.13(g)(3) that the statement be adjacent to the claim that is printed in the largest type on the panel.

Although section 403(r)(2)(B) of the act requires that if a nutrient content claim is made, that referral statement be immediately adjacent to such claim, the agency believes that for those claims that appear more than one time on a panel, the referral statement need only be presented with the most prominent claim. To require referral statements for multiple claims on the same panel would unnecessarily burden the panel and dilute any other information presented on the panel. FDA is proposing to require that the referral statement be adjacent to the claim that is printed in the largest type because that claim is the one most likely to initially be seen by the consumer.

In addition, the agency believes that it is not necessary to include a referral statement if a claim is made on the panel containing nutrition information, because such claim would be made in view of the nutrition information cited in the referral statement. FDA is proposing to codify this provision in § 101.13(g)(2).

D. Disclosure Statements

Section 403(r)(2)(B)(ii) of the act states that if a food that bears a nutrient content claim "contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the required referral statement shall also identify such nutrient." FDA is referring to this level as the "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 disease or health-related 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.

In the proposed rule on health claims published elsewhere in this issue of the **Federal Register**, the agency discusses how it arrived at the various proposed disclosure/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. For the general population, the intake of fat, saturated fat, cholesterol, and sodium in the total day's diet in excess of dietary recommendations increases the risk of diet-related disease. Therefore, because the agency's proposed DRVs for total fat, saturated fat, cholesterol, and sodium are based on recommended dietary intake levels, the agency tentatively decided to tie the disclosure/disqualifying levels to the DRVs.

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 ½ of the foods consumed during a day contains on average this amount, the total daily intake of the nutrient would exceed the DRVs 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 § 101.13(h) 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 grams (g) of food. These levels are 11.5 g for total fat, 4.0 g for saturated fat, 45 milligrams (mg) for cholesterol, and 360 mg for sodium.

The legislative history provides some guidance on how these disclosure statements about the presence of these nutrients should be made. It states that if FDA found, for example, that the fat in a food that bore a nutrient content claim was present at a level that increased the risk of disease or a health-related condition, then the referral statement would read, "See [nutrition panel] for information about fat and other nutrients." Congressional Record H5441 (July 30, 1990). Therefore, the agency is proposing in § 101.13(h) to require this information in the referral statement. Because the agency is proposing in § 101.13(g)(3) that if a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made, and because § 101.13(h) only requires the disclosure statement as part of the referral statement, only one disclosure statement per panel would be required by the proposed regulation.

E. Disqualifying Levels for Nutrient Content Claims

Section 403(r)(2)(A)(vi) of the act provides that FDA can, by regulation, prohibit a nutrient content claim if the claim is misleading in light of the level of another nutrient in the food. FDA has tentatively made such a finding with regard to cholesterol claims and the presence of saturated fat. This finding is discussed in the companion document published elsewhere in this issue of the **Federal Register**. In that document, FDA is proposing to prohibit a claim for cholesterol content in foods containing saturated fat at levels above 2 g per serving.

F. Amount and Percentage of Nutrient Content Claims

Section 3(b)(1)(A)(iv) of the 1990 amendments states that the agency "* * * shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms [that FDA has defined]." In discussing this provision (which at that time was numbered as section 3(b)(1)(A)(iii)), the legislative history states:

> * * * [t]he Secretary is required, in the regulations, to define the circumstances under which statements disclosing the amount and percentage of nutrients in food will be permitted. Those statements must be consistent with the terms that the Secretary has defined under section 403(r)(2)(A)(i) [definition of descriptive terms] and they may not be misleading under section 403(a) in the current law.
>
> Thus, if the Secretary defined "low fat" as less than 1% fat for a particular category of food, the Secretary might conclude that the statement "Less Than 1% Fat" is consistent with the defined term. However, the Secretary might conclude that the statement "Less Than 2% Fat" is not consistent with the definition of "low" because it implies that the product is low in fat when it is not. Following a similar analogy, the Secretary might prohibit the statement "98% Fat Free" while permitting the statement "More Than 99% Fat Free" for a product where "low fat" has been defined as less than 1% fat.
> (Congressional Record H 5841–2 (July 30, 1990))

Like Congress, FDA is concerned that consumers may be easily misled by statements about the percent or amount of a nutrient in a product. The agency received many comments to the ANPRM asserting that statements such as "____ percent fat free" on foods are confusing and misleading. These comments suggest that many consumers do not understand this type of claim or similar claims that a product contains a specified amount of a nutrient such as "contains ____ mg sodium." Additional comments suggested that such claims be prohibited.

A statement that a food contains X percent of a nutrient implies that the food is useful in maintaining healthy dietary practices. If the level of the nutrient in the food was not in fact useful in structuring a healthy diet, the claim would be misleading. For example, claims that a food is "____ percent fat free" 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 gives is incorrect, however, if the food contains a significant amount of fat.

Similarly, since many consumers have a limited knowledge and understanding of the amounts of nutrients that are recommended for daily consumption, a statement declaring that the product contained a specified amount of a nutrient could be misleading. By its very presence, such a statement could give consumers who were unfamiliar with the dietary recommendations the false impression that the product would assist them in maintaining healthy dietary practices relative to the amount of the nutrient consumed when it, in fact, would not. Consistent with the statute, FDA is proposing not to permit the use of claims that state the percent or amount of a nutrient in those circumstances in which they would be misleading and thus would misbrand the product.

The agency believes that foods bearing such claims must be useful in maintaining healthy dietary practices for the claims not to be misleading. Accordingly, in § 101.13(i), the agency is proposing that foods bearing statements about the amount or percentage of a nutrient in a food must meet the definition for "low" in the case of fat, saturated fat, sodium, and calories and "high" for fiber, vitamins, and minerals, and other nutrients for which that term is defined. These definitions are discussed below, in the regulations for the particular nutrients.

G. Nutrition Labeling

Although the 1990 amendments establish that most foods will bear nutrition labeling, some foods are exempt from these requirements. In addition, there are provisions that permit some foods to bear an abbreviated form of nutrition information.

Under current § 101.9, nutrition labeling is required on all products that contain an added vitamin, mineral, or protein or whose label, labeling, or advertising includes any nutrition claim or information. The agency derived its authority to issue regulations to require this nutrition labeling on all foods bearing a claim for added vitamins, minerals, or protein from sections 201(n), 403(a)(1), and 701(a) of the act (21 U.S.C. 321(n), 343(a)(1), and 371(a)). Under section 201(n) of the act, the label or labeling of a food is misleading if it fails to reveal facts that are material in light of representations actually made in the label or labeling. Under section 403(a)(1) of the act, a food is misbranded if its label or labeling is false or misleading in any particular. Finally, under section 701(a) of the act, the agency has authority to issue regulations for the efficient enforcement of the act.

The agency is proposing in § 101.13(m) that a nutrient content claim may be used on the label or in labeling of a food provided that the food bears nutrition labeling that complies with the requirements in § 101.9 or, where applicable, § 101.36.

The applicability of current regulations to restaurant foods was discussed in rulemaking promulgating § 101.10 *Nutrition labeling of restaurant foods* (39 FR 42375, December 5, 1974 and 41 FR 51002, November 19, 1976). In the preamble to the proposed rule, the agency discussed its belief that nutrition education is of prime importance and stated that it will take every opportunity to foster the dissemination of such information to the consumer, including the use of nutrition labeling in restaurants. However, the agency acknowledged that if nutrition information provided in restaurants necessitates the expense of nutrition labeling, the restaurant "may choose not to provide any nutrition information in advertising or labeling, on the basis that the added cost of providing detailed information * * * might cause the project of providing nutrition information not to be worth the expense" (39 FR 42375). Therefore, to encourage the dissemination of nutrition information in the food service industry, FDA proposed to exempt ready-to-eat foods from the requirement of bearing nutrition labeling on food labels if the required nutrition labeling was displayed prominently on the premises by other means, e.g., counter cards or wall posters, where the information would be readily available to the consumer when he is making a menu selection.

Subsequent action on this proposal led to the issuance of a statement of policy in § 3.207 (recodified as 21 CFR 101.10 in the **Federal Register** of March 15, 1977 (42 FR 14302)) that if any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more foods (e.g., a combination consisting of a hamburger, french fries, and milkshake), then, as an alternative to providing nutrition information about each separate food on the food label, the restaurant may instead provide information about the total nutritional value of the combination of foods, provided that the statement of total nutritional value follows the nutrition labeling format and provided that the nutrition information is effectively displayed to the consumer both when he/she orders the food, and when he/she consumes the food.

As discussed in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**, the 1990 amendments specifically exclude restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold (hereafter "restaurant food") from the requirement for nutrition labeling. However, as stated above, the agency believes that it has the authority to issue regulations requiring restaurants that choose to make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

FDA is not, at this time, making any specific provisions for the nutrition labeling of restaurant foods. FDA specifically seeks comment on how it should handle this issue. On one hand, many believe that it is important that consumers be given useful and meaningful nutrition information. On the other hand, many continue to be concerned, as FDA was in 1974, that the cost of compliance not be so high that restaurants will not be willing to offer and identify through nutrient content claims those foods that will assist consumers in selecting diets that provide health benefits. Therefore, the agency is requesting comments on whether and to what extent it has a basis for nutrition labeling when nutrient content claims are made on restaurant foods, or whether a requirement for such labeling would discourage restaurants from making nutrient content claims because of the cost associated with nutrition labeling.

If, based on comments received, FDA were to require nutrition labeling of restaurant foods, should the requirement apply only to large restaurant chains with fixed menu items? Additionally, should the content or format of nutrition labeling be different for the food service industry than for packaged foods? If so, how and why?

FDA recognized in its July 19, 1990 reproposal on mandatory nutrition labeling (55 FR 29504) that certain restaurant-type food service facilities cannot reasonably be expected to provide information concerning nutrient profiles, and that exemptive provisions should be established for such situations. The proposal advised that comments pointed out that nutrition labeling for foods served in restaurant-type facilities present significant feasibility problems in a number of situations. The comments made the following points: These facilities may not be able to develop consistent nutrient information on the foods that they sell because of frequent menu changes and variations in how the consumer wants the food prepared and served. Without nutrient consistency, frequent nutrient analyses would have to be performed to provide consumers with accurate nutrition labeling information. These analyses could become very burdensome. The cumulative costs of these analyses could place undue restrictions on some establishments. Firms could be inhibited from making frequent menu changes or forced to limit the options that consumers have in ordering a food.

Because of these problems, FDA proposed an exemption under section 201(n), 403(a), and 701(a) of the act for restaurant-type foods in the mandatory nutrition labeling proposal (see proposed § 101.9(h)(2), 55 FR 29516). Although the agency wanted to limit the exemptions to only those situations in which it is needed, FDA did not, and still does not, have sufficient indepth knowledge of the food service industry to develop adequate criteria to fairly impose such a limitation. The agency therefore requests comments on this issue.

A related question is what is to be done with § 101.10. Because § 101.10 was adopted under section 403(a) of the act, it is not subject to State enforcement under section 307 of the act. For this reason, and because § 101.10 has not been enforced by FDA, the agency believes that it is appropriate to make an affirmative statement about the continuing need for this provision. Thus, if FDA elects not to make restaurant labeling part of the Nutritional Labeling Education Act implementation, the agency will, in the final rule, delete § 101.10.

H. Analytical Methodology

The agency has proposed analytical methodology for measuring levels of nutrients in foods in the supplementary nutrition labeling proposal published elsewhere in this issue of the **Federal Register**. FDA is proposing in § 101.13(n) to use the analytical methodology specified in the final rule based on that proposal to determine compliance with the requirements for nutrient content claims.

I. Exemptions

The 1990 amendments provide certain exemptions from the requirements for nutrient content claims. These are discussed below.

1. Claims in a Brand Name

Section 403(r)(2)(C) of the act states:

> Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

Paragraph (a) that provision refers to is section 403(a) of the act which states that a food is misbranded if its labeling is false or misleading in any particular.

In discussing section 403(r)(2)(C), the House report states:

> Section 403(r)(2)(C) states that section 403(r)(2)(A) does not apply to claims contained in a brand name that was in use before October 25, 1989 (the date the Subcommittee reported the bill). However, if the brand name contains a term that has been defined by the Secretary pursuant to section 403(r)(2)(A)(i), then it must comply with that definition. The disclosure provisions in section 403(r)(2)(B) will also apply to brand names. In addition, section 403(a) of that constitute false and misleading labeling, irrespective of whether the brand name was exempt under this provision.
> (H. Rept. 101–538, *supra*, 20.)

Thus, manufacturers may continue to use brand names that include nutrient content claims that have not been defined by regulation so long as these claims appeared as part of a brand name before October 25, 1989 and are not false or misleading. Section 403(r)(2)(B) of the act, which requires the nutrition information referral statement, does apply to foods whose brand name includes such claims. Consequently, the labeling of products whose brand name includes such terms will have to bear an appropriate referral statement.

Accordingly, the agency is incorporating the provisions of section 403(r)(2)(C) of the act into its proposed regulations. Proposed § 101.13(o)(1) states that nutrient content claims not defined by regulation, appearing as part of a brand name that was in use prior to October 25, 1989, may be used on the label or in labeling of a food, provided they are not false or misleading under section 403(a) of the act.

2. "Diet" Soft Drinks

Section 403(r)(2)(D) of the act creates an exception from the requirement that a term may be used only in accordance with the definitions established by FDA for the use of the term "diet" on soft drinks, provided that its use meets certain conditions. First of all, the claim must be contained in the brand name of such soft drink. Secondly, the brand name must have been in use on the soft drink before October 25, 1989. Finally, the use of the term "diet" must have been in conformity with § 105.66. The act provides, however, that the claim remains subject to section 403(a) of the act, in that it would misbrand the food if it is false or misleading in any way.

Accordingly, the agency is proposing in § 101.13(o)(2) that if the claim of "diet" was used in the brand name of a soft drink before October 25, 1989, in compliance with the existing § 105.66, the claim may continue to be used. Any other uses of the term "diet" must be in compliance with amended § 105.66 and the other provisions of the part.

3. Vitamins and Minerals

Section 403(r)(2)(E) of the act states:

> Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

Accordingly, the agency is proposing in § 101.13(o)(3) to permit the use of statements on the label or in labeling of a food that describe the percentage of a vitamin or mineral in relation to the RDI as defined in § 101.9, without specific regulations authorizing claims for each specific vitamin or mineral. The agency is proposing to permit such claims unless they are expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

4. Infant Formulas and Medical Foods

Section 403(r) of the act does not apply to infant formulas subject to section 412(h) of the act (see section 403(r)(5)(A) of the act) or to medical foods as defined in section 5(b) of the Orphan Drug Act. Section 412(h) applies to any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight or who otherwise has an unusual medical or dietary problem. Under section 5(b)(3) of the Orphan Drug Act:

> [t]he term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

FDA is presenting its views on what constitutes a medical food in its supplementary proposal on mandatory nutrition labeling, which was published elsewhere in this issue of the **Federal Register**.

Therefore, under section 403(r)(5)(A) of the act, nutrient content claims can be made on foods formulated to meet the unique medical requirements of certain individuals even though FDA has not defined the terms in those claims by regulation. The agency is proposing to reflect this fact in § 101.13(o)(4).

As discussed above, FDA has tentatively concluded that all nutrient content claims are inappropriate for use on the labels of food intended specifically for use by infants and toddlers less than 2 years of age. Therefore, if this proposal is adopted, nutrient content claims will not be permitted on most infant formulas. The agency recognizes, however, that the labels of certain formula products carry statements such as "with added iron" or "low iron." Such statements are already permitted under § 107.10(b)(4), issued under the authority of section 412 of the act.

5. Restaurant Foods

Section 403(r)(5)(B) of the act states:

> Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

Section 403(r)(2)(A)(iii) through (v) of the act set forth certain labeling requirements and restrictions for foods bearing claims about cholesterol, saturated fat, and fiber. Section 403(r)(2)(B) of the act requires that the referral statement be on all foods that bear nutrient content claims. Although early versions of the bill that became the 1990 amendments exempted restaurant food from virtually all of the requirements for nutrient content claims the statute, as it was passed, does not. As the legislative history states:

* * * Restaurants that use content descriptors in connection with the sale of food (for example, the use of the word "lite" or "low, on a menu) must comply with the regulations issued by the Secretary under 403(r)(2)(A)(i). Restaurants would also be prohibited from stating the absence of a nutrient in food unless they complied with section 403(r)(2)(A)(ii). However, restaurants would be exempt from the disclosure requirements [listed above]. (Congressional Record 11584] (July 30, 1990).

Therefore, the agency is proposing in § 101.13(o)(5) that if a nutrient content claim is used for food that is served in restaurants or other establishments in which food is served for immediate human consumption, or for food that is sold for sale or use in such establishments, the claim must be used in a manner that is consistent with the definition that FDA has adopted. However, the agency is also proposing to provide, under section 403(r)(5)(B) of the act, that such claims are exempt from the requirements for disclosure statements in proposed §§ 101.13 (g) and (h), 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C).

6. Standards of Identity

Section 403(r)(5)(C) of the act states that nutrient content claims that are made with respect to a food because the claim is required by a standard of identity issued under section 401 of the act shall not be subject to section 403(r)(2)(A)(i) or (2)(B) of the act. Thus, a nutrient content claim that is part of the common or usual name of a standardized food may continue to be used even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts, or if FDA has not defined the term. Moreover, the label of the standardized food would not need to bear a statement referring consumers to the nutrition label.

It is clear, however, that Congress did not intend section 403(r)(5)(C) of the act to imply in any way that any new standards issued under the act would be exempt from the provisions for nutrient content claims in part 101. Rather, Congress intended that this exemption would apply only to nutrient content claims made in the names of existing standards of identity. The House Report states:

> This exemption was necessary only because of the pre-existing standards for identity. To the extent that those standards provided definitions of content claims that are different from the definitions in the regulations issued by the Secretary under the bill, one basic purpose of the bill will be partially undermined. The Secretary has the authority to correct this problem by amending the portions of the standards of identity pertaining to food labels to conform with the regulations issued under section 403(r). (H. Rept. 101-538, *supra*, 22.)

Therefore, the agency is proposing in § 101.13(o)(6) that nutrient content claims that are part of the name of a food that was subject to a standard of identity on November 8, 1990, the date of enactment of the 1990 amendments, are not subject to the requirements of § 101.13(b), (g), and (h) or to the definitions in subpart D of part 101. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal on the use of nutrient content claims and terms that are defined in standards of identity to name new foods.

7. Use of Terms Defined in Response to Petitions

Sections 403(r)(4)(A) (ii) and (iii) of the act authorize the agency to permit the use of certain types of claims in response to a petition, without requiring that the agency grant such approval by regulation. The claims covered by these sections are those made by use of a term that is consistent with a nutrient content claim defined by the agency, i.e., a synonym, or by an implied claim made as part of a brand name. The act sets forth specific timeframes and procedures for FDA's handling of these petitions, which FDA is proposing to codify.

As discussed below in section IV, FDA intends to list any approved synonyms in the regulation defining the underlying nutrient content claim. The regulations will be updated in the annual issuance of the CFR. On the other hand, because brand name approvals apply to individual firms, the agency intends to retain a separate, publicly available list of approved implied nutrient content claims that may be made as part of a brand name.

The agency is proposing in § 101.13(o)(7) to recognize approved implied claims made as part of a brand name (e.g., "healthy") as exceptions to the general requirement in § 101.13(b) that terms used in a nutrient content claim be defined by regulation.

III. Definition of Terms

A. General Approach

1. Use of Reference Daily Intakes and Daily Reference Values in Formulating Definitions

In a proposed rule related to nutrition labeling (55 FR 29476, July 19, 1990), FDA updated and revised the U.S. RDAs used in food labeling and proposed to replace the term "U.S. RDA" with "RDI." In the same proposal, the agency also introduced the term "DRV" and proposed DRVs for eight food components. The proposed DRVs for total fat, saturated fatty acids, unsaturated fatty acids, carbohydrates, and fiber are based upon a diet of 2,350 calories, which is the population-adjusted mean of the recommended energy allowance for persons 4 or more years of age, as calculated based on the 10th edition of the "Recommended Dietary Allowances" (Ref. 4). The DRVs for sodium, potassium, and cholesterol are, however, independent of calories. Throughout this notice, the term "calories" is used instead of the more precise term "kilocalories" because of consumer familiarity with the former term.

With the exceptions of the term "sugars free" and terms related to caloric levels in foods, the agency has limited the proposed definitions to nutrients for which there are proposed DRVs or RDIs. This approach has the advantage of linking nutrient content claims to established reference values, thereby providing a consistent and quantitative basis for defining terms. Additionally, because these reference values were determined using established scientific reports, such as the "Recommended Dietary Allowances" (Ref. 4) as well as recognized consensus reports and dietary recommendations such as the "Surgeon General's Report on Nutrition and Health" (Ref. 2), "Diet and Health: Implications for Reducing Chronic Disease Risk" report (Ref. 3), and "Dietary Guidelines for Americans" (Ref. 1), claims are limited to essential nutrients and nutrients of public health significance.

2. Criteria for Definitions of Terms

a. Serving size to evaluate nutrient content claims. FDA proposed standardized serving sizes for categories of foods in a 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.

In the 1990 serving size document, FDA proposed 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. For containers identified as a

single-serving containing 100 percent or less of the standard serving size, the agency proposed to evaluate the label claims 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 evaluating the appropriateness of a nutrient content claim. 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 nutrient content 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 (fl oz) container of skim milk containing 126 mg of sodium would meet the criteria for a "low sodium" claim, but a 10 fl oz 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 additional public comment on the impact of the 1990 amendments and the IOM report (Ref. 5) 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 asked for comments about the role that serving size should play in defining nutrient content claims 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 for this meeting, 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 used to evaluate the compliance with FDA criteria for 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 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 (§ 101.12(b)). 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, generally in metric measures, to label serving sizes most appropriate for their specific products.

In proposed § 101.12(g) of that document, 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 be used in determining whether the product meets FDA criteria for nutrient content claims as set forth in proposed subpart D of part 101.

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

However, when considering a 10 fl oz container, the label serving size is larger than the reference amount. Ten fl oz 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 fl oz container could not bear a "low sodium" claim.

While acknowledging the different treatment resulting from this approach, FDA tentatively concludes that it would be misleading to allow claims based only on the reference amount since, particularly with single-serving containers, the consumer would be expected to consume the entire labeled serving size. Likewise, it would also be misleading to allow claims based only on the labeled serving size. If claims were defined in this way, manufacturers could manipulate serving sizes so that their products could bear a claim.

In proposed subpart D of part 101, the agency is specifically providing that the quantitative criteria must be met "per label serving size and per reference amount customarily consumed." Rather than complicating the discussions concerning proposed quantitative amounts in this preamble, however, FDA will abbreviate "per label serving size and per reference amount customarily consumed" as "per serving."

The agency had also considered as an alternative approach, defining nutrient content claims based solely on the amount of the nutrient in a specific amount of food, such as the amount of nutrient per 100 g of food. This approach has the advantage of presenting a nutrient content claim for a food in a way that is more consistent with labeling used internationally, and it may allow consumers a method to more readily compare very dissimilar foods. However, FDA does not believe that this approach alone is appropriate for the initial definition of descriptors. Foods vary greatly in weight or density and are consumed in various amounts depending upon their nature and use in the diet. The agency believes that content claims for certain nutrients, fat for example, could be misleading and not useful to consumers when applied equally to 100 g of nuts and to 100 g of spinach. Therefore, FDA decided to not propose the amount of nutrient per specified weight of food as the primary basis for evaluating nutrient content claims, but as discussed in the following section, the agency will consider a weight-based criterion to preclude claims attributable only to small serving sizes.

b. *Need for criterion based on a designated weight.* After reviewing comments received in response to the 1989 ANPRM as well as analyses of food composition, FDA has tentatively concluded that in some cases an additional criterion to the amount of nutrient per serving is needed to prevent claims from being misleading. The use of a criterion based on a serving is generally appropriate, but for a certain limited number of foods with small serving sizes, the use of the serving size criterion alone would allow claims on foods that are dense in a nutrient on a per weight basis but that have such small serving sizes that the food

qualifies for a content claim. For example, butter and some margarines contain 120–130 mg sodium per serving but contain as much as 960 mg per 100 g of food. The agency considers this situation to be problematic because some of these foods may be consumed frequently during the day and, thus, ultimately make significant contributions to the diet despite their purporting to be limited in a particular nutrient. Furthermore, such claims may be counterproductive relative to educating consumers about the nutrient quality of foods.

The use of an additional criterion based on the amount of a nutrient per specified weight of food is consistent with FDA practice. As provided in current § 105.66(c), the agency has used an additional criterion based on a designated weight of food (i.e., 1 g) for the term "low calorie." Recent analyses of available information on composition (modification of USDA's Nutrient Data Base, Standard Reference Release 9 (Ref. 6)) conducted by FDA indicate that for nutrients other than calories, there are foods that would meet a "low" criterion for amount per serving but still, on a weight basis, contain a substantial amount of the nutrient (Ref. 7). For example, assuming the use of a definition of "low fat" as less than or equal to 3 g per serving, a dessert topping that contains approximately 2 g of fat per serving would meet the definition of "low fat," but contains as much as 25 g of fat per 100 g of food.

Therefore, the agency is proposing to require that the definition of certain descriptors include an additional criterion based on the amount of nutrient per specified weight of food, specifically per 100 g of food. (For an instance in which the agency is not proposing to use this criterion, see the discussion of "low saturated fat" in the companion document on fat, saturated fat, and cholesterol claims.) while the agency has tentatively concluded that a weight-based criterion is not an appropriate criterion when used alone, in conjunction with the per serving criterion it helps to preclude the possibility of misleading claims attributable to small serving sizes alone.

Despite the agency's previous proposal to require an additional criterion based on percent dry weight for terms related to fat descriptors (55 FR 29456), FDA is not proposing to include percent dry weight as an additional criterion for any descriptor. Comments received by the agency in response to the 1989 ANPRM, at the public hearings on the ANPRM, and in response to the tentative final rule on cholesterol descriptors have persuaded FDA that the use of percent dry weight as an additional criterion would prevent the use of certain descriptors (e.g., "low fat") on foods such as salad dressings modified to be low in fat as well as on certain vegetables that surpass the criterion established using percent dry weight because of high water content. For instance, a radish contains 0.5 g of fat per serving and 0.5 g of fat per 100 g of food (Ref. 7). However, on the basis of percent dry weight it contains 10 g per 100 g of dry matter (Ref. 8). The agency, therefore, is not proposing to include a percent dry weight criterion in the definition of any nutrient content claim.

c. *Additional criteria.* FDA also is proposing to include additional elements in the definitions of certain specific claims in response to section 403 (r)(2)(A) of the act. For instance, the agency is proposing in the companion document on fat, saturated fat, and cholesterol descriptors to limit cholesterol content claims based on the amount of saturated fat present in the food (e.g., proposed § 101.62(d)(1)(i)(B)). These additional criteria will be discussed in conjunction with the individual claims.

3. Need for Consistency of Terms and Limited Number of Terms

In reviewing the requirements of the 1990 amendments, the agency has given considerable attention to the apparent need to develop a system of nutrient content claims that: (1) Is consistent in definitions, (2) is in keeping with public health goals, (3) can be used by consumers to implement dietary recommendations. Over the years, FDA has stressed the importance of consistent definitions and descriptive terms as a necessary requirement for effective education and for preventing misleading labeling (Ref. 9). The definition of more terms than is necessary to convey the qualities or characteristics of a food relative to dietary recommendations has the potential to increase the difficulty of educating the public about the meaning and interpretation of nutrient content claims and could result in food labels that are needlessly confusing to consumers. An approach that limits the number of defined terms is consistent with that advocated by a report of the Committee on the Nutritional Aspects of Food Standards, International Union of Nutritional Sciences (IUNS) (Ref. 10), which stated that caution should be exercised to constrain the number of descriptors that are considered desirable. The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties of consumer understanding of a plethora of such terms.

Additionally, as suggested by the NAS report on nutrition labeling (Ref. 5), the use of consistent and targeted content claims increases consumers' confidence in the validity of the claim. Consumer discussions that occurred as part of focus group activities recently conducted by the agency (Ref. 11) revealed that the current plethora of terms has caused consumers to conclude that nutrient content claims are not so much targeted claims intended to be used in selecting foods to meet dietary recommendations as they are merely marketing techniques used by the manufacturer to get the consumer's attention and to sell a product. In these discussions, consumers stated that the frequent use and the number of terms currently appearing on food labels can result in "overload" and cause them to be skeptical of the validity of the statement.

Alternatively, some have argued that flexibility in the use of terms facilitates consumer understanding by attracting attention to the message being delivered. In addition, this argument suggests that more defined terms or flexibility to use various terms to convey nutritional information encourages competition among products and fosters nutritional improvements in products. The agency solicits comment on how it can balance those goals of consumer understanding and competition.

4. Synonyms

As discussed above, section 403(r)(2)(A)(i) of the act states that a nutrient content claim must be defined by regulation. In addition, section 3(b)(1)(A)(ix) of the 1990 amendments provides that those regulations may include similar terms commonly understood to have the same meaning. Although the agency does not have a comprehensive list of such terms that are actually in use, some synonymous terms have been suggested. Some have argued that the use of these terms defined by other label information, will be useful to industry as well as consumers.

In a letter of May 10, 1991 (Ref. 12), the Grocery Manufacturers of America, Inc. (GMA) submitted a list of synonyms that it considered to be illustrative of the type of synonyms that could be used. The GMA list is set forth below for comment.

No
free
meaningless
never a ..... (bit, trace, etc.)

none	
not a ____ (bit, trace, etc.)	
not any	
zero	
Very Low	
dab	pinch
dash	slight
hardly any	smidgen
inconsequential	tinge
insignificant	tiny
meager	touch
minimum	trifling
negligible	trivial
next to nothing	very little
Low	
few	short
little	small
Significant	
added	goodness
consequential	important
enhanced	meaningful
enriched	sizeable
fortified	source
good source	supplemental
High	
intense	major
loaded	rich
lots	
Very High	
chief	predominant
excellent	preeminent
fantastic	super
finest	superior
great	terrific
outstanding	

On the other hand, as stated above, the IOM has raised concerns that the proliferation of synonymous terms on food labels will be confusing to consumers who may believe that there are differences among the terms. Accordingly, and because of agency resource constraints and the strict timeframes under which this rulemaking is being issued, FDA is only providing for similar terms for those descriptors that refer to absolute values such as "free" in these regulations. However, if information submitted in comments substantiates that authorizing a number of synonyms will be useful and not misleading, FDA will include a range of synonymous terms in the final regulations. In addition, petitions requesting permission to use specific synonymous terms may be submitted after the procedural regulations proposed in this document become effective.

B. Terms Describing the Level of a Nutrient

1. "Free"

a. *Background.* Nutrient content claims, that a nutrient is absent from a food, have historically been considered to have the most relevance for persons on strict therapeutic diets. The agency is of the opinion that the inclusion of such foods as part of a total daily diet would be useful to consumers attempting to limit their intake of certain nutrients in accordance with dietary recommendations. Furthermore, FDA believes that the ability to make claims describing a product as "free" of a particular nutrient would provide an incentive to manufacturers to make available alternative foods that will be helpful in meeting dietary recommendations. Finally, under section 3(b)(1)(A)(I) of the 1990 amendments, FDA is required to define the term "free," unless it finds that use of the term would be misleading.

The comments that FDA has received in response to the proposals that it has issued over the years to define the term "free," as well as in response to the 1989 ANPRM, have generally supported the use of this term in nutrient content claims. The IOM report on nutrition labeling, while not recommending a specific definition for this term, discussed its meaning in the overall context of nutrition labeling efforts and did not recommend against its inclusion as a nutrient content claim (Ref. 5). The IUNS Committee suggested that the term "free" was useful, and that the definition should be based on assuring the public that the food contributes truly insignificant amounts of the component to the diet (Ref. 10). Internationally, several countries including Canada have established definitions for nutrient free claims, including claims for calories and sodium.

The agency is therefore proposing to define "free" for the following nutrients: total fat, cholesterol, sodium, sugars, and calories. FDA is proposing definitions for "free" for these nutrients because limiting the amounts of these nutrients in the diets of many individuals is of public health importance (Refs. 2 and 3). The terms "fat free" and "cholesterol free" are defined in the companion proposal published elsewhere in this issue of the **Federal Register.**

b. *Statutory limitations on circumstances in which an absence ("free") claims may be made.* For a food to be labeled as a [*nutrient*] free [*product*], under section 403(r)(2)(A)(ii)(I) of the act, the nutrient must usually be present in the food or in a food that substitutes, as that term is defined by the Secretary (and by delegation, FDA), for the food. Under this provision, an appropriate absence claim would be "sodium free Italian bread" because Italian bread usually contains salt. In addition, beaten, frozen whole egg substitutes can be labeled as "cholesterol free." Although these products inherently contain no cholesterol, they have been formulated for use in cooking as a substitute for beaten whole eggs, which do contain cholesterol.

FDA recognizes, however, that there may be some confusion as to the circumstances in which one food may be considered to substitute for another food. Therefore, in § 101.13(d), FDA is proposing to define when one food may be considered to substitute for another.

FDA is proposing that a substitute food is one that is used interchangeably with another food that it resembles in its physical characteristics (e.g., organoleptic properties and physical attributes) and in its performance characteristics (functional properties such as cooking and shelf life). Although FDA recognizes that substitute foods, such as substitutes for beaten whole eggs, may not be identical to the food for which they are a substitute, it believes that they should bear a substantial resemblance to that food and be able to be used like that food. (Substitutes for beaten whole eggs resemble beaten whole eggs and can be used in cooking like beaten eggs.) To the extent that a substitute food does not have the characteristics of the food for which it substitutes, FDA believes that that difference must be declared on the label or in the labeling of the substitute food, adjacent to the most prominent claim as defined in § 101.13(j)(2)(ii). FDA is proposing to require that this declaration be made in proposed § 101.13(d)(1).

For example, some foods with altered fat content cannot be used in cooking. The disclaimer would, therefore, state, adjacent to the most prominent claim, "Not for use in cooking." The agency tentatively concludes that information about such a difference is material under section 201(n) of the act because it bears on the consequences that may result from the use of the food, and that the substitute would be misbranded under section 403(a) of the act if the difference is not declared. To ensure that the disclaimer is presented with appropriate prominence, the agency is proposing in § 101.13(d)(2) that it be in easily legible print or type, no less than one half the size of the descriptive term (see section II.C. above).

In addition, the substitute food should not be nutritionally inferior, as defined in § 101.3(e)(4), to the food for which it substitutes. However, some foods, to meet the definition of the descriptive term for a particular nutrient, may be nutritionally inferior. Under § 101.3(e), these foods must be labeled as "imitation" foods. FDA believes that identifying imitation foods that meet the

descriptor definition may provide a benefit to the consumer, even though they are nutritionally inferior. Therefore, FDA tentatively concludes that such foods should be allowed to bear the appropriate nutrient content claim as long as they are appropriately labeled.

Section 403(r)(2)(A)(ii)(II) of the act states that absence (i.e., "free") claims may be made for foods if FDA allows such claims based on a finding that the claim would assist consumers in maintaining healthy diets, and the claim discloses that the nutrient is not usually present in the food.

FDA believes that highlighting that a food is free of a nutrient can help consumers maintain healthy dietary practices whether the food is inherently free of that nutrient or is processed to be that way. Furthermore, FDA surveys have shown that consumers want nutrient content claims and use them in making food selections, and that many respondents reported difficulty in understanding the quantitative information presented in nutrition labeling (Ref. 13). In addition, descriptive terms that highlight positive nutritional attributes (such as "fat free") help to educate consumers on the intrinsic properties of foods (Refs. 14 and 15). FDA believes that the definitions in this proposed rule respond to consumers' needs. Therefore, FDA has tentatively concluded that it is not necessary to limit absence or "free" claims to foods in which the nutrient is usually present or that substitute for foods that usually contain the nutrient.

However, 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 or specially processed or formulated to reduce the nutrient as compared to other foods of the same type. Accordingly, FDA is proposing for calories in § 101.60(b)(1)(ii) and for sodium in § 101.60(b)(1)(ii) 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, the relevant claim must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency is proposing a similar requirement for foods that are inherently fat or cholesterol free in the companion document published elsewhere in this issue of the **Federal Register**. For example, many fruits and vegetables would meet the definition for the term "fat free." If the agency adopts its proposed approach, a "fat free" claim on broccoli would have to be made as "broccoli, a fat-free food." FDA is proposing a similar rule if a food is inherently "low" in a nutrient.

This requirement is consistent with the general policy on nutrient content claims set forth in current § 105.66(c)(2) for low calorie foods, with that on "free" and "low" claims discussed in the preamble to the final rule on sodium claims (49 FR 15510 at 15517), and with that 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 content, for example, when in fact, all foods of that type are naturally free of, or low in, fat. Therefore, it is proposing such a requirement in § 101.13(e)(2). Conversely, FDA is providing in proposed § 101.13(e)(1) that if a food has been specifically processed, altered, formulated, or reformulated to remove the nutrient from the food, it may reflect this fact by using the terms "free" or "low," as appropriate, before the name of the food.

FDA is aware that the effect of proposed § 101.13(e)(2) will be to allow to allow "free" or "low" claims on foods that do not usually contain, or are usually low in, the nutrient (e.g., "Brand A soft drink, a fat-free food"). However, for the reasons stated above, the agency believes that this course is the appropriate one. FDA specifically requests comments on this aspect of its proposal.

c. *How definitions of "free" for nutrients were derived.* In arriving at the proposed definitions for "free," the agency chose the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food and that is dietetically trivial or physiologically inconsequential. This approach is consistent with that used by the agency in the past for defining "free." FDA established a policy of using "free" as a descriptor of physiologically insignificant components when it adopted the regulation for sodium descriptors (49 FR 15510, April 18, 1984). This approach is also consistent with the comments and recommendations submitted to the agency in response to the 1989 ANPRM.

The claim "(*nutrient*) free" is a representation that the food does not contain the nutrient. The agency believes that this representation can be made in good faith if the food inherently contains very small amounts of the nutrient because the amount present is physiologically insignificant. Such a representation cannot be made in good faith, however, if the manufacturer intentionally adds the nutrient to the food as an ingredient. In such circumstances, even though the nutrient might not be of dietary consequence, it is obvious when reading the ingredient statement that it has been added. The agency has received comments, including a letter from the state attorney general from Minnesota, writing on behalf of eight other state attorneys general, expressing the view that such labeling is misleading to consumers (Ref. 16). Thus, FDA tentatively concludes that representing the food as free of the nutrient when the nutrient is intentionally added, even at very small amounts, would cause confusion and be false and misleading under sections 201(n) and 403(a) of the act. To reflect this tentative conclusion, the agency is proposing to add an additional ingredient-based criterion to definitions for "free" for sugar and sodium, as discussed below and for fat, as discussed in the companion document on fat, saturated fat, and cholesterol that a product may not be labeled as free of a nutrient if that nutrient is added as an ingredient. However, some have suggested that this distinction creates a discrepancy between naturally occurring "insignificant" amounts and those that are added.

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 be not 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 product that contained a very small amount of a nutrient added as an ingredient (Ref. 16). The agency solicits comments on whether nutrient free claims should be allowed on products that contain a very small amount of 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 that, although 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,

under the regulations as proposed, the label could make other positive, true, 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 than ½ g 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 in some other product.

FDA is not proposing to include a criterion that is based on the amount of the nutrient per 100 g of food for the term "free." FDA considered the need to include this criterion and has tentatively concluded that because the level of each nutrient must be so low to qualify for a "free" claim as to be physiologically insignificant, even frequent consumption of such foods would not be sufficient to have any meaningful affect on the overall diet. For example, the proposed definition for "sodium free," discussed below is, an amount in a food equal to or less than 5 mg of sodium per serving. If a "sodium free" food were consumed as often as twenty times a day, the intake of sodium from "sodium free" foods would be no more than 100 mg of sodium, and it would likely be less. Given the proposed Daily Reference Value (DRV) for sodium of 2,400 mg per day, this intake of sodium would constitute less than 5 percent of the DRV and cannot be considered substantial or of physiological significance.

Additionally, consistent with the regulations on "free" claims that it has issued (current 21 CFR 101.13(a)(1)), FDA is proposing in the supplementary nutrition labeling proposal that foods meeting the criterion for "free" may declare the nutrient content as "zero" on the nutrition label. Such a declaration will prevent the confusion that would result if quantitative declarations other than zero were made on foods bearing nutrient-free claims. While some comments have suggested that the term "free" will mislead consumers into believing that a food so labeled is completely without the nutrient, the agency tentatively concludes that no harm will result because the foods that would be eligible to be labeled with this term contain a trivial amount of the nutrient compared to the total dietary intake of the nutrient for any particular individual.

d. *Synonyms for "free".* FDA is proposing to allow the use of the terms "no," "zero," "trivial source of," "negligible source of," and "dietarily insignificant source of," as synonyms for the term "free." For example, a food that meets the criterion for "sodium free" could also be labeled with the terms "no sodium" or "zero sodium." As discussed above, the agency is concerned about the proliferation of synonymous terms because of the potential to confuse and mislead consumers. However, the agency does not believe that there is potential for consumers to misinterpret the terms "no" or "zero," and therefore the agency is proposing to provide for the use of these specific synonyms. The agency requests comments on whether consumers commonly understand the meaning of all these terms and whether they are synonymous.

e. *Specific definitions*—i. *"Sodium free" and terms related to salt.* In its 1984 regulation on sodium descriptors (21 CFR 101.13), FDA defined a "sodium free" food as one containing less than 5 mg of sodium per serving. FDA established this definition to ensure that a food that met it would contribute only a trivial amount of sodium to the total diet for all individuals (49 FR 15510). Furthermore, while the agency recognized that it would be almost impossible to consume a diet consisting of nothing but "sodium free" foods, it stated that availability of such foods would be helpful in balancing the sodium intake from foods that necessarily contain larger amounts of sodium. According to FDA's 1988 Diet and Health Survey (Ref. 17), sodium remains the most commonly mentioned component that consumers try to avoid in their diet. Moreover, the recent National Food Processors Association survey on food labeling (Ref. 18) reported that 88 percent of shoppers felt label information on sodium was either somewhat or very important.

The agency is proposing to redesignate existing § 101.13 (21 CFR 101.13) as § 101.61 and to retain in paragraph (b)(1) of that section, the definition of "sodium free," as less than 5 mg of sodium per serving. The agency believes that this definition is consistent with the concept of a dietetically trivial amount in foods and is unaware of any evidence that would suggest that this definition should be changed.

Some comments on the 1989 ANPRM suggested that an additional criterion, such as 5 mg per 100 g of food, be included in the "sodium free" definition to avoid categorizing foods as "sodium free" when the serving size is small and consumption may be frequent. However, as discussed above, FDA is not proposing a second criterion for the use with definitions for "sodium free." The intake of foods containing less than 5 mg sodium, even if frequent, is unlikely to contribute a meaningful amount of sodium to the overall diet.

As mentioned above, FDA believes that the label of a food that bears a "(*nutrient*) free" claim can be misleading if that nutrient is also declared as an ingredient in the ingredient list. Most consumers recognize that salt is a significant source of sodium in foods, and the agency is aware that the terms "salt" and "sodium" may be used interchangeably by many consumers. Yet some consumers may not have a clear understanding of the difference between these two terms. These terms are not the same. Sodium chloride, or common table salt, contains almost 40 percent sodium and is only one of several sources of sodium in the diet. Other common sources of sodium include baking powder (sodium aluminum sulfate), monosodium glutamate, and baking soda (sodium bicarbonate). There are numerous other sodium compounds commonly used as ingredients, but their use is at such low levels that they are correctly perceived as not contributing significantly to dietary intake of sodium, e.g., sodium citrate and sodium bisulfite.

The agency is proposing in § 101.61(b)(1)(ii) to include in the definition of "sodium free" that the food must not contain added salt (i.e., sodium chloride) or an added ingredient that contains sodium. This provision is based on the agency's view that, as discussed above, consumers would be confused by the presence of a "sodium free" claim on a food with, for example, sodium citrate declared in the ingredient list. This provision is consistent with proposed definitions for fat and sugar. While FDA

recognizes that the use of trivial amounts of sodium-containing compounds included for flavor or preservation purposes is not likely to have a meaningful impact on the overall sodium content of the diet, the agency is concerned that consumers will note the presence of these ingredients in the ingredient list and be confused as to the significance of the "sodium free" claim. FDA, however, specifically requests comments concerning the appropriateness of restricting ingredients in foods making sodium free claims and of the alternative approach of allowing the claim in the presence of an appropriate disclosure statement.

In the past, FDA has defined or provided conditions for the use of "salt free" and other terms containing the word "salt" § 101.13(b)), so as to prevent the terms from being misleading to consumers. The agency has said elsewhere in this document that statements about an ingredient that lead one to make an assumption about the level of a nutrient are implied nutrient content claims which are not being defined at this time. Salt is an ingredient, and thus claims concerning salt content could be considered to be implied nutrient content claims. However, FDA is tentatively proposing to retain the current provisions for the use of the term "salt" in a somewhat modified form in § 101.61(c).

The agency believes that because of the confusion between "salt" and "sodium," any food bearing the claim "salt free" must meet the definition of "sodium free." Therefore, the agency is proposing this requirement in § 101.61(c)(1).

In § 101.61(c)(2), FDA is proposing to define the terms "without added salt," "unsalted," and "no salt added," which are currently defined in § 101.13(b). These terms may be used only if no salt is added to the food during processing but is added to the food for which the food that bears the claim will substitute (e.g., peanuts). In addition, in response to a comment, the agency is proposing to require a declaration on the food label that the food is not sodium free, if that is in fact the case, to avoid misleading consumers when claims that a food is unsalted or contains no added salt are made.

This proposed declaration is consistent with current FDA regulations (21 CFR 105.66) concerning the use of the term "sugar free." The concern that consumers could interpret this term as an indication that a food is low in calories prompted the agency to require that any food not low or reduced in calories but making a statement about the absence of sugar must bear a statement that it is not a low calorie or reduced calorie food.

ii. *Sugars free.* Several comments received by the agency in response to the 1989 ANPRN and public hearings suggested a need for the agency to define descriptor terms for the absence of sugar or sugars. The IOM report on nutrition labeling (Ref. 5) also recommended that FDA define descriptor to be used for the sugar content of foods.

(a) *Regulatory history: "Sugar" and "Sugars".* FDA has traditionally held that the term "sugar" in an ingredient list means "sucrose" and does not include other sugars. In 1974, FDA proposed to permit the term "sugar" to also include invert sugar (39 FR 20883). The agency withdrew that proposal on June 21, 1991 (56 FR 28592 at 28607) and at the same time denied a request to allow the term "sugar" in the ingredient list to include glucose and fructose (including high fructose corn syrup). "Sugar" is defined in 21 CFR 184.1854 (53 FR 44870, November 7, 1988). That regulation states that the terms "sucrose," "sugar," "cane sugar," and "beet sugar" are appropriate names for sucrose. Therefore, in the ingredient list, the term "sugar" is limited to sucrose.

FDA addressed the issue of the use of the terms "sugar free," "sugarless," and "no sugar" in its July 19, 1977 findings of fact and tentative order on label statements for special dietary foods (42 FR 37166). At that time, the agency stated that consumers may associate the absence of sugar with weight control claims and with foods that are low calorie or that have been altered to reduce calories significantly. The agency concluded that any food making a statement about the absence of sugar would have to bear a statement that the food is not low calorie or calorie reduced, unless the food is a low or reduced calorie food. The agency stated that without this disclosure, some consumers might think the food was offered for weight or calorie control.

Evidence had been introduced at the public hearing on special dietary food regulations to show that the "sugarless" claim is useful to identify foods like chewing gum, which is in sustained contact with the teeth, in which the use of a sweetener other than a fermentable or cariogenic carbohydrate may not promote tooth decay.

In the final rule on label statements for special dietary foods published in the **Federal Register** of September 22, 1978 (43 FR 43248), FDA required a statement that a food is not low calorie or calorie reduced (unless it is in fact, a low or reduced calorie food) when a "sugar free," "sugarless," or "no sugar" claim is made for the food. The agency also allowed for the use of alternative statements, such as "not for weight control" and "useful only in preventing tooth decay." The statements that the food is not low calorie or not useful for weight control were needed because the term "sugar free" meant only that the food was sucrose free. A "sugar free" food could contain other, fermentable carbohydrates.

More recently, in a 1981 report in entitled "Task Group Report on Nutrition Labeling of Sugars," a special task group comprised of representatives from FDA, USDA, and FTC developed guidelines for labeling of sugars in food products (Ref. 19). These guidelines were intended to serve as the criteria necessary to develop regulations for quantitative sugars labeling. The tri-agency task group concluded that quantitative label declarations for sugars should be based on the content (by weight) of total sugars, both added and naturally-occurring. They defined "total sugars" as the sum of all mono- and oligosaccharides through four saccharide units and their derivatives, such as sugar alcohols.

During the last several years, FDA has sent letters to food manufacturers that have set forth agency policy on the use of the term "sugar free." In a 1988 memorandum (Ref. 20) and memorandum of telephone conversation (Ref. 20a), the agency addressed the question of whether a "sugar free" claim would be considered appropriate for a food containing maltodextrin as an ingredient (e.g., a popsicle). FDA responded that, based on the recommendations of the tri-agency task group, a food product with a substantial amount of maltodextrin as an ingredient most likely would be considered misbranded if it bears a "sugar free" claim because while it may contain no added sucrose, it still contains significant amounts of indigenous sugars and sugars other than sucrose. FDA also responded (Ref. 21) to a question concerning the appropriateness of a "sugar free" claim on a product containing polydextrose by noting that at least 10 percent of polydextrose (by weight) qualifies as "sugar" and thus is subject to the same guidelines as specified for maltodextrin.

In mid-1989, FDA responded to a question about the appropriateness of a "sugar free" claim for a product sweetened with a nonnutritive sweetener but that contained lactose, polydextrose, sorbitol, and mannitol (Refs. 22 and 23). The agency pointed out that § 105.66(f)(1) states that "[C]onsumers may reasonably be

expected to regard terms that represent that the food contains no sugars or sweeteners, e.g., 'sugar free,' 'sugarless,' 'no sugar,' as indicating a product which is low in calories or significantly reduced in calories." Noting that the statement in § 105.66 says "no sugars or sweeteners," FDA concluded at the time that the absence of ingredients that, generically, are sugars or nutritive sweeteners is basic to a "sugar free" claim. Because lactose, polydextrose, and sugar alcohols are sugars or nutritive sweeteners, the agency could not conclude that the product was "sugar free."

Finally, in response to the 1990 amendments, FDA is publishing elsewhere in this issue of the Federal Register a supplementary proposal on nutrition labeling in which the agency is proposing a chemical definition for sugars and providing for the mandatory declaration of the sugars content of foods. FDA is proposing to define "sugars" as the sum of all free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units and to include sugar alcohols in that definition. However, FDA is proposing to permit a separate declaration of the amount of sugar alcohols on a voluntary basis. This definition of "sugars" is consistent with the guidelines developed by the tri-agency task group on sugars labeling (Ref. 19)

FDA is not, however, proposing a DRV for sugars because the leading consensus reports have not provided a quantitative recommendation for the intake of sugars.

Thus, in the ingredient label, the term "sugar" is limited to sucrose, and the agency is proposing to use the broader term "sugars" in the nutrition label.

(b) *Need for change.* In considering the appropriateness of defining the term "sugar free," the agency took into account the guidelines and regulations that it has developed on this term, the current and proposed definitions for "sugar" and "sugars," and the potential for the term "sugar free" to be misleading. The agency has received a comment indicating that this term, when used to refer to the absence of only sucrose, may be misleading to consumers, even though the nutrition labeling will list calorie content. Furthermore, the dietary guidelines issued jointly by DHHS and USDA stipulate that Americans should "use sugars only in moderation" and define "sugars" as table sugar (sucrose), brown sugar, raw sugars, glucose (dextrose), fructose, maltose, lactose, honey, syrup, corn sweeteners, high-fructose corn syrup, molasses, and fruit juice concentrate (Ref. 1).

The 1978 rule concerning the use of the term "sugar free" centered around sucrose or table sugar. However, more recent FDA regulatory policy, based primarily on the tri-agency report on sugars labeling, has specified clearly that the agency considers the term "sugar free" to be most appropriate for foods that do not contain sugars or nutritive sweeteners, although FDA has not addressed this issue specifically for food products such as chewing gum sweetened with sugar alcohols which may be useful in not promoting dental caries. As stated above, the proposed definition for "sugars" for nutrition label purposes includes not only mono- and oligosaccharides but also sugar alcohols (56 FR 28592)

Given the consumer interest in the sugars content of food, the fact that current dietary guidelines recommend that consumers "consume sugars in moderation" (Ref. 1), and the agency's longstanding practice of providing for the use of a descriptive term intended to indicate the absence of sugar in some form, FDA is tentatively proposing to define the claim "sugars free" in § 101.60(c). FDA is defining this term to mean the absence of total sugars rather than the absence of sugar (i .e., sucrose).

The agency considers it important for nutrient content claims to be consistent with the nutrition label, which serves as a source of specific information for consumers concerning the nutritional value of the food. As stated above, the agency has proposed to require that the nutrition label contain information on the sugars content. FDA is concerned that there would be potential for confusion if the nutrient content claim were to use the term "sugar," and the nutrition label were to specify information using the term "sugars." Such a discrepancy could make it more difficult to implement education efforts pertaining to label information.

The need for consistency is supported by the IOM report on nutrition labeling (Ref. 5). The report highlights the importance of the content claims on the principal display panel being supported by the quantitative values listed in the nutrition information panel. Furthermore, "sugars free" is consistent with the terminology used in government dietary recommendations, specifically "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 1), which advise that sugars should be consumed in moderation.

The agency acknowledges that it has been a common practice to use the term "sugar free" rather than "sugars free," but FDA believes that the term "sugars free" is more appropriate for the reasons stated above. The agency believes that anticipated education efforts to assist consumers in interpreting the nutrition label (including the term "sugars") will improve consumer understanding of the term "sugars free." Furthermore, even if consumers continue to interpret the term "sugars free" as synonymous with sucrose free (i.e., "sugar free"), consumers will not be misled or harmed because a "sugars free" food will in fact be sucrose free.

(c) *Definition.* FDA is proposing to define "sugars free" as less than 0.5 g of sugars (i.e., all free mono- and oligosaccharides and their derivatives that contain four or fewer saccharide units as well as sugar alcohols) per serving. In defining the term, the agency considered both the amount that would be trivial from a dietary intake perspective as well as that level that could be reliably detected using available laboratory methodologies. In the supplemental nutritional labeling proposal, FDA proposed that analytical values for sugars content that are less than 0.5 g per serving could be declared as zero on the nutrition label. On this basis, FDA is proposing in § 101.60(c)(1)(i) to define "sugars free" as containing less than 0.5 g sugars per serving.

In the past, FDA has not provided a definition for the term "sugars free" relative to its use in managing or planning diabetic diets, although the agency has provided for the use of certain declarative statements so as to avoid confusion among persons with diabetes (§ 105.67). Recently, the American Diabetes Association (ADA) issued a policy on the use of caloric sweeteners in recipes and foods intended for use by diabetics (Ref. 24). The new policy is more liberal than previous policy concerning the inclusion of caloric sweeteners in diabetic diets. The permitted intake of sucrose, honey, molasses, and other caloric sweeteners is 1 teaspoon per serving size. This amount of sweetener is equal to approximately 4 g of sugar per serving.

The proposed definition for "sugars free" is less than or equal to 0.5 g per serving, well below the 4 g amount suggested by ADA. Thus, the use of the term is not contradictory to current recommended diabetes management practices. However, the agency wishes to emphasize that definitions of nutrient content claims do not specifically address issues related to diabetes management, and that diabetes management should not be based solely on the consumption of "sugars free"

foods. Rather, diet planning for diabetics should encompass the entire diet and be supervised by a trained professional.

The agency believes that the amount of sugars allowed in a food bearing a "sugars free" claim is so small that even frequent consumption of such a food will not result in an intake of sugars that would affect the overall diet in any meaningful way. Therefore, FDA is not proposing an additional criterion based on the weight of the food.

However, the agency is proposing a criterion in the definition of "sugars free" to prevent the use of the term on the labels of products to which a sugar has been deliberately added (proposed § 101.60(c)(1)(i)). Despite the fact that these foods can meet the criterion of "sugars free," confusion could occur if the ingredient list for a food bearing the term included any sugars deliberately added. Therefore, the proposal states that to bear a "sugars free" claim, no ingredient in the food can be an added sugar. As stated in previous sections, the agency solicits comment on the appropriateness of this policy.

Finally, FDA continues to believe that any food that bears a statement about the absence of sugars should bear a statement indicating that the food is not low calorie or calorie reduced unless the food meets the requirements for a low or reduced calorie food. Without this disclosure, some consumers might think the food was offered for weight or calorie control. As discussed above, this requirement is already established in § 105.66(f) and will be recodified as § 101.60 (c)(1)(iii)(A) and (c)(1)(iii)(B).

(d) *Sugar alcohols.* The agency acknowledges that this approach for defining "sugars free" would preclude the use of the term on certain products such as chewing gums that contain sugar alcohols (also known as polyols) as nutritive sweeteners and have for some time stated on the label the potential benefit of their product in not promoting tooth decay.

The agency is concerned that these products serve a useful purpose in that they offer an alternative to chewing gums that contain sucrose. FDA also believes that there is some benefit to the consumer in label statements that identify these gums by noting the difference in the two types of products. Accordingly, the agency believes that gums containing no sucrose may continue to be able to bear the terms "sugar free," "sugarless," and "no sugar" alon with the other statements currently required in § 105.66(f). The agency is therefore proposing in § 101.13(o)(3) to permit these products to continue to bear sugar free claims provided that the label also bear, when the food is not low or reduced calorie, a statement such as "Not a reduced calorie food," "Not a low calorie food," "Not for weight control," or "Useful Only in Not Promoting Tooth Decay." As has been required in § 105.66(f), this term should be immediately adjacent to the claim each time it is used.

However, the determination of the usefulness in not promoting tooth decay of gums sweetened with sugar alcohols was based on data that are now over 20 years old. The agency intends to reevaluate this determination in light of new data and current scientific criteria. The agency solicits comments specifically on whether the terms "sugar free," "sugarless," and "no sugar" on chewing gum would be confusing in light of the total sugars declaration in the nutrition label and on whether those terms may be useful in spite of any such confusion. In addition, the agency specifically solicits data on the effects of consumption of these sugar alcohols and on any other types of products that should be included in the exemption in proposed § 101.13(o) (8).

(e) *Synonyms.* In § 105.66(f), the agency provided for the use of the term "sugarless" as well as "sugar free" and "no sugar." However, as specified earlier in the introductory section, the agency is proposing to allow five terms as synonyms for "sugars free." The agency is proposing these terms in § 101.60(c). However, the agency is proposing not to provide for use of "sugarless" for several reasons. To be consistent and thus synonymous with "sugars free," the term defined would have to be "sugarsless." The agency believes that the synonyms defined are sufficient to advise consumers of the absence of sugars in a food, and that there is no need to define additional terms at this time.

(f) *Unsweetened, no added sweeteners.* In the September 22, 1973 final rule on label statements for special dietary foods (43 FR 43248), FDA also addressed the terms "unsweetened" and "no added sweeteners." The agency concluded they were factual statements about the organoleptic properties of the foods. FDA is not aware of any reason to change this view. Therefore, unlike the term "sugar free," these terms, when used for foods with apparent inherent sugars content (such as juices), are not subject to the requirements of section 403(r) of the act for nutrient content claims. FDA is reflecting this fact in proposed § 101.60(c)(3).

FDA is unaware of any evidence to indicate that the use of these terms has been misleading to consumers. The agency advises that it will use the definition of sweeteners in proposed § 101.4(b)(21) in determining the appropriateness of the terms "unsweetened" and "no added sweeteners" on a food label. FDA included this definition in its proposal on ingredient declaration in the **Federal Register** of June 21, 1991 (56 FR 28592). The agency considers that the final rule on that proposal will provide an adequate basis for these terms.

(g) *No added sugars.* While FDA has not issued regulations for the use of the terms "no added sugars," "without added sugars," or "no sugars added," the agency has provided advice concerning their use. In a 1979 letter to the Sugars Association (Ref. 26), FDA stated that the terms "no sugar added" and "no sucrose added," when unqualified, may reasonably be interpreted by consumers to mean that these foods are low or reduced in calories. The agency also stated that such claims should be supplemented either by statements that disclose the presence of, or the usefulness of, the alternative sweetener or by other explanatory statements as appropriate to minimize the likelihood of consumer confusion.

In a 1984 letter to representatives of a food manufacturing firm (Ref. 27), FDA reiterated its earlier position concerning the term "no sucrose," stating that its unqualified use may be misleading, and that the agency had long felt that food labeling claims that highlight either the presence or absence of a particular sweetening substance, unless appropriately qualified by additional statements that are understandable to the ordinary consumer, have the potential to mislead and confuse. The letter also pointed out that the statements "no sucrose added" and "no sugar added," without further qualification, may reasonably be interpreted by consumers to mean that these foods are low or reduced in calories. It continued that therefore, such claims should be supplemented either by statements that disclose the presence of, or the usefulness of, the alternative sweetener or by other explanatory statements. FDA specifically stated that it did not object to a factual statement that a food is "sweetened with fructose (etc.) instead of sugar."

In 1985 (Ref. 28), FDA stated that it believed that the statement "No sugar—Honey Sweetened" was acceptable because "no sugar" implied no table sugar. In 1987 FDA responded to a request for clarification from a food manufacturer (Ref. 29) by stating that the term "no sugar added" may be used on the labels of fruit spread provided

that each time the statement appears, it is accompanied by a qualifying statement explaining the manner in which the product is sweetened, for example "sweetened with concentrated grape juice." On January 3, 1990, FDA sent a notice of adverse findings to a food manufacturing firm (Ref. 30) that included a statement that a label claim of "no sugar added" was false and misleading when applied to a product that contains sugar from sugar cane juice.

Thus, in providing advice on the use of the terms "no added sugar," "no sugar added," and "without added sugar," the agency has generally considered the intent of these claims to be limited to claiming the absence of so-called table sugar, that is, sucrose. FDA has expressed concern that consumers may expect such products to be low or reduced in calories and has therefore stated that statements as to whether the food is low calorie or reduced calorie content, as well as to the presence or use of alternative sweeteners, should accompany the claim.

Thus, for terms such as "no added sugar," as for "sugar free," FDA considered whether to continue to limit their application only to sucrose. Currently, a variety of added nutritive sweeteners are used in foods, and these sweeteners often contain sugars other than sucrose. Dietary guidelines (Ref. 1) stipulate that Americans should "consume sugars only in moderation" and indicate that sugars other than sucrose should be consumed in moderation.

Therefore, given current dietary recommendations, FDA has tentatively concluded that the use of a descriptive term that implies that the product has been made without adding sugars would be more helpful to consumers in implementing such recommendations than would a term that is limited only to sucrose (i.e., "sugar"). However, the agency believes that to avoid misleading consumers, such terms should be limited to foods that would be expected to contain added sugars. Claims concerning the absence of added sugars on products that would not normally contain added sugars, for example canned tuna or potato chips, are likely to mislead consumers into thinking that a particular brand may be more desirable when compared to other brands of the same product. Based on all of these factors, the agency is proposing to provide for "no added sugars" claims, to define them in terms of the other proposed definitions pertaining to sugars, and to specify provisions for their proper use.

The agency is proposing in § 101.60(c)(2) that claims for the absence of added sugars apply only to those foods to which sugars have not been added during processing or packaging. This provision is consistent with the provisions proposed above with respect to the addition of salt to foods. Also, consistent with earlier provisions, the agency is proposing to require that products bearing a "no added sugars" claim bear a statement that the food is not low calorie or calorie reduced, if applicable. Furthermore, the agency believes that it would be misleading to claim "no added sugars" if an ingredient that contains added sugars, for example jam, is added to the product. The agency also believes that it would be misleading to claim "no added sugars" if the sugars content of the product has been increased by the manufacturer using a means such as adding enzymes to the product. Consumers would expect that a product bearing a claim for "no added sugars" would contain only sugars naturally present in ingredients, when in fact the manufacturer would have deliberately "added" to the sugars content of the product via the addition of enzymes.

The agency is proposing in § 101.60(c)(2) to permit the use of the terms "no added sugars," "without added sugars," or "no sugars added." These claims will be permitted only if:

(1) No amount of sugars (as defined for nutrition labeling purposes in § 101.9) is added during processing or packaging;

(2) The product does not contain ingredients that contain added sugars, such as jam, jelly, and concentrated fruit juice;

(3) The sugars content has not been increased above the amount naturally present in the ingredients of the food by some means such as the use of enzymes;

(4) The food that it resembles and for which it substitutes normally contains added sugars; and

(5) The product bears a statement indicating that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

iii. "*Calorie free*". The agency has recognized that people who are interested in controlling their weight can be aided if the level of calories in a food is brought to their attention, particularly when the calorie level is low (42 FR 37166). Accordingly, FDA responded to the need for descriptive terms for claims concerning the caloric content of foods by defining "low calorie" and "reduced calorie" (43 FR 43248). However, the agency has not proposed a definition for "calorie free." Comments received by the agency in response to the 1989 ANPRM and at the public hearings stated that the term "no calories" or "calorie free" should be defined by the agency.

While FDA has not defined the term "calorie free," current § 105.66(e) provides for the term "diet" for use when a food is represented as being useful in reducing caloric intake or reducing or maintaining body weight. The term has often been used on foods that are virtually free of calories, such as specially formulated soft drinks. However, under § 105.66(e)(1), a "diet" food is not necessarily a food free of calories because "diet" may be used with products that are low or reduced in calories.

FDA is proposing to define "calorie free" because the ability to call attention to products free of calories will provide useful guidance to consumers who are seeking to control their caloric intake. The agency, however, notes that such a claim may be applicable to relatively few foods in the food supply and therefore, requests comments on the appropriateness of providing such a definition.

The agency is proposing in § 101.60(b)(1)(i) to define the term "calorie free" as less than 5 calories per serving. The proposed nutrition labeling regulation which is publishing elsewhere in this issue of the **Federal Register** provides for the declaration of the calorie content of a food as zero when caloric levels are less than 5 calories per serving. The agency believes that this level of calories can be considered trivial and of no physiological significance. Even frequent consumption of such "calorie free" foods would not result in a caloric intake great enough to affect in any meaningful way on the overall intake of calories. For example, if "calorie free" foods were consumed 20 times a day, the usual number of servings a person consumes, the intake of calories from such foods would be no more than 100 calories. As a point of reference, the population adjusted mean intake of calories per day is 2,350. Additionally, as discussed above, FDA is proposing five terms as synonyms for "calorie free."

2. "Low"

a. *Background.* Nutrient content claims that describe the level of a nutrient as "low" are among the mos common claims on labels but are not consistently defined or used (Refs. 5 and

10). FDA's first efforts to define the term "low" were made regarding calories, particularly so that the term could be used to assist in weight control. On September 22, 1978 (43 FR 43248), FDA issued a final rule that established a definition for "low calorie." In 1984 (49 FR 15519), FDA issued a rule defining "low sodium," and on November 25, 1986 (51 FR 42584), FDA proposed a definition for "low cholesterol" which was expanded upon in the tentative final rule on July 19, 1990 (55 FR 29456). The agency also has developed guidelines for use of the term "low fat" in experimental shelf-labeling programs (Ref. 31).

Current dietary recommendations (Refs. 1, 2, and 3) make clear the continued usefulness of identifying or calling attention to foods low in the nutrients of which consumers have been advised to limit their intake including fat, saturated fat, cholesterol, sodium, and calories. Comments from a variety of consumer and professional organizations strongly support the use of the term.

Definitions for "low" can also be found internationally. Canadian regulations and guidelines specify conditions for the use of the term to describe fat, cholesterol, sodium, and calorie content (Ref. 32), and a Codex Alimentarius standard for foods for special dietary uses defines "low sodium" (Ref. 33). Further, Codex guidelines that would define "low" for a number of other nutrients are in development, as is a European Community directive on labeling claims that includes claims relating to low content.

The agency is proposing to define "low" for the following nutrients: total fat, saturated fat, cholesterol, sodium, and calories. The definitions for "low fat," "low saturated fat," and "low cholesterol," and the basis for those definitions, are presented in the companion document published elsewhere in this issue of the **Federal Register**. FDA is not proposing definitions for low content claims for other nutrients because low levels of these other nutrients in foods are not of public health importance according to major consensus documents such as the "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) and The Surgeon General's Report on Nutrition and Health (Ref. 2).

While the agency has defined "sugars free," FDA does not believe that it is appropriate to define "low sugars." Unlike the claim "sugars free," which is based on the absence of sugars in a food, a definition for a "low" level of sugars (or any other nutrient) in foods should relate to the total amount recommended for daily consumption. Because the available consensus documents do not provide recommendations for daily intake of sugars, FDA is not proposing a reference value for this nutrient. The agency has thus tentatively concluded that without quantified recommendations for sugars intake, a definition for low levels of sugars in food cannot be specified.

b. *How definitions of "low" for nutrients were derived.* In the **Federal Register** of July 19, 1977 (42 FR 37166), FDA provided a basis for the definition of "low." Although the definition was specific to calories, the principle can be applied to other nutrients. The agency stated that "low" should designate foods of distinctly low nutrient value, but the level for "low" should not be restricted to foods that can be "eaten freely in numerous servings." Thus, FDA's view in 1977 was, and the agency continues to believe, that the designation "low" should not necessarily mean that the nutrient is present in the food in an inconsequential amount as with "free," but rather that the selection of a food bearing the term "low" should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit certain nutrients. The agency believes that to meet current dietary guidelines, it should not be necessary for persons to limit their diets solely to foods "low" in the nutrients that the guidelines recommend limiting. Rather, FDA expects that educational efforts will stress the importance of a total daily diet that is comprised of a mixture of foods, some of which may be "low" in a particular nutrient and some of which may not.

In establishing the proposed definitions for "low," FDA has tentatively concluded that there should be a single definition of what is low for each nutrient that would be applicable to all foods, rather than several definitions for use with specific categories of foods. As discussed in the companion document on claims for fat, saturated fat, and cholesterol content (published elsewhere in this issue of the **Federal Register**), FDA received a comment that requested that the agency define "low fat" differently for different foods, that is, that FDA vary the quantitative definition of "low" according to food category and designate as "low" those foods that are relatively low compared to other foods in the food category. The agency rejects this approach.

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 descriptors to compare products across categories and will likely find it difficult to use the descriptors for 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 (or highest) nutrient level in a category, the agency believes that such a system would have a high potential for misleading the consumers about the nutrient content of foods. The product that has the lowest nutrient content in a category is not necessarily low in the nutrient. Also, with 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 content of the nutrient than foods in other categories that did qualify.

Furthermore, in this document, FDA is proposing to provide for the use of relative claims on the labels of food products, claims that are intended to alert consumers that a particular product, when compared to a similar product, is lower or higher in certain nutrients. FDA believes that this approach is more appropriate for consumers to identify favorable or desirable products within a food category.

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 that "low sodium," for example, should have the same meaning whether it is applied to soup, frozen peas, or meat (Ref. 5). Accordingly, the agency concludes that establishing different cutoff levels for each nutrient content claim for different food categories would greatly increase the complexity of using such claims to plan diets that meet dietary recommendations. Therefore, the agency is proposing a single definition for "low" for each nutrient across the entire food supply.

FDA believes that the most logical starting point for the definition of "low" is the level that FDA has defined as the measurable amount of the nutrient in a serving of a food. In § 101.3(e)(4)(ii), FDA has defined this amount as 2 percent or more of the reference value (i.e., U.S. RDA), the level at which all of the nutrients in question can be measured in all or nearly all foods.

The reference value for the nutrients for which FDA is proposing to define the

claim "low" is the DRV rather than the U.S. RDA, but all the nutrients in question have proposed DRVs. Two percent of the proposed DRV, then, is an amount that can be considered to be low relative to overall recommended intakes.

Looking at this definition from a different perspective, FDA has generally estimated the number of servings of foods and beverages to be 16 to 20 per day. The Minnesota Nutrition Coordinating Center has estimated the average number of servings of foods and beverages to be 20 per day (Ref. 34). If the nutrient were contained in all foods, and 2 percent of the DRV was adopted as the basis of the proposed definition for "low," persons who selected only foods designated as "low" in the nutrient would have a daily intake of the nutrient that would be no more than 40 percent of the proposed DRV (i.e., 2 percent times 20 servings). Thus, 2 percent of the DRV as a definition for "low" provides for a quantitatively low amount in food that is sufficiently restrictive to allow consumers to select a variety of foods, including some that are "low" in a nutrient and some that are not "low," and still meet current dietary recommendations.

On the other hand, the agency believes that 2 percent of the DRV can be overly restrictive as a definition for "low" for those nutrients that are not contributed by all food categories or that are found in relatively few foods. FDA believes that in defining the term "low," the amount per serving for nutrients that are not found in all categories of foods can be larger than for nutrients that are ubiquitous in the food supply. For example, assume that nutrient X is spread across 20 foods/beverages in a day, while the intake of nutrient Y is contributed by only 10 foods/ beverages in a day, that is one-half as many as contribute to the intake of nutrient X. If the definition of "low" for nutrient X is established as 2 percent of the DRV, the consumption of only foods "low" in nutrient X results in an intake of 40 percent of the DRV, that is 2 percent times 20 foods/beverages. If the definition for "low" for nutrient Y is set at 4 percent (i.e., twice than 2 percent) the consumption of only foods "low" in nutrient Y also results in an intake of only 40 percent of the DRV because only 10 foods containing the nutrient are eaten in a day (i.e., 4 percent times 10 foods/beverages in a day). If the definition of 2 percent of the DRV for "low" had been applied to nutrient Y, then the intake of nutrient Y would be only half the intake of nutrient X. Thus, such a limit on nutrient Y would be overly restrictive.

However, this general approach cannot be precisely refined because there are only limited data available to determine the number of foods eaten in a day that may be expected to contribute the various nutrients. Furthermore, distributions of nutrients among food categories may not reflect the patterns of consumption of consumers. FDA is thus tentatively proposing to apply a rough and simplistic "rule of thumb" for adjusting the 2 percent DRV definition for "low" for those nutrients that appear to be less than ubiquitously distributed among foods and therefore are assumed to be consumed less frequently than nutrients that are present in virtually all foods consumed during the day.

The agency used the FDA Regulatory Food Composition Data Base (Ref. 6) to examine the availability of nutrients from foods in 18 USDA-defined food categories (for example, vegetables; fruits; cereal grains and pasta; milk, cheese and eggs; meat, poultry and fish; legumes; nuts; and fats and oils) (Ref. 35). For this analysis, FDA considered that a nutrient is found in a food category if over half of the foods in the category contain 2 percent or more of the proposed RDI or DRV for the nutrient in question. The agency further considered a nutrient to be:

(1) Ubiquitously distributed if it was found in more than 75 percent of the food categories;

(2) Moderately distributed if it was found in 51 to 75 percent of the food categories; and

(3) Not widely distributed if it was found in 50 percent or fewer of the food categories.

After gathering the results of this review, the agency applied factors to adjust the "low" definition for a nutrient (i.e., 2 percent of the DRV) depending on the nutrient's estimated distribution across food categories. However, because of the variable nature of diets selected by individuals, precise factors could not be developed, so the agency applied general factors.

If the nutrient is available from approximately 50 to 75 percent of food categories, FDA believes that it is reasonable to expect that it may be available from perhaps as few as half of the foods/beverages consumed. In other words, assuming that as many as 20 foods/beverages are consumed in a day (Ref. 34), it is reasonable to expect that a nutrient that is moderately distributed in the food supply is available from perhaps as few as 10 of the foods/ beverages. In this case, the agency has used a factor of 2 times 2 percent or 4 percent of the DRV (i.e., doubling) in arriving at the definition of low. If the nutrient is found in half or less of the foods consumed, that is, if it is not widely distributed, FDA believes that it is reasonable to find that the nutrient will be consumed in seven or fewer foods a day. In this case, a factor 3 times 2 percent, or 6 percent, of the DRV, is reasonable. If the nutrient is ubiquitous across food categories, FDA is not proposing to adjust the definition of "low."

As described below, in arriving at the definitions for "low," FDA evaluated each nutrient in light of this general rule of thumb, past policy, other available data and information, and current public health recommendations.

c. *Criterion based on weight.* As discussed above in section III.A.2.b. of this document, the agency believes that in addition to a criterion based on the amount of a nutrient per serving, a criterion based on the amount of nutrient per quantity of food is needed to control claims on nutrient-dense foods with small standard serving sizes. Without a limitation on the amount of nutrient per 100 g of food, declarations for "low" levels of a nutrient could be misleading. Analyses of FDA's Regulatory Food Composition Data Base (Ref. 6) suggest that there are a number of foods that would meet the "low" criterion for amount per serving but that would still contain a substantial amount of the nutrient on a weight basis (Ref. 7). For example, as stated above, certain margarines or spreads contain about 130 mg of sodium per serving but contain over 900 mg per 100 g. In this circumstance, a small serving size would result in a nutrient-dense food qualifying for a "low" content claim if only the per serving criterion is used.

A criterion based on weight is currently provided in § 105.66(c) for the term "low calorie." That regulation stipulates that a "low calorie" food must not provide more than 0.4 calories per g of food. Similarly, FDA is proposing to include a second criterion based on the amount of the nutrient per 100 g of food in the definition for "low" for all but one of five nutrients identified above.

d. *Foods inherently "low" in a nutrient.* Consistent with the agency's conclusion pertaining to foods inherently "free" of a nutrient, the agency believes that the use of terms such as "low sodium" or "low fat" on foods that are inherently low in that nutrient can be misleading (see proposed § 101.13(e)(2)). Accordingly, FDA is proposing for calories in § 101.60(b)(2)(ii) and for sodium in

§ 101.61 (b)(4)(iii) to require that for claims of low nutrient content on foods that meet the definition for "low calories" or "low sodium" without benefit of special processing, alteration, formulation, or reformation to decrease the nutrient content, that the label refer to all foods of that type and not merely to the particular brand to which the labeling attaches. For example, applesauce would inherently meet the definition for "low sodium." Therefore, if the agency adopts these proposed provisions, a jar of applesauce could be labeled with a statement such as "applesauce, a low sodium food." The agency is proposing in § 101.61(b) (2) (iii) a similar requirement for "very low sodium foods." These requirements are consistent with the general policy on "free" nutrient content claims discussed above.

The agency is proposing a similar requirement for "low fat," "low saturated fat," and "low cholesterol" claims in the companion document published elsewhere in this issue of the **Federal Register.**

e. *Synonyms.* FDA is proposing as synonyms for "low" the terms "little or (few)," "small amounts of," and "low source of." The agency is proposing these synonyms to provide flexibility for industry. FDA requests comments on whether consumers commonly understand these terms to have the same meaning as "low."

f. *Specific definitions.*— i. *"Low sodium and very low sodium".* In defining sodium claims for the current regulation on sodium labeling (21 CFR 101.13), FDA considered the number of servings of food that the average American consumes each day (49 FR 15534, April 18, 1984). Based on 20 servings per day as a reasonable average number of servings for adults and a criterion of 140 mg of sodium per serving, the agency estimated that the consumption of 20 "low sodium" foods would contribute about 2,800 mg of sodium per day. FDA stated that it was likely that persons on "mildly restricted" diets would consume a number of sodium free foods or foods containing very low levels of sodium, thereby providing some flexibility in the diet to allow for the consumption of sodium from other sources such as drinking water or table salt. In the 1984 final rule, FDA also cited evidence that more than 50 percent of the foods in the analysis that it did at the time fell below 140 mg per serving, suggesting that the term would have a reasonably broad application in the food supply.

Thus, in 1984, FDA defined "low sodium" as less than or equal to 140 mg sodium per serving. FDA had originally proposed that the term "low sodium" be defined as 35 mg or less per serving (47 FR 26580). However, comments on the proposed definition persuaded the agency that 35 mg or less of sodium was a level too low to be broadly useful to the general public. The agency therefore modified its definition of this term. However, the agency added the term "very low sodium" and defined it as less than or equal to 35 mg sodium per serving. In the 1984 final rule, FDA concluded that "very low sodium foods" would be useful to individuals in the population wishing to reduce their total sodium intake to a more moderate level and would be especially useful to individuals on medically restricted diets.

Thus, the descriptive terms for sodium have been defined and used for approximately 8 years, and the agency believes that consumers have become familiar with the terms "low sodium" and "very low sodium." In general, comments received in response to the 1989 ANPRM and at the public hearings did not indicate a need to change the definitions for these terms. Several comments supported keeping the existing criteria. For these reasons, the agency is proposing to retain 35 mg or less per serving as the first criterion for the definition of "very low sodium" and 140 mg or less per serving as the first criterion for the definition of "low sodium."

The agency is aware that this definition for "low sodium" is not consistent with the general basis on which FDA is proposing to define "low" claims. With the exception of all fruits and raw vegetables, sodium is present in or added to many categories of foods in the food supply. Therefore, if sodium were considered to be ubiquitous in the food supply, the general rule of thumb could result in an initial definition for "low sodium" of 2 percent of the DRV or 48 mg of sodium per serving. Clearly, 48 mg of sodium per serving is considerably lower than 140 mg of sodium per serving. Even if the agency were to conclude that sodium cannot be considered to be ubiquitous, and consequently the value representing 2 percent of the DRV for sodium was doubled, the criterion would still be only 96 mg or less sodium per serving.

The agency considered defining the term "low sodium" as 96 mg or less per serving (i.e., that amount reflective of approximately 4 percent of the DRV for sodium), and not defining "very low sodium." Such an action would be consistent with the most recent dietary recommendations and with the agency's general goal of limiting the number of descriptor terms. However, such an action would be contrary to the majority of comments received by the agency in response to the 1989 ANPRM concerning the level for "low sodium." Therefore, FDA is proposing to retain the definition for "low sodium" as 140 mg or less per serving and to define "very low sodium" as 35 mg or less per serving.

The agency specifically requests comments concerning these definitions. FDA is interested in comments concerning: The appropriateness of the definitions given recent consensus reports and dietary recommendations such as the NAS Diet and Health report; whether substantially increased public health benefits could be realized by using a criterion lower than 140 mg per serving for defining sodium; and the utility of retaining both the "low sodium" and "very low sodium" terms.

FDA is proposing a second criterion for defining "low sodium" as 140 mg or less sodium per 100 g and "very low sodium" as 35 mg or less sodium per 100 g. The per 100 g criterion is needed to control claims on sodium-dense foods with small serving sizes because, as explained above, these foods may be consumed frequently, resulting in a substantial total daily intake of sodium. Because the claim would be misleading to consumers unless both the per serving and per 100 g criteria are met, the agency is proposing that both must be satisfied to meet the definition. Examples of foods for which the proposed sodium descriptors could not be used because they do not meet both criteria for "low" include olives with 105 mg sodium per serving but 750 mg per 100 g and butter/spreads with about 120 mg sodium per serving but over 800 mg per 100 g. In the case of "very low," the foods excluded as a result of the second criterion include canned beef gravy with 28 mg of sodium per serving but 50 mg per 100 g. (However, canned beef gravy would be able to bear a "low sodium" claim.)

Accordingly, the agency is proposing in § 101.61(b)(2)(ii) that the term "very low sodium" may be used on the label and labeling of foods that contain 35 mg or less of sodium per serving and per 100 g, and in § 101.61(b)(4)(ii) that the term "low sodium" may be used on the label and in labeling of foods that contain 140 mg or less of sodium per serving and per 100 g.

ii. *"Low calorie".* Obesity is a major health problem in the U.S., and dietary recommendations consistently stress the need to maintain a healthy weight. FDA believes that people can be helped to control their weight if foods that are low in calories are brought to their attention (42 FR 37166, July 19, 1977).

In 1978, FDA established in 21 CFR 105.66 a definition for "low calorie" (43 FR 43248, September 22, 1978). In the preamble to its tentative rule (42 FR 37166, July 19, 1977), FDA accepted the concept that the designation "low calorie" should apply to foods of distinctly low caloric value in a single serving. However, as stated above, the agency rejected the view that low calorie foods are only those that are so low in caloric value that they can be eaten freely, without adding significantly to the caloric content of the total diet. The agency stated that the proposed definition of "low calorie" would require that consumers apply reasonable judgment in selecting "low calorie" foods as part of an overall dietary pattern. FDA said that consumers could determine from nutrition labeling how much of a particular food they could consume per day without adding significantly to their total caloric intake. The agency stated that this approach was appropriate because caloric requirements vary considerably from person to person.

In 1978, FDA defined, in § 105.66(c)(1)(i), "low calorie" as 40 calories or less per serving (43 FR 43248, September 22, 1978). The agency stated that this definition would include only foods of distinctly low caloric value while at the same time allowing a reasonable number of foods to be labeled as "low" in calories, as supported by analyses of available data bases. FDA also provided for a second criterion for the definition of "low calorie" of 0.4 calories or less per g of food (i.e., 40 calories per 100 g) (§ 105.66(c)(1)(i)). The agency stated that this level was appropriate because available data indicated that foods generally considered the most useful types of low calorie foods (e.g., most soups, juices, fruits, and vegetables containing 40 calories or less per serving) also satisfy this second, density-based criterion.

In response to the 1989 ANPRM and recent public hearings, the agency received numerous comments from a variety of consumer and professional organizations strongly supporting the use of the term "low calorie." In the time since the 1978 rule, public health policy and dietary recommendations relative to caloric intake have not changed appreciably, although there is evidence that the problem of obesity may have increased (Ref. 3). The concepts articulated in the 1977 rule remain appropriate for current dietary recommendations and, in the opinion of the agency, remain appropriate as a basis for defining "low calorie."

While a DRV for calories has not been established, FDA used a reference caloric intake of 2,350 calories in establishing the DRVs for other nutrients. This reference level is the population-adjusted mean of the recommended energy allowance for persons four or more years of age, as indicated in the 10th Edition of the "Recommended Dietary Allowances" (Ref. 4). The agency used this reference caloric intake in reviewing the current definition for "low calorie." Calories are ubiquitous across food categories (Ref. 35), and therefore using the general approach described above, 2 percent of 2,350 calories (i.e., 47 calories) would be a reasonable starting point for the definition of "low calorie." Because the current definition of 40 calories per serving is sufficiently close to this calculated amount of 47 calories per serving, FDA tentatively concludes that it is not necessary to alter the long-established criterion of 40 calories per serving. Therefore, FDA is proposing in § 101.60(b)(2)(i) to retain the definition of a "low calorie" food as a food containing 40 calories or less per serving.

The agency continues to believe that the inclusion of a weight-based criterion in the definition of "low calorie" is appropriate and prevents claims from being misleading to consumers. However, as originally stated in the **Federal Register** of September 22, 1978 (43 FR 43248 at 43250), the agency believes that although sugar substitutes would not meet the weight-based criterion, they should continue to be excluded from this criterion.

Sugar substitutes contain calories. In fact, many contain more than 40 calories per 100 g. However, they have considerably less weight per degree of sweetness than sugars. Consequently a considerably smaller amount of sugar substitute than sugar may be used and still provide the same degree of sweetness. Because sugar substitutes are used on a sweetness rather than a weight basis, FDA believes that a weight based criterion is not appropriate for these foods. Such a criterion would mean that sugar substitutes could not make low calorie claims even though they are frequently used as ingredients in low calorie foods. By continuing to not require sugar substitutes to meet the 40 calories per 100 g requirement, sugar substitutes can continue to be labeled as "low calorie." Therefore, FDA is proposing in § 101.60(b)(2)(i) for the term "low calorie" to provide that, in addition to containing no more than 40 calories per serving, such foods, except for sugar substitutes, must contain no more than 40 calories per 100 g of food.

3. "High" and "Source"

a. *Background.* The agency considered several approaches for defining terms useful in making nutrient content claims to emphasize the presence of a nutrient. Earlier, in response to the increased use of descriptive terms as part of shelf-labeling programs in supermarkets, the agency had suggested definitions for the terms "source," "good source," and "excellent source" (Ref. 9). The agency defined these terms as providing 10 percent or more, 25 percent or more, and 40 percent or more of the U.S. RDA, respectively, per serving of food, and in the case of dietary fiber, 2 g or more, 5 g or more, and 8 g or more, respectively, per serving of food.

The report from the IOM Committee on nutrition labeling (Ref. 5) favored a system in which vitamins and minerals, when listed on the label, would be described qualitatively using words rather than quantitatively using numbers or percentages of the U.S. RDA. However, the committee did not specifically address the need for criteria for nutrient content claims.

While FDA is proposing to retain quantitative listings of nutrients in the nutrition label, the agency believes that there is merit in the IOM Committee's recommendations concerning the use of certain descriptive terms, especially when used for nutrient content claims intended to emphasize the presence of a nutrient.

The IOM Committee suggested definitions for the terms "contain," "good source of," and "very good source of." However, it commented that the term "excellent source" would provide an unintended incentive for unnecessary vitamin and mineral fortification. In addition, the IOM Committee's review of the vitamin and mineral content of a variety of foods indicated that very few foods would be eligible to use the term "excellent source" as currently defined by FDA, even though many of the foods are recognized as important sources of specific nutrients. The IOM Committee further pointed out that most vitamins and minerals do not occur naturally at high levels in any one food. The IOM Committee's report stated that an adequate diet must be assembled from a variety of different foods, and it emphasized that such a varied diet was the type of dietary pattern that food labeling should encourage. The IOM Committee recommended that FDA definitions of descriptive terms should be based on more "modest" definitions than the 40 percent of U.S. RDA

currently used to define the term "excellent source."

The agency agrees that consumers should be encouraged to consume a wide variety of foods. The agency also believes that the criteria for descriptive terms should be consistent with the levels of nutrients occurring naturally in foods, and that definitions for terms should allow for a reasonable number of foods to make the claim. For these reasons, the agency does not believe that descriptive terms such as "high" can be considered useful to consumers if they can identify only very few foods or only specially formulated foods. Such criteria could discourage the consumption of a wide variety of foods. Furthermore, the use of criteria that take into account the amounts of nutrients occurring naturally in foods is in line with the recommendations provided in "Nutrition and Your Health: Dietary Guidelines for Americans" issued jointly by DHHS and USDA (Ref. 1). Those recommendations emphasize the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements.

b. *How definitions of "high" and "source" were derived for nutrients.* As directed by the 1990 amendments (section 3(b)(1)(A)(iii)(VI)), FDA is proposing to define the term "high" for use in nutrient content claims. The agency is proposing in § 101.54(b)(1) that the term "high" may be used when a serving of the food contains 20 percent or more of the proposed RDI or the proposed DRV. The agency is also proposing in § 101.54(c)(1) that the term "source" unmodified by an adjective may be used to describe a food when a serving of the food contains 10 to 19 percent of the RDI or the DRV.

The use of 20 percent or more of the proposed reference value as a standard for the presence of upper levels of a nutrient (i.e., "high") is generally consistent with the IOM Committee recommendation for "very good source" for vitamins and minerals. The IOM Committee stated that a criterion of more than 20 percent of the reference value would encompass a sufficient number of items in the food supply to ensure that the use of the criterion would encourage consumers to select a varied diet (Ref. 5).

In evaluating the appropriateness of the criterion of 20 percent or more of the RDI or DRV as the basis for the definition of "high," FDA used its Regulatory Food Composition Data Base to examine the types of foods that contain nutrients at levels that meet or surpass 20 percent of the proposed reference value (Ref. 36). Sixteen nutrients with RDIs and one with a DRV (i.e., potassium) were considered in this analysis. Other nutrients with RDIs or DRVs were excluded either because the agency is not proposing to define "high" for these nutrients (e.g., fat), or because the nutrients values in the data base were absent or insufficient (i.e., missing values for more than 25 percent of the foods). For the majority of the 17 nutrients considered, at least 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV (i.e., the proposed definition for "high"). For these nutrients there was at least one and often more than one food category that contained a substantial number of foods containing 20 percent or more of the RDI or DRV.

Those nutrients for which fewer than 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV were calcium, magnesium, copper, manganese, potassium, pantothenic acid, and vitamin A. However, even with these nutrients (with the exception of potassium), there was a substantial number of foods in at least one food category that would qualify for "high" claim if the proposed definition were used. Thus, based on this evaluation, the agency agrees with the IOM Committee's conclusion that this criterion would permit a sufficient number of food items to allow consumers to use the claim in selecting a varied diet. Therefore, the agency tentatively concludes that a criterion of 20 percent or more the RDI or DRV provides an appropriate basis for upper-level content claims and can readily be used by consumers to implement current dietary guidelines.

While the IOM Committee has suggested the use of the term "very good source" for levels above 20 percent of the label reference value, the agency is proposing to define this level as "high" to be consistent with the 1990 amendments. Additionally, while the IOM Committee suggested a definition of more than 20 percent of the reference value, FDA has tentatively concluded that a definition of 20 percent or more is more consistent with the agency's approach of defining the term "low" in that the definition includes the integer. The inclusion of the integer makes little practical difference in terms of the types and numbers of foods omitted or included (Ref. 37).

As discussed previously, the agency is concerned that the use of many descriptive terms could overburden consumers and result in consumer confusion or frustration. The agency believes, for example, that allowing the terms "rich" and "high" to describe two different levels of a beneficial ingredient, would be confusing and misleading to consumers who could reasonably be expected to have difficulty distinguishing "rich" from "high."

While the 1990 amendments specify that FDA should define the term "high," the statute does not preclude the agency from defining other appropriate terms for making nutrient content claims to emphasize the presence of a nutrient. The agency is concerned that the use of only the term "high" will encourage persons to focus their attention solely on foods "high" in nutrients, when, in fact, a healthy diet can include a range of foods that are not necessarily "high" in a particular nutrient. Therefore, to expand the number of foods to which consumers' attention may be drawn and from which consumers are encouraged to select and still be likely to meet dietary recommendations, FDA is proposing to define the term "source" unmodified by an adjective.

FDA believes that it is appropriate and beneficial to consumers to allow the use of this term, which characterizes a mid-range of nutrient content. In defining the term "source," FDA intends to allow food manufacturers and retailers to make a nutrient content claim for a food that provides a significant amount of the nutrient in a serving of the food but for which the nutrient level cannot be described as "high." FDA believes that this information will be helpful to consumers in selecting a healthy and nutritious diet.

The agency is proposing that for a food to be considered to be a "source" of a nutrient, the food must contain 10 to 19 percent of the proposed RDI or DRV per serving. FDA believes that a criterion of 10 to 19 percent is consistent with the criterion 11 to 20 percent of the RDI or DRV suggested by the IOM Committee for the term "good source of," a term intended to reflect a mid-range of nutrient content. The proposed definition of "source" is also consistent with the agency's suggestion that, for the purposes of grocery store shelf-labeling, the term "source" could be used when a serving of the food contains 10 percent or more of the U.S. RDA of the featured substance (Ref. 31). Consequently, the term "source," used to denote that a food contains at least 10 percent of the RDI or DRV of a nutrient, has been introduced to, and used by, consumers in grocery-store shelf-labeling and is likely to be familiar to them.

FDA is not proposing to define the term "contains," such as "contains vitamin C" or "contains fiber." While the IOM Committee has proposed the

use of the term "contains," this recommendation was made in the context of describing, on the nutrition label, the levels of nutrients in a food in lieu of use of percentages of the U.S. RDA. The IOM Committee's system of terminology, therefore, represented a descriptive scheme that graded the levels of nutrients from upper to lower levels.

The agency is concerned that consumers would not be able to distinguish easily between "source" and "contains" when used as nutrient content claims, and that consumers would find these terms confusing. More importantly, the agency believes that for the purposes of nutrient content claims, the use of "high" and "source" provides appropriate opportunities to call attention to the positive aspects of the nutrient content of foods, and that these terms adequately reflect levels of nutrients in foods that can be especially useful to consumers in planning overall diets. Furthermore, the agency has long held that levels of nutrients of less than 10 percent of the US RDA could not be used as content claims because current nutrition labeling regulations prohibit claims that a food is a significant source of a nutrient when the nutrient is present in the food at a level of less than 10 percent of the US RDA per serving. FDA is unaware of evidence suggesting that the policy should be changed and therefore is not proposing a descriptive term for nutrient levels of less than 10 percent of the RDI or DRV per serving.

FDA recognizes that limiting defined descriptors to "high" and "source" for the purpose of emphasizing the positive aspects of the presence of a nutrient is a change from previous agency guidance which permitted the use of the terms "excellent source," "good source," and "source," and that Canadian guidelines also permit a variety of such terms (Ref. 38). The agency, however, has tentatively concluded that limiting the number of descriptors will assist consumer understanding of, as well as confidence in, nutrient content claims by providing for consistent, clear, and limited messages concerning the presence (or absence) of nutrients in foods. The agency requests comments concerning its approach and whether an additional term describing an upper level amount of a nutrient (such as "very high") is necessary and appropriate.

However, the agency is proposing to include synonyms for the two defined terms. FDA is proposing to allow the use of "rich in" and "a major source of" as synonyms for "high." It is also proposing to allow the terms "good source of" and "important source of" as synonyms for "source." FDA is including these synonyms to provide some flexibility in the use of these terms.

FDA recognizes, however, that this aspect of the proposal may be controversial. Concerns about the use of synonyms for terms like "high" and "source" have been raised by IOM and the IUNS Committee (Ref. 10). The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties for the consumer in understanding a plethora of such terms (Ref. 10). FDA requests comments on this issue and on consumer understanding of the terms that it has proposed as synonyms for "high" and "source."

c. *"High" and "source" not defined for total carbohydrate and unsaturated fatty acids.* FDA has tentatively concluded that definitions for "high" and "source" for the nutrients total carbohydrate, including complex carbohydrates, and unsaturated fatty acids would be misleading. Therefore, FDA is proposing to exclude these nutrients from the coverage of these terms (proposed § 101.54(a)).

In proposing declarations of nutrient content as part of the nutrition label, FDA is proposing to define total carbohydrate as consisting of both complex carbohydrates and sugars. Available consensus reports and current dietary recommendations generally encourage the increased consumption of complex carbohydrates, while suggesting that sugars intake be limited (Refs. 1, 2, and 3). Therefore, a nutrient content claim such as "high in carbohydrate," or "source of carbohydrate," provides misleading dietary advice. At best, the claim is ambiguous in that it does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.

Furthermore, the agency does not believe that allowing more specific claims relative to levels of carbohydrate in foods, such as "high in complex carbohydrates," can be supported based on recommendations provided in the major consensus reports (Refs. 2 and 3) concerning complex carbohydrate and sugars intake because quantitative recommendations for these nutrients are not provided. Additionally, while the agency has tentatively proposed to require declarations of complex carbohydrates and sugars content on the nutrition label in response to the 1990 amendments, the agency has expressed concern about the appropriateness of including these nutrients. The inclusion of complex carbohydrates and sugars within the mandatory nutrition label may be misleading to consumers because it may suggest that these nutrients have greater public health significance than has been established by existing diet and health studies. In particular, the identification of a specific benefit for complex carbohydrates is confounded by the fact that diets high in complex carbohydrates are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables, which are high in fiber, vitamins, and minerals and low in fat (Ref. 2). Thus, the extent to which complex carbohydrates provide a health benefit separate from that provided by the fiber, vitamins, minerals, and reduced level of fat is unclear.

Nutrient content claims concerning "high" amounts of unsaturated fatty acids in foods are problematic for several reasons. Unsaturated fats are comprised of various mono- and polysaturated fatty acids. Different types of unsaturated fatty acids are known to have different effects on health. Some have been shown to lower serum cholesterol levels when substituted for saturated fatty acids (Ref. 3). On the other hand, there is a growing body of evidence suggesting that *trans* isomers of unsaturated fatty acids may be associated with increases in serum cholesterol levels (Ref. 3). The agency has expressed concern about the appropriate definition of unsaturated fatty acids in its supplementary proposal on nutrition labeling. FDA is proposing to provide for voluntary declarations for the amount of unsaturated fatty acids in a food, which would be based on the sum of all polyunsaturated and monounsaturated fatty acids (i.e., both *cis* and *trans* isomers). If claims for "high" unsaturated fatty acids were permitted, *trans* isomers would be included in the level of unsaturated fatty acids reflected in such claims. However, FDA has acknowledged the controversy concerning the inclusion of *trans* isomers in the definition of unsaturated fatty acids. The agency is specifically asking for comments on the appropriateness of including these isomers in the definition for unsaturated fatty acids, given currently available research and public health goals, in the supplementary proposal on mandatory nutrition labeling.

Furthermore, high levels of intake of unsaturated fatty acids, particularly high polysaturated fatty acid intakes, may increase risk of certain cancers (Ref. 2). The NAS report "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) recommended that intakes of polyunsaturated fatty

acids not exceed 10 percent of total calories, and that intake be maintained at the current U.S. level, i.e., approximately 7 percent of total calories. Claims for "high unsaturated fatty acids," however, could promote increased intakes of polyunsaturated fats.

Therefore, FDA has tentatively decided not to define the claim "high" for unsaturated fatty acids here. FDA believes that such claims are potentially misleading because there is some evidence suggesting that certain components of unsaturated fatty acids may be associated with the increased risk of certain cancers because current dietary recommendations advise against increases in at least one component of unsaturated fatty acids, and because the current science base has suggested that the benefits of polyunsaturated fatty acids derive not from increased intake but rather from their substitution for saturated fatty acids.

d. *Special requirements for fiber claims for foods not low in fat.* Consistent with section 403(r)(2)(A)(v) of the 1990 amendments, FDA is proposing to require that unless a food meets the definition for "low fat" (i.e., contains 3 g or less of fat per serving and per 100 g of food), as proposed in § 101.62(b)(2) of the companion document on claims for fat, saturated fat, and cholesterol content, the claims "high fiber" or "source of fiber" shall be accompanied by a declaration of the amount of total fat in a serving of the food. Therefore, FDA is proposing in § 101.54(d) that if a claim is made that a food is high in fiber, or is a source of fiber, and the food is not low in total fat as defined in § 101.62(b)(2), then the label must disclose the level of total fat per labeled serving in the referral statement (e.g., "Contains [*X g*] of total fat per serving. See [*nutrition panel*] for nutrition information").

C. Relative Claims

1. Introduction

Among the terms the agency is required by the 1990 amendments to define, unless they are found to be misleading, are "light" (or "lite"), "reduced," and "less" (section 3(b)(1)(A)(iii)(III), (b)(1)(A)(iii)(IV), and (b)(1)(A)(iii)(V), respectively). Claims that include these terms are intended to help guide consumers to foods that may be useful in meeting current dietary recommendations. In addition, these terms provide a basis for comparing the level of a nutrient in one food to its level in another food. The agency refers to these claims as "relative claims" to distinguish them from the "absolute" nutrient content claims using, for example, "low" or "high." However, the term "light" has been used not only as a comparative term to indicate that there is less of a nutrient in this particular food compared to another food, but it has also been used to directly describe a characteristic of the food itself without direct comparisons to another food.

The agency is also proposing to define the circumstances under which the terms "fewer" and "more" may be used. Together with "less," FDA considers "fewer" and "more" to be a subset of relative claims referred to as "comparative claims."

Although there is a certain amount of overlap in the proposed definitions of these terms, the agency is really defining them to create a continuum for "light" claims, to "reduced," and finally to "less," with decreasing rigor in the requirements for use of the terms. FDA's tentative view is that such an approach will limit consumer confusion with respect to the meaning of these terms. However, FDA recognizes that, as an alternative, the terms could be used subject to a single set of definitional requirements, with full disclosure, as part of the claim, of the reference food, the percent the nutrient has been decreased, and the quantitative amount of the nutrient in the labeled food and the reference food. This alternative approach is discussed below in section IV.

2. General Requirements

The general requirements for relative claims, including comparative claims, are set forth in proposed § 101.13(j).

a. *Reference foods.* Relative claims compare the amount or percentage of a nutrient in one product to the level of that nutrient in another food. The agency uses the term "reference food" to denominate the food to which the labeled product is compared. Because a relative claim may be made with respect to a variety of reference foods, FDA believes that for such a claim to be complete and not misleading, the claim must be accompanied by a statement that compares the food for which the claim is made to a specified reference food. This information is important because the amount of a nutrient in a food product, potato chips for example, may vary widely. Some brands or formulations may be relatively low in a nutrient, such as fat, while others are relatively high. Consequently, the declared percentage reduction in a nutrient in a food making a claim will vary depending on the food to which the comparison is made. Conversely, two products showing the same percentage reduction in a nutrient, 25 percent for example, may vary considerably in the absolute amount of the reduction, depending on the product to which such altered food is compared.

The agency believes that a food bearing a relative claim, but not the identity of the reference food, would be misbranded under section 403(*a*) and 201(n) of the act because a fact material to understanding the significance of the claim would not be revealed. Information about the nature of the modification of the product, which would be essential in judging the usefulness of the product, would not be declared. The agency believes, therefore, that the identity of the food that serves as the basis for the relative claim must be stated on the label.

To ensure that the comparisons made are appropriate, FDA is proposing criteria for selecting reference foods. FDA first developed these criteria in response to comments on its proposal on cholesterol content claims (51 FR 42584, November 25, 1986). These criteria were discussed in the subsequent tentative final rule (55 FR 29456, July 19, 1990). In that document, the agency tentatively concluded that appropriate reference points for "reduced" and comparative claims would be: (1) An industry wide norm, (2) the manufacturer's regular product, or (3) a similar product or class of products as found in a current valid composite data base.

Although FDA is proposing to retain these general points of comparison, the agency considers it necessary to alter the application of these references to accommodate the expanded scope of the descriptors found in this document.

The agency is now proposing an industry-wide norm as a reference point for all relative claims in § 101.13(j)(1)(i). An industry-wide norm takes into account all foods in a particular product class. Consequently, it provides the broadest base and the least opportunity for abuse of any of the reference foods. As defined in the cholesterol tentative final rule, an "industrywide norm" is an average value that is determined by calculating the weighted average of the nutrient in question on a unit or tonnage basis according to the national market share of all foods of the type for which the claim is being made. This concept utilizes national market share information that is readily available to both industry and government. The agency believes that by calculating the industry-wide norm on a unit or weight basis rather than on the basis of dollar sales, the price variability between various brands of similar products (generic or store brand versus national

brands, for example) will not affect the result.

As an example of the calculation for "industry-wide norm," if brand A has a market share of 75 percent and contains 100 mg of cholesterol per 10-ounce (oz) serving, and brand B has a market share of 25 percent and contains 200 mg of cholesterol per 10-oz serving, then the industry-wide norm is 125 mg of cholesterol per 10-oz serving.

FDA is proposing in § 101.13(j)(1)(ii) that reduced and comparative claims may also be made using "a manufacturer's regular product." In the cholesterol tentative final rule, FDA defined this food as a food actually offered for sale to the public on a regular basis for a substantial period of time in the same geographical area, by the same business entity or by one entitled to use its trade name. This criterion will prevent misleading comparisons by precluding a manufacturer from specially formulating a product that is particularly high in a nutrient for limited distribution, for the sole purpose of providing a favorable basis of comparison for another product. A manufacturer's regular product provides a reference to a known specific food and consequently provides a meaningful basis for "reduced" and comparative claims which compare one product directly to another.

Finally, FDA is proposing in § 101.13(j)(1)(iii), for comparative claims only, that a food may also be compared to a similar product or class of products whose compositions are published in a current, valid composite data base, such as the revised sections of USDA's Agriculture Handbook No. 8: "Composition of Foods, Raw, Processed, Prepared" (Ref. 39). By including valid data bases as a basis of comparison, the agency would permit comparative statements based on comparisons of foods within a product class. A product class would include foods for similar dietary uses, i.e., foods that are used interchangeably and have similar product characteristics. For example, this reference point would allow a potato-based snack food to make comparisons with potato chips or with corn chips and a waffle to be compared with a pancake or french toast. This approach would also allow certain new types of products that have a nutritional advantage over existing foods to make a comparative statement. Such a comparative statement might read, for example, "potato puffs, contains 25 percent less fat than potato chips." Because a valid data base, such as USDA's Agriculture Handbook No. 8, (Ref. 39) includes a wide variety of foods within a product category, the agency believes that this reference is inappropriate for "reduced" or "light" claims.

b. *Need for information to accompany claim.* The agency believes that even though terms used in relative claims will be defined by regulation, the claims may be misleading unless they are accompanied by certain material facts that are necessary if consumers are to understand the change that has been made in the food. The agency considers that in the presence of a relative claim: (1) The percent of change in the nutrient level, and (2) the amounts of the nutrient in the labeled food and the reference food are material facts under sections 403(a) and 201(n) of the act.

As will be discussed in detail later, the agency is proposing to permit relative claims on foods based on nutrient differences of 25 percent and above for diminished levels of a nutrient and 10 percent or more of the DRV or RDI for increased levels of a nutrient. Consequently, information about the percent difference in the level of the nutrient between the food and the reference food is necessary for the consumer to evaluate the claim.

Even if a product declares the percent reduction in a particular nutrient compared to the reference food (or the percent more of the DRV or RDI compared to the reference food for "more" claims), the amount of that nutrient in the product relative to the reference food is also necessary information. Information on the amount of nutrient present is necessary for consumers because it provides an additional basis on which they can evaluate the significance of the change, and because it helps them in composing a diet to meet nutritional requirements.

FDA is proposing that statements about the relative amount of a nutrient in the labeled food compared to the reference food state the amount of the nutrient in each food, i.e., "This cheesecake contains 150 calories per serving compared to 200 calories per serving of our regular brand."

As discussed in section II.C. of this document on referral statements, the agency believes that required accompanying information should be in type size no less than one-half the size of the claim. Therefore, consistent with current regulations and proposed requirements for referral statements, the agency is proposing that the required information accompanying a claim about the relative amount of a nutrient be in type no less than one-half the size of the type of the claim but in no case less than one-sixteenth of an inch. One sixteenth of an inch, as discussed above, is the minimum size normally permitted (per § 101.2(c)) for information required on the principal display, or information panel of food labeling.

The agency recognizes that the information that it is proposing to require accompany a relative claim is considerable, but it considers this information necessary to ensure that the claim is not misleading. On the other hand, FDA also recognizes that a requirement that this information be included each time a relative claim is made would overburden the label to the point that the usability of the required information could be diminished. Therefore, the agency believes that the quantitative information required to accompany the claim should be required with only the most prominent declaration of the claim on the food.

Accordingly, based on the foregoing discussion, the agency is proposing in § 101.13(j)(2) that for foods bearing relative claims, the label must bear immediately adjacent to a relative claim in the most prominent location on the label, and in type no less than one-half the size of the type in the claim but in no case less than one-sixteenth of an inch, the following information: (1) The identity of the reference food, (2) the percentage by which the amount of the nutrient in the food differs from the amount in the reference food, and (3) quantitative information comparing the amount of the subject nutrient in the food per labeled serving with that in the reference food (§ 101.13(j)(2)(i)).

The agency is also proposing that the determination of which use of the claim is in the most prominent location will be made based on the following factors, considered in order: (1) A claim on the principal display panel adjacent to the statement of identity, (2) a claim elsewhere on the principal display panel, (3) a claim on the information panel, or (4) a claim elsewhere on the label or labeling (proposed § 101.13(j)(2)(ii)). These factors are based on the fact that the statement of identity is the most critical information on the package, and that the principal display panel, followed by the information panel, are the most important label panels. In addition, these requirements are reiterated in the appropriate paragraphs for relative claims for the individual nutrients e.g., in § 101.54(e)(1)(iii) for "more" claims, § 101.56(b)(3) for "light" claims, § 101.60(b)(4)(ii) and (b)(5)(ii) for calorie claims, and § 101.61(b)(6)(ii) and (b)(7)(ii) for sodium claims.

c. *Absolute difference in nutrient levels for relative claims with*

decreased levels of nutrients. The agency is concerned that relative claims that highlight a decrease in the amount of a nutrient will be made on products that normally contain only a small amount of that nutrient. In such products, a large percentage reduction would produce only a small change in the actual amount of the nutrient present. For instance, a food containing only 50 calories per serving could be reformulated to contain 35 calories per serving and thereby qualify to use a relative claim when, in fact, the difference of 15 calories cannot be considered of nutritional significance. A claim for such a nutrient content difference would be misleading.

Therefore, the agency believes that an additional criterion that specifies a minimum reduction in the amount of the nutrient is necessary to ensure that manufacturers do not make changes based on inconsequential changes in their products.

Currently, no guideline or definition that can be used for determining the amount of a nutrient in food that can be considered consequential or nutritionally meaningful is available. However, FDA believes that the definition for a "low" claim on a per serving basis should be used as such an amount. The agency considers this level to be appropriate because the amount specified as "low" is not inconsequential relative to the overall intake of the nutrient. A person who chose a diet exclusively of foods that qualified for a "low" claim for a particular nutrient would be expected to consume as much as 50 percent of the recommended levels for that nutrient. Yet, because the definition of "low" is tied to the measurable amount of the nutrient, it is clearly a small amount.

Accordingly, FDA is proposing in § 101.13(j)(2)(iii) that a relative claim for a decreased level of a nutrient may be made on the label or in labeling of a food only if the nutrient content for that nutrient differs from that of the reference food by at least the amount specified in the definition of "low" for that nutrient. Consequently, to bear a relative claim for decreased levels of calories, for example, a food would have to have a decrease from the reference food of more than 40 calories per serving.

3. Reduced

a. *Background.* FDA has recognized the potential dietary benefits of foods that have been fabricated or altered to reduce their nutrient content. FDA regulations, proposed regulations, and guidelines provide for the use of the term "reduced" for content of sodium (21 CFR 101.13(a)(4)), fat (Refs. 3 and 31), cholesterol (55 FR 29456, July 19, 1990), and calories (21 CFR 105.66(d)). Canadian regulations provide for the use of the term "reduced" for altered foods, specifically for the content of calories (Ref. 32) and carbohydrates (Ref. 33).

In response to the 1989 ANPRM and the public hearings, FDA received a variety of comments concerning the term "reduced." Many supported the use of the term, although a few comments suggested that the term was redundant to the agency's provision for comparative statements, and that the term could be misleading to consumers who would interpret the claim to be synonymous with "low." Several comments stated that there is a need to limit the descriptor to a "significant standard of reduction" or a difference of "nutritional significance" to consumers. Other comments argued that, in defining this term, it is necessary to avoid using unreasonably restrictive criteria that could not be met technologically. These comments stated that such criteria would not provide incentives for alterations in food products. However, the comments generally supported the use of levels such as the 33.3 percent for calories, the 50 percent for fat, and the 75 percent for sodium that FDA has established as the reduction levels. Some comments stated that for consumer ease of understanding, and to provide for industry incentives to reduce nutrients in foods, general use of 33.3 percent for all nutrients was desirable. Other comments supported the use of a 50 percent reduction for all nutrients.

The agency believes that consumers associate the term "reduced" with a beneficial reformulation of the food product, and many comments support this belief. Furthermore, given the considerable increase in public awareness and concern about diet and health, the term is viewed by industry and by public health professionals as being particularly effective in causing consumers to select one product over another. Therefore, FDA agrees that the term should be defined, and that the definition of the term should be limited to reformulations that reflect considerable decreases in the level of the nutrient and that have the potential to result in a significant impact on dietary intake of the nutrient. Moreover, as stated above, section 3(b)(1)(A)(iii)(IV) requires that FDA define this term.

In defining the term "reduced," FDA acknowledges the possibility that consumers could interpret the term to be synonymous with the term "low" but believes that consumer education efforts can help to alleviate the potential confusion. Moreover, the possibility of misinterpretation does not outweigh the potential benefits of encouraging the availability and consumption of foods containing reduced levels of certain nutrients. Furthermore, as described above, the agency is proposing to require declaration of quantitative comparisons both in terms of percent reductions and absolute amount reductions. These proposed provisions should decrease the possibility of consumer misinterpretation of the term "reduced."

FDA is proposing to define "reduced" for the following nutrients: total fat, saturated fat, cholesterol, sodium, and calories. The rationale for defining "reduced fat," "reduced saturated fat," and "reduced cholesterol," and the proposed definitions for these terms, are set forth in the companion document on claims about these nutrients published elsewhere in this issue of the **Federal Register**. FDA tentatively concludes that reduced claims for nutrients other than these five are not appropriate because the reduction of other nutrients in the diet is not identified as being of public health importance in the major consensus reports currently available (Refs. 2 and 3).

b. *How definitions of "reduced" for nutrients were derived.* To justify a "reduced claim" and the consequent emphasis on the fact that a reduction in a nutrient has occurred, FDA believes that there should be a substantial reduction in the amount of nutrient present in the food, which in turn could result in a substantial reduction in the amount of the nutrient in diets of individuals. While there is general agreement that the availability of foods reduced in specific nutrients is beneficial from a public health perspective (Refs. 5 and 45), there are no scientific data available to indicate precisely the extent to which reductions of these nutrients in available foods are needed, nor the extent to which such reductions could affect the diets of individuals. Nonetheless, FDA has developed a general approach to the use of this claim.

In defining "reduced," and what would constitute a substantial reduction in the level of a nutrient in a food, an important consideration is the distribution of the nutrient in the food supply. If a nutrient is provided by all general categories of foods, such as fruits, vegetables, grain products, and dairy products, the nutrient can be considered to be ubiquitous in the food supply. The extent of reduction necessary to justify a "reduced" claim for nutrients that are ubiquitous is likely

to be different than that necessary for nutrients that are found in only some or a few food categories. If the dietary reduction of a nutrient can be spread out over all or most food categories, smaller reductions on a food-by-food basis would be needed to achieve a substantial dietary impact than would be needed if the nutrient is present in only some food categories.

A second important consideration in defining "reduced" is the need to provide a consistent definition for this term for all nutrients, so that consumer education efforts can be more easily implemented. Comments have suggested that consumers will more readily recall the meaning of the term "reduced" if it is limited to one level of reduction, such as one-third or one-half. The agency agrees that consistency in definition is desirable.

Therefore, in developing the general criteria for the use of the term "reduced," the agency considered the level of reduction that would result in a substantial reduction in the nutrient content of foods as well as the need for consistency of terms. In addition, FDA considered two other factors. In response to comments, FDA considered the technological feasibility of reducing levels of nutrients in foods. Finally, in developing these definitions, the agency reviewed the quantitative differences between current levels of intake for these nutrients and recommended levels of intake.

FDA is proposing to define the term "reduced" as a difference of 50 percent for all specified nutrients except calories. The agency has tentatively decided that there are no compelling reasons to change the current definition for "reduced calorie" of a 33.3 percent reduction in calories (§ 105.66(d)(1)(i)). For the other four nutrients, reductions of 50 percent are feasible, even in the case of total fat. Current technology has demonstrated that for many foods, including dairy products, a reduction in total fat of 50 percent or more is achievable (Ref. 40).

In addition to a percentage reduction, FDA is proposing to include an absolute reduction criterion in the definitions for "reduced" for particular nutrients. To bear a "reduced" claim, the food must contain a level of the nutrient that is reduced from that in the reference food by an amount that exceeds the per serving criterion for "low" for that nutrient. FDA explained the basis for its reliance on that criterion in section III.C.2.c. of this document, above.

c. *Reference foods for "reduced" claims.* As discussed above (section III.C.2.a. of this document), FDA is proposing in § 101.13(j)(1) two reference points against which a food can be compared to develop a "reduced" claim that is not false or misleading: (1) An industry-wide norm and (2) a manufacturer's regular product.

The agency believes that these reference points are appropriate for "reduced" claims because they reflect points of comparison that are accurately and consistently quantifiable and that thus can provide a meaningful basis of comparison. An industry wide norm represents a reference point calculated on the basis of all foods of the particular type for which the claim is being made. Likewise, the manufacturer's regular brand, which has been available for sale to the public on a regular basis for a substantial period of time and in the same geographic area by the same business entity or one entitled to use its trade name, provides the consumer with a valued reference point to which they should be familiar.

The agency, however, does not consider the third reference point, i.e., a similar product or class of similar products in a current valid composite data base, to be an appropriate point of reference for comparing "reduced" foods. Such a reference point reflects a much wider variety of products than the other two. The agency believes that "reduced" comparisons should be made to a product or type of product that is most like the product bearing the 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 not necessarily any 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" 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 lowered the amount of 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.

d. *Specific definitions*—i. *Reduced sodium.* FDA is proposing to define "reduced sodium" in § 101.61(b)(6)(i) as a reduction of at least 50 percent and a minimum reduction of more than 140 mg per serving. This definition is different than the current FDA regulation (21 CFR 101.13(a)(4)), which provides that for a food to be labeled "reduced sodium," its level of sodium must be reduced by 75 percent. No weight based criterion is specified in the current regulation.

In its 1984 rule on sodium descriptors (49 FR 15510), FDA stated that it intended the "reduced sodium" descriptor to be reserved for those products in which there has been a very substantial reduction in the level of sodium, and that the feasibility of a 75 percent reduction in sodium had been demonstrated for a few products such as cheese and soups. The agency stated that it did not consider a 75 percent reduction to be too severe, unrealistic, or technologically infeasible.

Few data are available to determine the extent to which foods have been reformulated to meet the current criterion for "reduced sodium." A review of data in FDA's 1988 Food Labeling and Packaging Survey (FLAPS) data base revealed that of the 1,265 foods in the data base, none had "reduced sodium" in their brand name or elsewhere on the label (Ref. 41). Information from a market survey for the period of January to June 1989 (Ref. 42) reveals that about two dozen products from over 222,000 products were recorded as having "reduced sodium" or "reduced salt" in their brand name.

While the results of those surveys may suggest that the current criterion may be too difficult to meet, a firm conclusion cannot be drawn because these surveys are selective and not comprehensive. However, the agency recognizes that a 75 percent reduction in sodium may be too difficult to achieve to provide incentive to the food industry to develop and promote reduced sodium foods. The agency therefore believes that some reduction in this criterion would be appropriate.

One reason to consider a 50 percent reduction as a more appropriate criterion for "reduced sodium" is the desirability of harmonizing the criteria used to define the term "reduced" among the various nutrients. As discussed above, consistency of definition will facilitate education efforts and potentially decrease the level of confusion concerning the overall use of the term. In the companion

document concerning fat, saturated fat, and cholesterol descriptors, FDA is proposing a 50 percent reduction as the definition for "reduced fat," "reduced saturated fat," and "reduced cholesterol."

Furthermore, evidence from FDA's Regulatory Food Composition Data Base (Ref. 35) suggests that while sodium is not ubiquitous in the food supply, it is present in many foods. As a result, there are a large number of potential candidates for a "reduced sodium" claim. While a 50 percent reduction is obviously smaller than a 75 percent reduction, if more manufacturers make reduced sodium foods as a result of this decrease in the criterion, the 50 percent reduction criterion may ultimately be as effective, or more effective, in lowering sodium intake than would be a 75 percent reduction in fewer foods.

Additionally, the agency has estimated that a general reduction of 50 percent in sodium intake is needed to meet current dietary recommendations (Ref. 43). While such an estimate cannot form the basis for defining precisely the necessary level of reduction of a nutrient needed, in the case of sodium it supports that a 50 percent reduction in individual foods is not inconsistent with current public health goals in that the proposed level of reduction in foods corresponds to the apparent need for reduction in the general diet.

FDA is therefore proposing in § 101.61(b)(6) to amend the current regulation for reduced sodium foods (§ 101.13(a)(4)) by establishing 50 percent for "reduced sodium" as a minimum reduction. The agency specifically asks for comments concerning this proposed criterion, its public health impact, and nutritional significance, as well as the extent to which the benefits of consistency among definitions and increased availability of sodium reduced foods should be considered.

The agency is also proposing in § 101.61(b)(6) to limit the use of the term "reduced sodium" to those foods for which the total reduction in sodium levels exceeds 140 mg per serving. As discussed above, this second criterion will prevent "reduced sodium" claims on foods that have undergone inconsequential reductions in sodium levels.

ii. *Reduced calorie.* FDA is proposing in § 101.60(b)(4)(i) to define the term "reduced calorie" as a level of reduction of at least 33⅓ percent and a minimum reduction of 40 calories per serving. This proposed definition is consistent with current agency regulations concerning the use of this term (§ 105.66(d)) but differs from the other current proposed levels of reduction for sodium, total fat, saturated fat, and cholesterol, all of which are proposed to be defined as a reduction of at least a 50 percent for the designated nutrient.

FDA first defined the term "reduced calorie" in 1978 (43 FR 43248). At that time, concerns about the term centered on ensuring that it applied to foods that have special value for reducing or maintaining body weight or caloric intake. The agency had tentatively defined "reduced calorie" as one that had at least a one-third reduction in calories (42 FR 37166). Comments received by the agency generally suggested that a lower number, such as a 25 percent reduction, be used. However, the agency adopted the 33⅓ percent reduction because it is feasible for many foods to achieve such a reduction, and because the agency felt that consumers expect a substantial reduction when "reduced" is used. FDA acknowledged that not all foods could be calorically altered but stated that it was important to have a reasonably large reduction in those that can be altered and that are offered for sale primarily on the basis of their caloric reduction.

Comments received by FDA in response to the 1989 ANPRM and public hearings generally supported the use of the term "reduced calorie." No comments expressed concern that the current level used to define this term was inappropriate. One comment, however, suggested that all terms for "reduced" should be defined as a 25 percent reduction, and one comment suggested that the level of reduction for all relevant nutrients should be one-third.

In arriving at a definition for "reduced calorie," FDA considered that the ubiquity of calories across all food categories suggested that the reduction in calories in each food necessary to achieve an overall reduction of public health significance could be less than that necessary for nutrients such as cholesterol or fat. Additionally, the agency considered the public health recommendations relative to weight control, which stress the desirability of only moderate reductions in calories coupled with an increase in exercise or energy (calorie) expenditure (Refs. 2 and 3).

Diets with a moderate reduction in calories are the most advisable for general use because they present less risk that the intake of essential nutrients will be inadequate when the caloric intake is controlled. A one-third reduction criterion allows a greater variety of nutritious foods to bear claims of usefulness in reducing or maintaining caloric intake or body weight, and variety is important in maintaining the motivation to adhere to a calorie control program. Finally, the agency considered that the current definition of "reduced calorie" has been used for a considerable time without apparent difficulty for manufacturers or consumers.

For these reasons, the agency continues to believe that the percentage reduction specified in its current definition of "reduced calorie" in 21 CFR 105.66(d) is appropriate and that there is no compelling reason to change this criterion. Thus, FDA is proposing to recodify this provision as § 101.60(b)(4). Additionally, as discussed above in section III.C.2.c. of this document, the agency is also proposing that declarations concerning reductions in calories be limited to those foods in which there has been a reduction of more than 40 calories per serving.

4. "Light" or "Lite"

a. *Reduced calorie/reduced fat products.* The 1990 amendments, in section 3(b)(1)(A)(iii)(III), instruct the agency to define the term "light" or "lite." (For purposes of this notice, the term "light" will be used to mean either "light" or "lite.")

The term "light," as it has been used for a number of years, connotes a wide variety of meanings such as low or reduced calorie; reduced in fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. However, surveys (Refs. 44 and 45) conducted in 1982 and early 1990 found that consumers (70 percent in 1982 and 69 percent in 1990) believe that the term "light" means that the caloric level has been altered in some manner. The similarities in the consumer responses in these two surveys demonstrate considerable stability in consumer perception of the term "light," even though the extent and variety of uses of this term in food labeling have increased many-fold since 1982.

In addition to being a relative claim that compares a food to another food, the term "light" has been used to directly describe the food itself. Without specifying a reference food, the term "light" has been used to imply that the food bearing the term is somehow better nutritionally than other similar but unspecified foods not bearing the term. In this way it has been used more like the absolute claim "low."

The legislative history reflects this use of "light." It states that "an example of an implied claim * * * would be the statement "lite," which implies that the product is low in some nutrient

(typically calories or fat), but does not say so expressly." (H. Rept. 101-538, *supra*, 19.) When "light" has been used as an implied claim, the consumer has generally not been given any explicit product-to-product comparisons to support the claim. The use of "light" without such comparisons results in a direct statement about the food, suggesting that the food itself was somehow more healthful.

Thus, it is not surprising that "light" appears to have great appeal to consumers. In a 1990 Gallup Poll (Ref. 45) many consumers said that they consume "light" products. Sixty-five percent said they consume "light" cheese, yogurt, and sour cream, and 46 percent said they consume "light" ice cream and frozen desserts. Because a majority of consumers associate "light" with a reduction in calories even though there are other meanings for the term, the potential for misuse of the term is created. For example, the use of the term "light" on a food oil may lead consumers to believe that the product has been reduced in calories or fat, when the term is actually being applied to the food to refer to its color.

Because the term "light" appears to be meaningful to a majority of consumers, and because of the potential for misuse of the term, the agency believes that use of the term must be limited to foods that, compared to other products in their class, contribute substantially to the reduction of calories and fat in the diet. Although FDA currently has no regulations governing the use of "light," the agency believes that its definition should be based primarily on consumers' perception that the word "light" means "reduced" in calories. As discussed above, the agency is proposing to retain the definition of "reduced calorie," currently in § 105.66 (⅓ reduction in the number of calories compared to a reference food) in proposed § 101.60(b)(4)(i). Therefore, the agency is proposing in § 101.56(b)(1) that the terms "light" or "lite" may be used without further qualification to describe a food provided that the food has been specifically formulated or processed to reduce its calorie content by 33⅓ percent or more from the reference food that it resembles and for which it substitutes.

Recently, however, FDA has also allowed the term "light" to be included as part of the name of dairy products that are altered to have, in addition to one-third fewer calories, at least 50 percent less fat, but to otherwise possess the same nutritional properties, as the food for which they substitute. The agency has issued a number of temporary marketing permits allowing manufacturers to test market modified standardized foods on this basis (e.g., "lite sour cream"—55 FR 12736, April 5, 1990, "light ice cream"—55 FR 3772, February 5, 1990 and "light egg nog"—55 FR 46998, November 8, 1990.)

Because manufacturers of high fat products, such as sour cream and egg nog, have petitioned FDA to use the term "light" to describe the altered versions of their products, and because other normally high fat products, such as cheese foods, are currently using the term "light," the agency believes that it is necessary to establish criteria for use of the word "light" on altered products that substitute for foods that normally contain relatively high amounts of fat.

The agency believes, however, that it would be misleading to permit the term "light" to be used on a product that normally contains relatively high levels of fat and in which the fat has been reduced but not the calories. As the research discussed above shows, consumers expect a "light" product to primarily be reduced in calories. Therefore, FDA is proposing that for a food in which fat contributes 50 percent or more of the calories to bear the term "light," it must be reduced both in calories and in fat by the percentage of nutrients that would allow the food, for both calories and for fat, to bear the term "reduced" (i.e., 33⅓ and 50 percent respectively). The agency selected 50 percent of calories from fat as the point at which the fat content contributes so significantly to the calorie level in the food (i.e., half) that the fat level must be reduced along with the calorie level to justify a "light" claim.

Consequently, the agency is proposing in § 101.56(b)(2) that a food that derives more that 50 percent of its calories from fat may use the term "light" or "lite" provided that, in addition to the caloric content being reduced by 33⅓ percent, its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes.

It has been suggested as an alternative, rather than to prohibit a "light" claim on a product containing more than half of its calories from fat that has not been reduced also by 50 percent in fat, that such product should bear some type of statement informing the consumer that the product was not reduced in fat. Such a statement might be "Contains X percent fat," or "Contains X percent calories from fat." Would it be misleading to call such a product "light" without the defined fat reduction? The agency requests comments about this approach and about what statement might be required. 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.

As with "reduced" foods, so as not to allow nutrient content claims for reductions in foods that are inconsequential, the agency believes that a minimum reduction in calories and, where appropriate, fat should be required to justify an unqualified "light" claim. Consistent with the proposed requirements for "reduced calorie" and "reduced fat" claims, the agency believes that these minimum reductions should be more than 40 calories and 3 g of fat. The agency is proposing this minimum reduction in § 101.56 (b)(1) and (b)(2).

Also, as with "reduced" foods, the agency considered what types of products would be appropriate as reference foods for "light" claims. Because a "light" claim is really two "reduced" claims, it would seem possible to make "light" claims on the basis of the same reference foods as "reduced" claims. However, FDA's experience with foods presently on the market that bear "light" claims has led it to tentatively conclude that for "light" claims, comparisons to a single food in the product class (i.e., the manufacturer's own brand) may be misleading. This is particularly the case if the reference food differs significantly from the norm for the product class and contains the nutrient at a level that is at the high end of the range for the product class.

An example of a food with respect to which a comparison with a manufacturer's own brand could be misleading is chocolate chip cookies. An informal label survey (Ref. 58) revealed a wide variety of fat and calorie levels on a per serving basis for an equally wide variety of chocolate chip cookies. In fact, using the criteria from the serving size proposal published elsewhere in this issue of the **Federal Register**, even two chocolate chip cookies from the same manufacturer were found to differ widely in their fat and calorie content. A serving of one variety of chocolate chip cookies (two ½ ounce cookies) contained 100 calories and 4 g of fat, while the same size serving of another variety contained 180 calories and 10 g of fat. Clearly comparison with either cookie could result in vastly different claims. Consequently, the agency believes that the manufacturer's own brand may be misleading as a reference food for "light" products, and the agency is no

proposing the manufacturer's own brand as an appropriate reference food.

Therefore, because of the potential for abuse of this term, FDA is proposing that the reference food for "light" claims be only an industry wide norm as defined in § 101.13(j)(1)(i). The agency, however, solicits comments on this issue.

b. *"Light" sodium products.* Some product labels have used the term "light" to describe the salt or sodium content of the food. Because this use of the term results in "light" being used on foods that have not been reduced in calories, the agency considers that this use could be misleading. Therefore, FDA believes that the term "light" should not be used on products solely in reference to their sodium content. Accordingly, the agency is proposing in § 101.56(c) that a product other than a salt substitute that is low, reduced, or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather must use, as appropriate, the terms "reduced sodium" or "low sodium."

Although the agency is proposing that the primary basis for the definition of "light" should be a reduction in calories, and that all other unqualified uses of the term are not permitted, the agency believes that the definition for "light" as used with salt substitutes can be viewed differently. Salt substitutes are offered for sale as products that contain virtually no calories. Because a salt substitute clearly contains no calories, a "light" claim would not imply that such a product has been reduced in calories and would not be misleading. In addition, salt substitutes that use the term "light" have been on the market for a number of years, and consumers have become familiar with, and understand, the concept of "light" salt as being reduced in sodium. Therefore, the agency is proposing to permit "light" to be used on salt substitutes that contain at least 50 percent less sodium than table salt. This proposed use of the term is consistent with the approach used for defining "reduced sodium." Accordingly, the agency proposes in § 101.56(d) that the term "light" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to table salt.

However, because these salt substitutes may contain significant amounts of sodium, the resulting product may not meet the definition for a low sodium food. The agency therefore invites comments on the use of "light" for these products.

c. *Other uses of the word "light."* As stated previously, the use of the word "light" on food labels generally means reduced calories. However, in some cases it has been used to convey other meanings. The agency believes that the unqualified use of the term may mislead consumers into believing that a food is reduced in calories when this term is actually used to refer to properties of the food other than calories. Consequently, the agency believes that unqualified use of the term "light" when not referring to calories (or sodium in the limited circumstances discussed above) should be prohibited.

If the term is meant by the manufacturer to refer to an organoleptic or other quality, such as texture, color, flavor, weight, or density, all of which may be a logical basis for the use of the term "light," FDA believes that that fact must be clearly and plainly conveyed on the label. For example, the label may state "light in color," "light in texture," or use other terms that clearly convey the nature of the product. In addition, so as not to give undue prominence to the term "light" in relation to the term it modifies, FDA is proposing that this qualifying information be in the same type size, style, color, and prominence as, and in immediate proximity to, the word "light."

Therefore, the agency is proposing in § 101.56(e) that the term "light" may not be used to refer to a food that is not reduced in calories by ⅓ and, if applicable, in fat by 50 percent, unless: (1) It describes some physical or organoleptic attribute of the food, such as color or texture, and the qualifying information (e.g., light in color, light in texture), so stated, clearly conveys the nature of the product, and (2) the qualifying information is in the same type size, style, color and prominence as the word "light" and in immediate proximity thereto.

The agency recognizes that there are some long standing uses of the term "light" to characterize the particular nature of the product or distinguish it from a similar product with slightly different attributes. Examples of such products are light corn syrup as opposed to dark corn syrup, light brown sugar as opposed to dark brown sugar, and light molasses as opposed to dark molasses. Such light products are generally recognized to be both lighter in color and in flavor (i.e., less intense or more delicate) than their darker counterpart. The agency considers that the long standing use of the term "light" on these few products, whose special "light" characteristics are commonly understood, is sufficient reason to permit their continued use.

Therefore, FDA is proposing in § 101.56(f) that in those rare cases where the word "light" has come, through common use, to be part of the statement of identity, the agency will not require that statements of identity for such products be further characterized. If this provision is adopted, light brown sugar will not be required to be labeled "light color brown sugar" or otherwise meet the requirements for nutrient content claims. The agency is proposing in § 101.52(f) that if a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food (e.g., "light brown sugar," "light corn syrup," or "light molasses)" to the point where it has become part of the statement of identity such use of the term "light" will not be considered a nutrient content claim subject to the requirement as specified in part 101.

FDA specifically asks for comments as to whether the approach to the term "light" outlined in this document is adequate to eliminate the misuse of this term.

5. Comparative Claims

a. *Less or fewer.* The agency recognizes that there are some foods that can achieve meaningful reductions in the level of certain nutrients but for which reductions of ⅓ of calories or 50 percent or greater for nutrients are not feasible. While these foods cannot bear a "reduced" claim, the agency believes that such foods should be permitted to be labeled with comparative statements using the term "less" or, because it is grammatically correct, "fewer" in the case of calories, that specify the extent to which the nutrient has been reduced. For example, the label of a pound cake could bear the statement, "25 percent fewer calories than our regular pound cake—this pound cake contains 150 calories compared to 200 calories per serving in our regular brand." The agency believes that the use of comparative claims provides manufacturers with an incentive to lower the nutrient content of a food even though it may not be technologically possible to achieve nutrient levels that are sufficiently low to allow the product to be labeled as "reduced."

To ensure, however, that the reductions are nutritionally meaningful, and that consumers are not misled by claims for reductions that are inconsequential, the agency believes that a comparative statement should be permitted on the label or in labeling of a food only if the food has been formulated or processed so that it contains a decrease in the level of the nutrient that is 25 percent or more compared to the reference food. This

requirement is consistent with the agency's current policy for comparative claims for sodium (49 FR 15521, April 18, 1984) and the tentative final regulation for cholesterol (55 FR 29456).

The proposed 25 percent reduction requirement is based on agency findings in those notices that products in which there has been a 25 percent or greater reduction in the amount of a nutrient will serve a useful role in the diet of those individuals who are attempting to limit their consumption of that nutrient. In addition, the agency made the finding in the 1984 sodium notice that because of variations in nutrient content within a food or class of food, any less of a reduction, such as the 10 percent that was originally proposed for sodium, would not always assure that the altered product contained less of the nutrient than the regular product. 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 these diets if such claims are reliable, and the absolute reduction referred to by the comparative claim is nutritionally significant. This alternative will also be discussed in the supplemental NPRM referenced in section IV above.

Currently, Canadian guidelines and regulations provide for comparisons when differences are at least 25 percent (Ref. 38). This criterion is also consistent with USDA guidelines that permit comparative fat claims for meat and poultry products when fat is reduced by 25 percent or more (Ref. 46).

In addition, so that the reductions are nutritionally consequential, as with "reduced," the agency is proposing that the minimum reduction for comparative claims be more than the value of "low" for that nutrient. Although the reduction in the amount of a nutrient is less for a comparative claim than for a "reduced" claim, it is still important that the reduction be of nutritional consequence. There is no basis to find that a decrease in the level of a nutrient smaller than the amount necessary to justify a "low" claim would be consequential. Therefore, FDA is proposing to require the same minimum quantitative decrease in a nutrient for a "less" claim as for a "reduced" claim.

i. *Sodium.* In the preamble to the final rule on sodium descriptors (49 FR 15510 at 15521), the agency stated that a minimum sodium reduction of 25 percent was necessary for a product to make a comparative statement about sodium. This guidance was not codified in the regulation, but it did serve as the basis, as discussed above, for sodium claims using the term "less." The agency sees no reason why the requirements for use of the term "less" in describing the level of sodium in a product should be any different than those proposed for the other nutrients. The proposed definition for "reduced sodium" is in accord with the definitions for "reduced" for all other nutrients except calories. Moreover, such an approach is in line with the agency's goal of making the definitions for the various terms as consistent as possible to help prevent consumer confusion.

As discussed above, the agency is also proposing that the minimum amount by which a nutrient must be reduced for a food to bear the term "less" should be more than the value of "low" sodium, i.e., 140 mg per serving.

Therefore, the agency in proposing in § 101.61(b)(7) that a comparative claim using the term "less" may be used to describe the sodium content of a food provided that: (1) the food has been formulated or processed to reduce its sodium content by 25 percent or more with a minimum reduction of more than 140 mg per serving from the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), or (j)(1)(iii); and (2) the food meets the requirements of § 101.13(j)(2).

ii. *Calories.* The agency believes that comparative statements should be permitted when the level of calories in a food is reduced by 25 percent compared to a reference food, even though there is only an 8 percentage point difference between the levels at which a "reduced calorie" claim and a comparative statement may be made. Permitting comparative claims will allow claims to be made about the decrease in calorie levels in foods that cannot meet the "reduced" criterion because of technological or other reasons. The agency believes that it is important to provide for comparative labeling for these foods because of the nutritional benefit that such foods can contribute to the diet. If a person who generally consumed a diet containing a normal amount of calories, i.e., 2,350, were to consume a diet consisting solely of foods decreased in calories by 25 percent, he or she could achieve a significant weight loss.

In addition, as discussed above, in order to prevent comparative claims being made for calorie reductions that are inconsequential, the agency believes that, as with all other nutrients, a minimum quantitative reduction should be established. This criterion, if adopted, will ensure that the reduction is nutritionally consequential. Consistent with the requirements for the various nutrients, the agency believes that this value should be more than 40 calories (the level set for "low" calories) per serving.

Therefore, the agency is proposing in 101.60(b)(5) that a comparative claim using the term "fewer" may be used to describe the caloric content of a food provided that: (1) The food contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per serving from the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), or (j)(1)(iii); and (2) the food meets the requirement of § 101.13(j)(2).

However, because there is only an 8 percentage point difference between the lower level of calories for "light" and "reduced" (33⅓ percent) versus comparative claims (25 percent), the agency solicits comments on the usefulness of allowing comparative claims in addition to "reduced" and "light" claims for calories.

iii. *Sugars.* Although the terms low or reduced sugars have not been defined, the agency believes that a term that highlights a difference in the amount of sugars in a product relative to another food would assist consumers in following the dietary guidelines relative to sugar. The agency believes that the term "less" may be useful in providing this information.

The agency can see no reason to define a comparative value for "less" to be used with sugars that is different from the value for "less" for the nutrients previously defined. Therefore, the agency is proposing in § 101.60(c)(4) that a comparative claim using the term "less" may be used to describe the sugars content of a food relative to the amount of sugars in another food provided that the food contains at least 25 percent less sugars than the food to which it is compared.

However, because the agency has not established a DRV for sugars, it does not have a basis for defining an insignificant amount of sugars to be used as a second criterion. The agency believes that, as for other claims using the term "less," a second criterion establishing a minimum quantitative reduction is necessary and

solicits comments on how such a second criterion might be derived.

The agency, advises however, that regardless of whether any comments provide a suitable basis for a second criterion, that it intends to establish such a criterion to insure that claims of less sugars are not misleading because the decrease in the amount of sugars is nutritionally insignificant.

b. *More.* Although the 1990 amendments do not require that FDA define the term "more," the agency recognizes that there may be instances when a manufacturer could make a statement on the label or in labeling that a food product contains more of a desirable nutrient than is in a reference food. Such claims may be made for food products containing nutrients such as dietary fiber, potassium, protein, vitamins, and minerals. In addition, claims using the term "more" may be useful in certain limited circumstances to describe the level of complex carbohydrates and unsaturated fatty acids.

FDA considers that such claims are currently governed by § 101.9(c)(7)(v), which states, in part, that: "No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving (portion)." In its proposal of July 19, 1990, on mandatory nutrition labeling, the agency retained and expanded this regulatory provision, in proposed § 101.9(c)(11)(iv) (55 FR 29515), to read: "No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for complex carbohydrates, fiber, unsaturated fatty acids, or potassium or at least 25 percent less on a weight basis for fat, saturated fatty acids, cholesterol, and sodium per serving (portion)." In the supplemental proposal on nutrition labeling, FDA is proposing to delete the above provision from the nutrition labeling regulations because the issue of descriptors used on food labels or in labeling is being dealt with in the present document. The agency feels that the paragraph in question is more appropriately regarded as a general principle governing comparative claims than one relating to nutrition labeling.

After careful consideration, FDA is proposing to retain its existing approach that a food must contain at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium before a comparative claim using the term "more" would be permitted. The agency is proposing to retain the level of 10 percent more of RDI or DRV for a number of reasons.

First, the difference must be on the basis of the RDI or DRV, rather than on a weight basis, for the relative difference to have dietary significance. For example, consider a product containing 100 mg of calcium. On a weight basis, it would have 10 percent more calcium than a product containing 90 mg and 25 percent more than a product containing 80 mg. However, in terms of the proposed RDI for calcium (900 mg), the three products contain 11, 10, and 9 percent of the RDI, respectively. These differences are dietarily insignificant.

Secondly, there must be at least a 10 percent difference relative to the RDI or DRV before consumers can be assured that there is truly a difference in the foods being compared. This finding is consistent with the agency's proposed definition of "source" discussed elsewhere in this document. A nutrient must be present in a food at a level of at least 10 percent of the RDI or DRV before that food can be designated as a source of the nutrient. Consequently, the agency believes that a nutrient must be present at a level of at least 10 percent more of the RDI or DRV than in the reference food before the food can be designated as a better source of the nutrient. Because of natural variability of nutrients in food, there is a real possibility that the foods being compared would have virtually no difference in nutrient content if values of less than 10 percent of the RDI or DRV were compared. This percent of the DRV or RDI functions similarly to both the first and second criteria for other relative claims because it ensures that the comparison is always meaningful and significant.

Thirdly, the agency considered requiring at least a 25 percent difference relative to the RDI and DRV in the reference foods before permitting comparative claims using the term "more". This level would be somewhat analogous, and symmetrical, with the proposed requirement for comparative claims using the term "less." However, FDA has tentatively rejected this approach because of the agency's concern that a level higher than 10 percent of the DRV or RDI would result in inappropriate fortification of foods in an attempt to make superiority claims.

The agency's policy on appropriate fortification of foods is stated in § 104.20 (21 CFR 104.20). The fundamental objective of that policy is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. However, to the extent that food does not conflict with § 104.20, the agency believes that a statement using the term "more" can be used to compare the amount of certain specified nutrients in one food to the amount of such nutrients in similar foods.

Therefore, the agency is proposing in § 101.54(e)(1) that a comparative claim using the term "more" may be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food provided: (1) That the food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or for potassium than the reference food that it resembles and for which it substitutes; (2) where the claim is based on a nutrient that has been added to the food, that fortification is in conformity with the policy on fortification in § 104.20; and (3) that it meets the requirements of § 101.13(j)(2) except that the percentage (or fraction) that the nutrient varies compared to the reference food should be expressed as a percent of the Daily Value (e.g., "Contains 10 percent more of the Daily Value for fiber than our regular wheat bread. Fiber content has been increased from 1 g to 3.5 g per serving.") Moreover, FDA believes that it is consistent with section 403(r)(2)(A)(v) of the act to require that if a "more" claim is made for fiber, the level of fat be disclosed on the label unless the food meets the definition of "low fat." This type of claim, like a "high" claim, emphasizes the amount of fiber in the food. Therefore, FDA is including "more" claims in the coverage of proposed § 101.54(d).

As discussed earlier, the agency does not believe that claims for specific amounts of carbohydrates (such as "high in complex carbohydrates") can be supported based on dietary recommendations in the major consensus reports because quantitative recommendations for carbohydrate consumption are not included. However, FDA believes that label statements using the term "more" to characterize the relative difference in carbohydrate content of two food products would be useful to consumers, provided that the claim is based only on the difference in complex carbohydrates as defined in § 101.9(c)(6)(i) of the supplementary proposal on mandatory nutrition labeling and not on the levels of other carbohydrates. The agency believes that this is appropriate because the major consensus reports (Refs. 1, 2, 3, and 5) advocate using sugars in moderation but recommend increasing consumption of

foods that contribute complex carbohydrates to the diet. A statement comparing carbohydrate contents of foods that can be used interchangeably in the diet would be useful to consumers in constructing a diet that adheres to the various dietary recommendations.

However, the agency believes that a statement concerning the percent increase in carbohydrate relative to the Daily Value contained in one product as compared to another is misleading because the DRV for carbohydrate is based on total carbohydrate, and under the proposal, the increased content that forms the basis of the claim must be provided by complex carbohydrates only. There is no DRV for complex carbohydrates. Further, mention of the Daily Value may suggest to consumers that this food component has greater public health significance than has been established by existing diet and health studies. Therefore, the agency is proposing in § 101.54(e)(2) that a comparative claim using the term "more" may be used to describe the difference in the level of complex carbohydrates, in two foods, provided that the food that bears the claim contains at least 4 percent more of the DRV for carbohydrates (i.e., 13 g) and that the difference in the level of carbohydrates between foods consists of only complex carbohydrates as defined § 101.9(c)(6)(i).

The agency is proposing 4 percent of the DRV as the criterion for this claim because 10 percent of the DRV for carbohydrates is 32 g, an amount of complex carbohydrate that would be unreasonable to expect to be found in excess of what is present in a reference food. For instance, most ready-to-eat cereals, which are a good source of complex carbohydrates, contain less than 18 g of complex carbohydrates. In fact, the agency is aware that a 4 percent differential may be difficult to reach. However, a lower value, e.g., 2 percent, is associated with definitions for low levels of nutrients and does not seem appropriate. FDA recognizes that the definition it is proposing from past requirements for claims of superiority and requests comments on the public health validity of the change.

In addition, the agency has received several requests urging that it permit claims comparing the amounts of unsaturated fat in products. The guidance provided in the consensus documents (Refs. 1, 2, 3, and 5) is that total fat and saturated fat consumption should be reduced, and that unsaturated fat should not be increased above current consumption levels. Furthermore, some recent data (Refs. 47 and 48) suggest that "trans" fatty acids, which are unsaturated fatty acids, act like saturated fatty acids relative to their effect on blood cholesterol. Additionally, high levels of intake of unsaturated fatty acids, particularly polyunsaturated fatty acids, may increase risk of certain cancers (Ref. 2). For these reasons, as discussed earlier, the agency has tentatively concluded that claims for "high" in unsaturated fatty acids are potentially misleading.

However, FDA believes that label statements using the term "more" to characterize the relative amount of unsaturated fatty acid in two food products would be useful to consumers, provided that the total fat level in the product bearing the claim is not increased above the total fat level in the product of comparison and provided that the level of *trans* fatty acids in the product bearing the claim does not exceed 1 percent of the total fat content. The agency believes that this proposed action is appropriate because the major consensus reports, such as the NAS report "Diet and Health," advocate substituting unsaturated fatty acids for saturated fatty acids as a means of achieving greater health benefit from the diet. However, because all major consensus reports place considerable emphasis on reducing total fat intake, the agency considers it misleading for a product to claim to have more unsaturated fatty acids if the product has more total fat than the food being used for comparison. In addition, because of the recent data suggesting that *trans* fatty acids may act like saturated fat in raising serum cholesterol, the agency believes that it would be misleading for products containing measurable amounts of *trans* fatty acids to bear claims of "more" unsaturated fatty acids. The agency is proposing a limit on *trans* fatty acids of 1 percent of the total fat because the analytical techniques for measuring *trans* fatty acids below that level are not reliable. Further, the agency believes that a reference to the DRV for unsaturated fatty acids on the panel containing the unsaturated fatty acid claims would be misleading because it would imply to consumers that it is a dietary goal for unsaturated fatty acids that should be attained, when in fact it is the consumption of total fat that should be moderated.

For these reasons, the agency is proposing that a food bearing a "more unsaturated fat. claim must contain at least 4 percent more of the DRV for unsaturated fatty acids (i.e., 2 g) than the reference food. The DRV for unsaturated fatty acids, like that for complex carbohydrates, is sufficiently large that the agency has tentatively concluded that it is unreasonable to require a differential of more than 4 percent of the DRV for unsaturated fat to make a claim of "more." Again, comments, including data are requested on the proposed definition of the claim.

Therefore, the agency is proposing in § 101.54(e)(3) that a claim for more unsaturated fatty acids only be permitted on those foods that contain at least 4 percent more of the DRV for unsaturated fat, do not contain more than the reference food, and in which the level of *trans* fatty acids does not exceed 1 percent of total fat. The agency requests specific comment on this issue.

6. Modified

The declarations discussed above for making relative claims do not include terminology that is suitable for use in a statement of identity with a comparative claim in the way that .reduced" and "light. may be used. For example, "25 percent Less Fat Cheese Cake" is awkward.

Consequently, the agency believes that an appropriate term should be proposed for use with comparative claims. Although the agency recognizes that numerous terms may be adequate to convey this information, given the need, as discussed above, for a term that consumers can recognize and understand, FDA is proposing that the term "modified" be used. FDA has chosen this term because it is applicable to both positive and negative alterations in nutrient content, i.e., comparative statements using either terms "more" or "less."

Under proposed § 101.13(k), the term "modified" may be used in the statement of identity of a food that bears a comparative claim that complies with the requirements in Part 101, followed immediately by the name of the nutrient whose content has been altered, e.g., "Modified fat cheese cake." This statement of identity must then be immediately followed by the comparative statement such as "Contains 35 percent less fat than ____" and all other information required in 101.13(j) for comparative claims. This information is necessary because it presents information that is material in light of the "modified" representation. Consumers must be advised of the nutrient modified, the extent of the modification of that nutrient, and the factual basis on which the extent of modification has been calculated. Without this information, the food would be misbranded under sections 201(a) and 403(a) of the act.

D. Use of Descriptors With Meal-type Products

The agency received many comments to the ANPRM and during the public hearings requesting that it define and allow for the use of descriptors for meal-type products. FDA is aware that nutrient content claims are frequently used on such products even though the agency has not developed definitions specific to that use. In its proposed rule on cholesterol descriptors (51 FR 42584 at 42591), FDA acknowledged that it is not reasonable to expect nutrient content claims on meal-type products to meet the same criteria as those used for individual food items. At that time, FDA 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 descriptors (55 FR 29456), the agency withdrew from this position because there was no clear definition of the term "meal" and asked for further comment.

The GMA submitted a letter to the agency (Ref. 12) in which they suggested that a "meal-type product" be defined as a food that: (1) Makes a significant contribution to the diet by providing at least 200 calories per serving or weighing at least 6 oz per serving; (2) contains ingredients from 2 or more food groups; and (3) is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Under GMA's proposed definition, such representations may be made either by statements or by photographs or vignettes.

FDA finds merit in this 3-part definition and, lacking any other equally-comprehensive definition, is proposing in § 101.13(1) to adopt it with the qualification that the product must contain two of four specified food groups. However, the agency recognizes that, with this definition, there may be a tendency to assume that a level of 200 calories is appropriate for all meals consumed in one day. This assumption would suggest that three meals and a snack provide only 800 calories per day. The agency, however, assumes that some of the meals would contain more than 200 calories, especially if the product contained only two food groups. Such meals might then consist of a 200 calorie 7 ounce main dish and a fruit or vegetable, starch, or dairy product. If these types of products meet this assumption, it will ensure that a minimum daily intake would be greater than 1,000 calories.

The agency requests specific comments on the appropriateness of this definition of a "meal-type product" as well as on the appropriateness of specific amounts (e.g., 200 calories and 6 oz) and specific product types (e.g., "main dish") used as a basis for this definition.

1. Definition of "Free"

FDA is not proposing separate definitions for "free" for meal-type products. The term "free" is an absolute term implying absence of a nutrient. Therefore, whenever a food is labeled "free," whether it is an individual food item or a meal-type product, it would be misleading unless it met the definition for "free" for the particular nutrient that is the subject of the claim.

2. Definition of "Low" and "Very Low"

GMA suggested that for meal-type products, the nutrient descriptor "low" should be defined on the basis of the amount of the nutrient per 100 g of the meal-type product and suggested specific levels for calories (105 calories per 100 g), total fat (3.5 g or less per 100 g), saturated fat (1.2 g or less per 100 g), cholesterol (20 mg or less per 100 g), and sodium (200 mg or less per 100 g) (Ref. 12). FDA has considered these levels in conjunction with its proposed values for nutrient content claims for individual foods (foods as sold separately, not as part of a meal), discussed earlier in this document. With the exception of calories, the suggested values are similar, or identical, on a 100 g basis to the definitions for the various nutrients proposed for individual foods in this document and in the companion proposal on fats, saturated fat, and cholesterol published elsewhere in this issue of the **Federal Register**.

The agency finds merit in defining nutrient content claims for meal-type products on the basis of the amount of the nutrient per 100 g. This approach alleviates the necessity to accommodate variations in serving size for the various types of meals. A review of such products on the market shows that it 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 (Ref. 1).

FDA believes that it will be beneficial if the agency used the same quantitative amounts except calories per 100 g as the definitions of "low" that it is proposing for individual foods in this and the companion document on fat, saturated fat, and cholesterol claims. Such consistency will assist consumers and health professionals to be able to recall and use these amounts.

Accordingly, FDA is proposing in § 101.61(b)(5) that a "low sodium" claim may be made for a meal-type product that contains 140 mg or less sodium per 100 g of product. The agency is proposing similar definitions for fat, saturated fat, and cholesterol claims in the companion document.

In the case of low calorie claims, FDA is proposing that an individual low calorie food be defined as containing 40 calories or less per serving and per 100 g of food. The agency recognizes that if it applied this criterion on a 100 g basis to meal-type products, the use of "low calorie" claims on meal-type products would essentially be precluded (e.g., a 10 oz meal would have to contain 113 calories or less to bear a "low calorie" claim). Obviously, such a definition would be unrealistic for two reasons: (1) It is unlikely that a reasonably sized balanced meal could be created that contained so few calories and still made a significant contribution to the daily food intake of an individual; and (2) such a meal is consistent with a 400–500 calorie daily diet (i.e., 113 calories X 4 eating occasions), and such very low calorie diets should be followed only under the strict supervision of a physician. Therefore, FDA is not proposing that 40 calories per 100 g be part of the definition for a low calorie meal.

GMA has suggested that a meal-type product be allowed to make a "low calorie" claim if it contains 105 calories or fewer per 100 g of product. This value would allow a 10 oz "low calorie" meal type product to contain 298 calories. This value appears appropriate for the wide diversity of meal-type products (i.e., meals or meal components intended for breakfast, lunch, or dinner which are offered either as a whole meal (three or more components) or as part of a meal (main dish, entree, or pizza). A value of 105 calories for a low calorie meal-type product would allow many FDA-regulated products within this wide variety of meals or portions of meals to make low calorie claims. The U.S.D.A. has conducted a preliminary evaluation of this value for meal-type products containing meat and poultry and found that approximately 40 percent of such products with a brand name that might imply a "low calorie" claim (e.g., "lean") would not be classified as "low calorie" using the 105 calorie per 100 g criterion (Ref. 12a). As stated previously, the agency assumes that, particularly in the case of entrees and main dishes, meal-type products will not be consumed as the single component of a meal but will be supplemented with a fruit or vegetable, starch (e.g., bread or rolls), o

beverage (e.g., milk or juice) to provide a balanced meal. Consequently, the agency believes that this definition for meal-type products is in line with a 1,200 calorie per day diet.

FDA notes that calorie restricted diets often contain 1,200 calories, frequently broken down into three meals and a snack each day (Ref. 49). Under this scenario, meals would be expected to contain approximately 300 to 350 calories (i.e., 900 to 1,050 calories per day as meals and 150 to 300 calories per day as a snack). Accordingly, FDA has tentatively concluded that 105 calories per 100 g is a reasonable definition for a "low calorie" meal-type product and is proposing this value in § 101.60(b)(3). Nevertheless, the agency requests comments on whether consumers would actually consume meal-type products alone, and whether they depend on these products for the major portion of their caloric intake throughout the day. If so, comments are requested on whether the criterion of 105 calories per 100 g of product for low calorie meal type products is too low.

The agency also is concerned, however, about the application of this definition to meals that are atypically large in size within this class of foods. For example, a 16 oz dinner could have 475 calories and meet the definition for "low calorie." Accordingly, FDA is considering the application of upper limits for each nutrient for meal-type products. Comments are requested on the need for such limits and, if needed, where such limits should be drawn and why.

Finally, the agency has proposed a definition of 35 mg of sodium per serving and per 100 g for "very low sodium" in individual foods in § 101.61(b)(3). The agency is uncertain as to whether there needs to be a comparable value for meal-type products, since it could prove very difficult to create a very low sodium meal. Such a definition might be virtually meaningless. On the other hand, FDA does not wish to preclude the use of a definition which might be of value in assisting consumers to choose products that have minimum amounts of sodium if such products are feasible. The agency has tentatively concluded that a definition for "very low sodium" meal-type products would serve some purpose and is consequently proposing such a definition. However, the agency seeks comments on the usefulness and necessity of this definition.

3. Relative Terms

Inasmuch as the primary criterion for the use of relative claims (i.e., "reduced," "light," and comparative claims) is a percent reduction, FDA does not believe that it is necessary to propose different criteria for meal-type products. While acknowledging the difficulty in reducing the calorie, fat, and cholesterol content of meal-type products, FDA believes that the consumer expects significant differences in products bearing these claims and would be best served by adherence to the proposed definitions for individual foods.

The second criterion for the use of relative terms on individual foods is a minimum reduction in amount of nutrient equivalent to the value established for "low" for that nutrient per 100 g. Again, FDA believes that the criterion for individual foods would be appropriate for meal-type products. This requirement will allow the proposed regulations for relative claims on individual foods to apply equally to meal-type products.

a. *Reduced.* The agency is, however, concerned about providing for the use of the term "reduced" with meal-type products because of the difficulty in establishing an appropriate reference food. The proposed definition for "reduced" for individual foods is based on a comparison of a product to another product of the same type, e.g., one cupcake to another. A comparison of meal-type products could be of a broiled fish fillet to a piece of fried, breaded fish. Such a comparison would equate two products that, although they had the same basic ingredient, i.e., fish, were distinct in their method of preparation, additional ingredients, taste, and appearance. Such a comparison would be inappropriate for a "reduced" claim because it would be comparing products that were insufficiently similar to make a valid comparison. The agency is of the opinion that there is an insufficient basis on which to establish a reference criterion, and consequently there is no basis on which to establish a definition for "reduced" meal-type products. Therefore, the agency is not proposing to provide for the use of "reduced" claims on meal-type products.

b. *Comparative claims.* Comparative claims, however, by their very nature provide for comparisons of foods within a product category, provided the basis of comparison is adequately stated in the claim, e.g., comparison of a snack food to another snack food. Comparative claims, using the terms "less," "fewer," and "more," would be appropriate for comparing similar meal-type products such as broiled fish to fried, breaded fish because both of these somewhat dissimilar products would be in the same product category. Therefore, the agency is proposing to incorporate the provisions for comparative claims for meal-type products into the comparative claims provisions in the various nutrient sections.

c. *"Light".* FDA is proposing a more narrow reference food criterion for "light" claims on individual foods than for "reduced" claims. It follows, then, that since the agency is proposing not to permit "reduced" claims on meal-type products, it would do likewise for "light" claims. However, the agency recognizes that there might be some basis to find that an alternative course is appropriate.

The agency believes that the term "light" could be useful to consumers in selecting meal-type products by highlighting products that contain fewer calories than would be expected in a normal meal. Because there is no identified set of reference foods to which "light" meal products could be compared, the agency has considered using a different criterion for the definition of "light" meal-type products. The agency is considering allowing use of the term "light" on meal-type products that meet the criteria for "low calorie" meals. At 105 calories per 100 g or approximately 300 calories per 10 oz portion, the criterion for "low" calorie meals is very nearly one fourth of the intake in a calorie restricted diet of 1,200 calories a day (Ref. 49). The agency believes that such products would meet the consumer's expectations that the food is low or reduced in calories.

In addition, FDA is also considering a second criterion that "light" meal-type products not contain fat, saturated fatty acids, sodium, or cholesterol at a level that exceeds one-fourth of the DRV of the nutrient. This criterion would ensure that light meal-type products would not only be low in calories but would also not contribute amounts of these nutrients that would cause total daily intake to exceed recommended values.

These criteria for the term "light" on meal-type products would permit some meal-type products to bear "light" claims and would ensure that such claims are not misleading. The agency solicits comments on the need to provide for use of "light" on meal-type products and on possible guidelines for selection of reference foods. Comments are also requested regarding this definition "light" meal-type products, including the criterion relative to other nutrients and on possible guidelines for selection of reference foods. If the comments warrant, the agency many propose appropriate definitions and requirements for use of the term "light for meal-type products.

4. "Source" and "High" Claims

As with the definition for "low" for meal-type products, the agency believes that the criteria for "high" and "source" should be the same percentages of the RDI or DRV proposed as for individual foods but on an amount per 100 g basis, not per serving. Therefore, consistent with these definitions, the agency is proposing in § 101.54(c)(2) that "source" be defined for a meal-type product as 10 to 19 percent of the RDI or DRV per 100 g of product, and in § 101.54(b)(2) that "high" be defined as 20 percent or more of the RDI or DRV per 100 g of product. Consequently, to be considered a "source" of a nutrient, a 10 oz meal-type product would contain 7 to 13.5 g of fiber. (25 g of fiber is the DRV for fiber. 10 to 19 percent of the DRV is 2.5 to 4.75 g. 10 oz × 28.35 g/oz = 284 g. 284/100 g = 2.8 g. 2.5 (10 percent of the DRV) × 2.8 = 7 g; 4.75 × 2.8 = 13.5 g.)

Consistent with section 403(r)(2)(A)(v) of the act, which states that a claim may not state that a food is high in dietary fiber unless the food is low in total fat (as defined in § 101.62(b)), the agency is proposing in § 101.54(d) that claims that a meal-type product contains "more" fiber be required to disclose the level of total fat on a per serving basis.

5. Disclosure Statements

The disclosure levels proposed in § 101.13(h) and discussed above in section II.D. of this document were derived for levels of nutrients found in individual foods. Because the definition of meal-type products encompasses a broad range of products, from entrees that may be a small portion of the total meal to complete meals, the issue of modifying these levels for use with such products become complex. Because of this complexity, the agency was not able to devise specific disclosure levels for use with meal-type products. FDA solicits comments on whether the disclosure levels should be different for meal-type products, and if so, what the levels should be and why.

E. Redesignation of Certain Requirements in Section 105.66 to Section 101.60

Because these proposed regulations on nutrient content claims include provisions similar or identical to some provisions in § 105.66, the agency has found that it is necessary to examine § 105.66 to determine what changes are necessary in that regulation in order to conform it to the 1990 amendments.

As discussed above, FDA is proposing to recodify current § 101.13, Sodium labeling, with minimal revisions, in new Subpart D—Specific Requirements for Nutrient Content Claims, so that it could be codified in close proximity to the requirements for other nutrient content claims. Section 105.66 is not amenable to that approach.

Section 105.66 was originally promulgated to provide regulations for label statements useful on products for reducing or maintaining caloric intake or body weight. Consequently, terms such as "low calorie," "reduced calorie," and "sugar free," which were thought to be useful attributes of a food in the maintenance or reduction of body weight, were included in this section. Over time, more and more people have become concerned with healthier eating and have begun to follow the guidelines established in Dietary Guidelines of Americans (Ref. 1), including the maintenance of a healthy weight. Consequently, terms such as "low" or "reduced calories" and "sugarless" have come to be used on foods intended for consumption by the general population. As such, they have lost their special significance in the labeling of foods intended solely for special dietary uses.

As is discussed elsewhere in this document, these terms are now more appropriately defined under the 1990 amendments as nutrient content claims. Consequently, the agency is proposing to place requirements for terms such as "low" and "reduced calorie," comparative claims, and sugar claims, originally provided for in § 105.66, in § 101.60. Requirements for label statements about nonnutritive sweeteners, "diet" foods, and other related terms are being retained in § 105.66.

Because definitions of terms in proposed § 101.60 would be redundant of certain provisions in § 105.66, the agency is proposing to delete, paragraphs (c), (d), and (f) of § 105.66 and to replace them with statements referring to the appropriate section in 101.60 for criteria for use of the respective term.

In addition, the agency is proposing to delete from § 105.66 any inappropriate reference to specific nutrient content claims or similar terms and any statement that is inconsistent with the 1990 amendments.

There is, however, a significant portion of § 105.66 that remains appropriate for regulating foods that are for special dietary uses. Such foods are those specifically represented or purported to be useful as part of weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although such products can be useful in reducing or maintaining body weight). The agency is retaining those provisions in § 105.66. FDA plans to reexamine the provisions remaining in § 105.66 and to initiate additional rulemaking as appropriate.

In the interim, the agency is proposing to make the following specific changes to the remaining paragraphs in § 105.66: It is proposing to delete the words "caloric intake or" from the title, paragraph (a), paragraph (b)(2) and paragraph (e)(2) of the section because, as stated above, it considers information relative to the caloric content of a food to be of value to the general public in selecting diets that meet dietary guidelines. Consequently, the agency believes that this concept is more consistent with § 101.60 than § 105.66. It is also proposing to delete from paragraph (a) the words "including, but not limited to, any food that bears representations that it is low or reduced in calories" because "low" and "reduced" calories are defined in § 101.60.

FDA is also proposing to delete in § 105.66(a)(2) the phrase "The labeling provided for in paragraph (c) or (d) of this section or," because the terms "low" and "reduced," which were provided for in those paragraphs, are now defined in § 101.60. The agency is not proposing to delete the remainder of the sentence "a conspicuous statement of the basis upon which the food claims to be of special dietary usefulness." The agency cautions, however, that it will not consider reliance on this provision as justification for an undefined nutrient content claim.

In addition, the agency is proposing to delete from § 105.66(e)(1) the phrases "or other such terms representing or suggesting that the food is low calorie or reduced calorie or that the food may make a comparative claim or special dietary usefulness" and "in compliance with paragraph (c) or (d) of this section" because the terms are no longer codified in this section. The agency recognizes, however, that provisions for the terms "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," may, consequently, not be clear. However, as stated above, the agency intends to reexamine § 105.66, particularly this paragraph, so that it can establish a more cohesive policy regarding foods for special dietary uses. The agency envisions that use of the term "diet," except on soft drinks exempt under section 403(r)(2)(D) of the act, and on products addressed in § 105.66(e)(2), will require that such foods meet the general requirements of § 105.66.

Finally, the agency is proposing to delete § 105.66(e)(3) and include reference to "formulated meal

replacement or other food that is represented to be of special dietary use as a whole meal," in paragraph (e)(1). The agency recognizes that this is a departure from the previous regulation that exempted such foods from paragraph (e)(1) pending issuance of a regulation governing them. However, in order that such claims not be prohibited as implied nutrient content claims under the 1990 amendments, they are being included in paragraph (e)(1) until such time as more appropriate regulations can be issued. FDA views claims that are permitted under § 105.66 to meet the requirements of section 403(r) of the act.

IV. An Alternative Approach to Comparative Nutrient Content Claims

The proposed approach to comparative nutrient content claims discussed in the preceding sections involves the adoption of specific and distinct definitions for such comparative terms as "reduced," "fewer," and "less," including minimum percentage reductions or differences that must be achieved to justify the claim (e.g., a "less" claim requires at least 25 percent less of the nutrient in question). FDA is concerned about whether the terms defined in the various nutrient content claim rules strike the proper balance between allowing an adequate number of terms such that consumers can distinguish the nutrient content across foods and minimizing the proliferation of terms that may tend to confuse consumers. It is possible that the comparative terms FDA proposes to define might still cause confusion, due to the natural vagaries of language, the fact that it will take a significant amount of time before consumers are familiar with the definition of the terms, and the fact that the terms are really only distinguished by the regulatory definition rather than some innately understood differences: In common parlance, "reduced," "fewer," and "less" do not have established, distinct meanings for most consumers as they apply to describing relative levels of nutrients in food.

In addition to avoiding consumer confusion and thus fostering the consumer's ability to select healthier foods, FDA also wants to provide manufacturers maximum flexibility in their use of nutrient content claims, consistent with the goals and requirements of the act. This is consistent with FDA's goal of assuring that the approach to defining nutrient content claims it ultimately adopts provides a clear incentive to manufacturers to produce innovative products that are improved in the nutritional attributes addressed by the comparative nutrient content claims e.g., products that are truly "reduced" in fat or contain "less" cholesterol than the products for which they substitute.

Consequently, FDA solicits comment on a very distinct regulatory approach that in essence defines all comparative nutrient content claims as synonyms and requires a numeric disclosure of the comparative difference. Unlike words, numbers are not as easily manipulated and therefore avoid the confusion of distinctly defined terms. Therefore, a number of terms given identical definitions could be used with conspicuous full disclosure of the percent by which the nutrient has been decreased and a comparison of the quantity of the nutrient in the labeled food and the reference food. For example, the following nutrient claims could be used interchangeably: "____ percent reduced calories," and "____ percent fewer calories," with a disclosure in absolute terms of the comparative amounts (in this example, the number of calories per serving in the labeled food and the number in the food to which it is being compared).

Under this approach, or even as a separate alternative, there would not be any single across-the-board minimum percent of reduction or difference required to support the claim, such as 25 percent, but any claimed reduction or difference in the level of a nutrient would have to be large enough to be considered nutritionally significant in accordance with criteria adopted by FDA.

FDA intends to seriously evaluate these alternatives as part of its continuing effort to devise an optimal approach to nutrient content claims. To facilitate a full airing of the issues, FDA is considering holding a public meeting on nutrient content claims and, within 60 days of the publication of this proposal, the agency will publish a supplemental notice of proposed rulemaking. FDA will then fully evaluate the alternative approach outlined above and the one proposed in this document and by November 8, 1992, FDA will select and adopt as a final rule the approach to comparative nutrient content claims that best achieves the agency's goals of avoiding consumer confusion, empowering consumers to choose healthier diets, and providing incentives for food manufacturers to produce nutritionally improved food products.

V. Petitions for Nutrient Content Claims

Section 403(r)(4) of the act provides that any person may petition the Secretary to make nutrient content claims that are not specifically provided for in FDA's regulations. It describes procedures for petitions that seek to define additional descriptors, to establish synonyms, and to use an implied nutrient content claim in a brand-name.

On March 14, 1991, the agency stated in a notice in the **Federal Register** (56 FR 10906) that it was developing procedural regulations that would prescribe the type of information needed to support each of these three types of petitions, in addition to the other types of petitions permitted by 1990 amendments. The agency stated that the most efficient use of its resources would be to establish these procedures in final form before considering, or acting on, any such petitions. The agency, therefore, advised that it is likely to deny any petition submitted under the 1990 amendments until final procedural regulations are issued. The agency requested information and comments on appropriate requirements for these petitions.

Ten comments pertaining to petitions for nutrient content claims were received from the food industry, industry trade associations, and consumer organizations. The agency has considered the comments, and many of the recommendations made in the comments are incorporated, or were otherwise used, in the development of this section of the proposed rule.

The agency is proposing to codify the procedural requirements for petitions for nutrient content claims in new § 101.69. Because the statute prescribes distinctly different procedures for petitions that relate to nutrient content claims, synonyms for those claims, and implied nutrient content claims in brand names, FDA will treat each separately in the following discussion. In the proposed procedural regulations the Commissioner of Food and Drugs is designated as the official authorized to act on these petitions consistent with the delegation of authority from the Secretary to the Commissioner under 21 CFR 5.10.

The agency is also proposing to amend § 5.61 (21 CFR 5.61) to add paragraph (g) to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition, all the functions of the Commissioner concerning petitions for label claims under section 403(r) of the act (i.e., petitions concerning nutrient content claims and health claims) that do not involve controversial issues. Such functions consist of issuing notices that seek comment on a petition; issuing notices of proposed rulemaking and final rules concerning authorized terms

for nutrient content claims; and issuing letters concerning the filing, denial, and granting of a petition. This redelegation is proposed to facilitate timely agency action on these petitions given the short timeframes for agency action imposed by the act.

A. Statutory Provisions

1. Nutrient Content Claim (Descriptor) Petitions

Section 403(r)(4)(A)(i) of the act grants to any person the right to petition the Secretary (and by delegation, FDA) to issue a regulation to define a nutrient content claim that has not been defined in the regulations issued under section 403(r)(2)(a)(i) of the act. The statute requires that such a petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons (section 403(r)(4)(B)) of the act.

These provisions of the act also apply to petitions to the agency to issue a regulation relating to a health claim to be made of a food label. However, because health claims and nutrient content claims are distinct types of claims that convey different types of information to consumers, the specific data requirements to substantiate these two types of petitions will differ significantly. Therefore, the procedural requirements for petitions relating to health claims are proposed separately in a proposal published elsewhere in this issue of the **Federal Register** that addresses the general requirements for health claims for food.

Section 403(r)(4)(A)(i) of the act provides that within 100 days of receipt of a petition for a regulation concerning descriptors, FDA must either issue a final decision denying the petition or file the petition for further action. If FDA denies the petition, it is not made available to the public. If it files the petition, FDA must either deny it or publish a proposed regulation responsive to the petition within 90 days of filing.

2. Synonym Petitions

Section 403(r)(4)(A)(ii) of the act grants to any person the right to petition the Secretary (and by delegation, FDA) for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i) of the act. The statute provides that within 90 days of the submission of a petition, FDA must issue a final decision denying the petition or granting such permission.

3. Brand-Name Petitions

Section 403(r)(4)(A)(iii) of the act also allows petitions requesting use of an implied claim concerning the level of a nutrient in a food in the food's brand name. The claim must not be misleading and must be consistent with the terms defined by FDA by regulations under section 403(r)(2)(A)(i) of the act. The agency is directed in the act to publish notice of an opportunity to comment on the petition in the **Federal Register**, to make the petition available to the public, and to issue a final decision no later than 180 days after the date of submission to grant or to deny the petition. The petition is to be considered granted if the Secretary does not act on it within 180 days.

B. Comments

1. Nutrient Content Claims Petitions

a. *Procedural issues.* Two comments stated that FDA appears to take the position that "free," "low," "light" or "lite," "reduced," "less," and "high" are the only nutrient content claims for which the agency is required to issue regulations within two years after the enactment of the 1990 amendments. The comments disagreed with this interpretation and contended that the congressional intent, and the wording of the 1990 amendments, contemplate a two-track system operating concurrently. The first track consists of establishment (by the agency) of definitions for the above nutrient claims identified in the 1990 amendments. The second track consists of agency consideration of those nutrient descriptors for which petitions are submitted by interested persons.

The comments stated that at no time did Congress indicate that FDA had authority to limit itself to the former and ignore the latter. The comments pointed out that any nutrient content claim that is not the subject of an FDA regulation issued by the effective date of the statute may not be used. The comments stated that as a result of this fact and of FDA's planned course of action, all nutrient content claims not explicitly required by statute to be the subject of a regulation would not be defined and thus could not be used after the effective date of the statute. Therefore, the comments requested that FDA withdraw the statement that it may defer or deny nutrient content claims petitions until it has adopted final procedural regulations and state that all petitions will be handled in the manner required by the new law.

The agency rejects these comments for three reasons. First, as explained in the March 1991 **Federal Register** notice, the 1990 amendments place an extraordinary burden on FDA's resources. FDA has great discretion in determining how its resources can best be used. Not only does the agency lack the resources to handle a large influx of petitions on nutrient content claims, but because the petitions would be submitted before FDA identified the kinds of information that a petition would have to include to substantiate the need for a new descriptor, it is questionable whether the petitions would contain the substantive information needed by the agency to make a decision. Such a situation would likely result in a waste of the agency's resources, as a great deal of effort would need to be spent in looking at inadequate petitions.

Secondly, and most importantly, the nutrient content claims petitions would request regulations that are in addition to or perhaps amendments of the regulations established by the agency in this rulemaking. As the agency stated in the March 14, 1991 notice, it is premature to request amendment of a regulation (by addition or revision) before the regulation is final. The procedural regulations will be made final at the same time as the substantive regulations, and therefore, the agency's procedure for handling petitions before final regulations is appropriate.

Consistent with the most effective use of its resources in pursuing this end, the agency believes that the nutrient content claims that it considers first should be those that are of greatest concern and usefulness to consumers because of their potential to be misleading. The agency is addressing those terms in this proposed rule. The agency notes that in doing so, it has not limited itself to the terms enumerated in section 3(b)(2)(A)(iii) of the 1990 amendments but has proposed to define a number of other terms (e.g., "source" and "more") that are of most significance to consumers.

b. *Evaluation criteria.* Several comments recommended that a nutrient content claim petition include a quantitative definition of the proposed descriptor, and that the definition be supported by data proving that the new term is quantitatively significantly different than those terms defined pursuant to section 403(r)(2)(A)(i) of the act. One comment further recommended that the petitioner be required to explain, using scientific data, why the agency-defined nutrient content claims are inadequate to describe the product's characteristics.

The agency agrees that petitions for nutrient content claims should address

the level of the nutrient that must be present to justify the use of the claim and is proposing to require in § 101.69(m)(1) in format item A that a petitioner specify the level at which a nutrient must be present for the use of the claim to be appropriate. The agency also believes that before it approves any additional claims, it should consider whether such approval would result in the availability of additional useful information to consumers that will enhance their ability to select foods of nutritional value. Therefore, the agency is proposing to require in § 101.69(m)(1) in format item B that the petitioner address what nutritional benefit to the public will derive from the use of the proposed claim, and why such benefit is not available through the use of the existing terms defined by regulation.

Other comments added that scientific or statistical data supporting the accuracy of the term, in and of themselves, are not sufficient, if such studies are not accompanied by broad-based, statistically valid studies demonstrating consumers' understanding of the term.

FDA believes that a petition should demonstrate that consumers will understand the proposed term. However, it does not believe that an extensive database would be required in all cases to substantiate that a proposed term would be understood. Therefore, the agency is proposing in § 101.69(m)(1) in format item C that a petition include data and information that demonstrate that the proposed term will be understood by consumers, but it is not specifying the type or degree of such data.

Another comment suggested that petitions include recommendations from health organizations. Information, including recommendations, from health organizations may be useful in evaluating potential nutrient content claims, and petitioners are free to include such recommendations. However, the agency does not believe that such recommendations should be required for a petition to meet the burden of proof contemplated by the act and is not proposing to require them. In addition, health organizations will be able to participate in the rulemaking process for these petitions by commenting on any proposed regulation issued in response to a petition.

Other comments suggested that in considering nutrient content claim petitions, the agency is required to use the statutory criteria established in section 403 (a) and (r) of the act, and that because these criteria are quite specific, no other elucidation of the statutory provision is necessary or desirable.

While the agency agrees that the statutory provisions cited in the comments, along with section 201(n) of the act, will provide the ultimate standards against which any petitions for additional terms must be judged, it believes that an additional elucidation by regulation is appropriate. The agency believes that by setting forth the kind of showing that will be necessary to justify a claim, it will facilitate the process. As a result the petitions that will be filed will be more focused, and potential petitioners will be able to judge in advance whether submitting a petition would likely be a useless gesture.

2. Synonym Petitions

a. *Procedural issues.* In general, the comments that addressed the procedures to be followed for synonym petitions dealt with four major areas: Publication of a notice of receipt of a synonym petition, opportunity for public comment, publication of the agency's decision, and necessity for codification of the final decision.

One comment stated that under section 403(r)(4)(A)(ii) of the act, there is no statutory requirement for a comment period, and therefore, none should be afforded. Other comments suggested that all petitions received by the agency should be published in the **Federal Register** with a 30-day comment period.

The agency received a similar range of comments on the need to publish a notice of denial of a synonym petition. While some comments argued that there is no need to publish such a notice, others argued that if a petition is denied, publication of this fact would discourage others from petitioning for use of the same term, thereby promoting more efficient use of the agency's resources.

One comment stated that a petition under section 403(r)(4)(A)(ii) requires only a decision by the agency in the nature of an advisory opinion and not the establishment of a regulation. The comment said that only if the petition is granted should notice of availability of the advisory opinion be published in the **Federal Register**. Others felt that it is appropriate that if the petition is granted, the synonymous term should be codified. These comments argued that this approach is consistent with the requirement in the 1990 amendments that all new nutrient content claims be codified. These comments also said that codification will lead to consistency of terms used for the labeling of food and, thereby, better consumer understanding of label statements.

The proposed procedures for agency action on synonym petitions are discussed below along with the factors that the agency considered in arriving at its tentative positions. Given the very short timeframe established by the act, the agency is proposing neither to solicit public comment on the petition nor to establish regulations for authorized synonyms. However, it intends to publish expeditiously a notice of its decision on the petition.

b. *Evaluation criteria.* Some comments recommended that the agency require petitioners to prove that the ordinary meaning of the term is not misleading and is synonymous with the agencydefined term. Inclusion of consumer surveys or other market research data was recommended to demonstrate that consumers understand the new term to be synonymous with the agency-defined term, and that consumers are not confused by the new term. The comments also stated that the petitioner should be required to show why the existing terms are inadequate.

The agency generally agrees with the views expressed in these comments. It has included provisions in proposed § 101.69(n), the regulation on synonym petitions, that require that the petitioner address these items. This approach would differ under the alternative discussed in section IV above.

3. Brand-Name Petitions

One comment requested that the agency provide adequate time for comment on the notice that it is required to publish in the **Federal Register**. Other comments suggested that the agency consider codifying its decision to grant a brand-name petition, or, if this is not practicable, any final decision by the agency should be made public 30 days before its effective date, so that interested parties can petition for reconsideration.

The proposed procedures for agency action on brand-name petitions are discussed below along with the factors the agency considered in arriving at its tentative positions. FDA is proposing to provide 30 days for comment on the petition and to issue its decision by letter to the petitioner. In addition, the agency intends to announce the approval of a brand name in the **Federal Register**.

C. Proposal

1. Provisions Applicable to All Petitions for Nutrient Content Claims

The agency is proposing to establish § 101.69 as the general procedural regulation for all types of petitions for nutrient content claims. Proposed § 101.69(a) through (l) are general

provisions applicable to all such petitions. Section § 101.69(a) through (f) address general issues, such as how specific types of information can be incorporated into the petition and set forth standard agency requirements pertaining to clinical and nonclinical studies submitted to the agency for review. The agency is proposing in § 101.69(g) that the availability for public disclosure of petitions for nutrient content claims will be governed by the provisions of § 10.20(j), the general provision that governs the availability of material submitted to the Dockets Management Branch, such as petitions, comments, and objections.

Proposed § 101.69(h) requires all petitions to include either a claim for a categorical exclusion under § 25.24 or an environmental assessment under § 25.31. Section 101.69(i) sets forth how the submitted data in the petition are to be organized and identified and permits the petitioner to incorporate by reference any data from an earlier petition. Section 101.69(j) requires that the petition be signed by the petitioner, or his attorney or agent, or (if a corporation) by an authorized official. Section 101.69(k) requires that the petition include a statement signed by the person responsible for the petition that the petition is a representative and balanced submission containing all information, favorable and unfavorable, to the evaluation of the proposed claim. Section 101.69(l) states that all applicable provisions of part 10 may be used by the agency, the petitioner, or any outside party with respect to any agency action on a petition submitted under this section. The agency advises, however, that actions requested under part 10, e.g., a request for reconsideration of a decision on a § 101.69 petition, are not subject to the timeframes prescribed in the 1990 amendments for the petitions themselves.

2. Provisions for Descriptor Petitions

Proposed § 101.69(m)(1) sets forth the proposed data requirements specific to descriptor petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed descriptor is not misleading and is consistent with the purpose of the 1990 amendments, i.e., to make the food label more meaningful and understandable to consumers.

Proposed format item A requires a statement identifying the descriptive term and the nutrient whose level the term is intended to characterize. The statement should address why the use of the term as proposed will not be misleading and provide examples of the claim as it will be used on labels or labeling, as well as examples of the types of foods on which the claim will be used. The statement must specify the level at which the nutrient must be present, or what other conditions concerning the food must be met for the appropriate use of the term, as well as any factors that would make the use of the term inappropriate.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that the claim would describe. The explanation must also state what nutritional benefit to the public will derive from the use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. The explanation of any claim proposed for a specific group within the population should address the specific nutritional needs of that group. This format item also requires the petitioner to provide data and information, to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Proposed format item C requires data showing the amount of the subject nutrient that is present in the types of foods for which the claim is intended and specifies requirements for the assay methods used for these determinations. This information is necessary to assure the agency that the claim is realistic, and that there are foods that will actually be able to bear the claim.

Proposed format item D requires a detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that the dietary analysis is representative of that group.

The procedures for agency handling of the petition are set forth in proposed § 101.69(m)(2) through (m)(4). These items reflect the timeframes in the act for agency action on descriptor petitions. Further, the agency is proposing for descriptor petitions (and also synonym and brand-name petitions) to notify the petitioner of receipt of a petition within 15 days of submission and to deny the petition at such time if it is incomplete. If a petition is not denied at this time, a docket number will be assigned to the petition and any subsequent actions under the provisions of Part 10—Administrative Practices and Procedures regarding the petition will reference that docket number.

3. Provisions for Synonym Petitions

Proposed § 101.69(n)(1) sets forth the proposed data requirements specific to synonym petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed synonym is not misleading and is consistent with the purpose of the 1990 amendments. Because the agency foresees using many of the same criteria in evaluating a synonym petition as it is proposing to use for descriptor petitions, many of the proposed data requirements for synonym petitions are similar or identical to those proposed for descriptor petitions.

Proposed format item A requires a statement identifying the synonymous term and the nutrient content claim (defined by a regulation) with which the synonym is claimed to be consistent. The statement should address why the use of the synonymous term, as proposed, will not be misleading. The statement should also provide examples of the claim as it will be used on labels or labeling, as well as examples of the types of foods on which the claim will be used. The statement must specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. The explanation must also state what nutritional benefit to the public will derive from the use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. Any claim proposed for a specific group within the population should address the specific nutritional needs of that group. This format item also requires data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Proposed format item C requires a detailed analysis of the potential effect

of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that dietary analysis is representative of that group.

The proposed procedures for agency handling of a synonym petition are set forth in proposed § 101.69(n)(2) through (n)(4). These items reflect the timeframes in the act for agency action on synonym petitions. The agency is not proposing to provide for the publication of a notice soliciting public comment on the petition because, in contrast to petitions for new descriptors, the statute does not require such notice for synonym petitions, and under the statutory requirement of action on the petition in 90 days, there simply is not time to do so. Consistent with the act, the agency is proposing to issue its decision concerning a synonym petition by letter to the petitioner.

Although the act does not require that permission to use a synonym be provided by regulation, the agency is proposing that it will publish expeditiously a notice of its decision on the petition. Such notice will serve to inform the public of agency decisions and provide an opportunity for interested persons to petition the agency for reconsideration of the action under part 10. In addition, to avoid confusion about which synonymous terms have been approved by the agency, and because the procedure defined in the statue will result in a final agency decision that has the force and effect of law, FDA is proposing that when a synonym petition is granted, it will include the synonymous term in the applicable descriptor regulation.

4. Provisions for Brand-Name Petitions

Proposed § 101.69(o)(1) sets forth the proposed data requirements specific to brand-name petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed implied claim is not misleading and is consistent with the purpose of the 1990 amendments. Because the agency foresees using many of the same criteria in evaluating a brand-name petition as it is proposing to use for descriptor and synonym petitions, many of the proposed data requirements for brand-name petitions are similar or identical to those proposed for descriptor and synonym petitions.

Proposed format item A requires a statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of the nutrient as defined by regulation, and the brand-name of which the implied claim is intended to be a part. The statement should address why the use of the brand-name as proposed will not be misleading. The statement should provide examples of the types of foods on which the brand-name will appear and must include data showing that the actual level of the nutrient in these foods qualifies them to bear the term defined by regulation.

Proposed format item B requires a detailed explanation, supported by any necessary data, of why use of the proposed brand-name is requested. This format item must also state what nutritional benefit to the public will derive from the use of the proposed brand-name. If the branded product is intended for a specific group within the population, the claim should address the specific nutritional needs of that group.

Proposed format item C requires a detailed analysis of the potential effect of the use of the proposed brand-name on food consumption and of any corresponding changes in nutrient intake, with the latter item specifically addressing the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis must address the dietary practices of that group, with data sufficient to demonstrate that dietary analysis is representative of that group.

The proposed procedures for agency handling of a brand-name petition are set forth in proposed § 101.69(o)(2) through (o)(5). These items reflect the timeframes in the act for agency action on brand-name petitions.

FDA recognizes that a short timeframe for brand name decisions is necessary in order to prevent inappropriate inhibition of production and marketing planning. Given the need for such planning and the need to ensure that the consumer is protected, the agency recognizes the need for it to make decisions on implied nutrient content claims in brand names within the 100 day timeframe.

The agency advises that it intends to deny a petition if it determines that the requested claim is not an implied nutrient content claim. FDA will make this determination using criteria consistent with any that have been developed for implied claims under section 403(r) of the act. The agency also intends to deny petitions for implied claims that do not include as a part of the label statement enough appropriate information so that it is clear that consumers will not be misled by the claim. In addition, FDA intends to deny a petition if it is not complete as prescribed in this regulation, or if the information in the petition is not clearly persuasive that the requested claim should be approved. Of course, as discussed above, any petitioner may request reconsideration of a denial under the provisions of 21 CFR part 10.

The agency is proposing to publish the **Federal Register** notice seeking comment on the petition as soon as possible after receipt of the petition (probably within 20 days) and to provide 30 days for public comment on the petition. The agency believes that 30 days is the longest comment period possible consistent with the agency's responsibility to act on the petition within 100 days. Consistent with the act, the agency is proposing to issue its decision concerning a brand-name petition by letter to the petitioner. However, to avoid confusion about which brand-names containing implied nutrient content claims have been approved by the agency, FDA is proposing that when a brand-name petition is granted, it will publish expeditiously a notice in the **Federal Register** informing the public of the granting of the petition.

As with synonym petition proceedings, the rulemaking prescribed by for implied nutrient content claims in brand names will result in binding final agency decisions. However, FDA does not plan to list approved brand name claims in the regulations. Unlike approved synonyms, which are available for use by any manufacturer of a qualifying food, approved brand name claims are proprietary and can be used by only one firm. Consequently, there is less need for a list of approved brand name claims in the Code of Federal Regulations than there is for a list of approved synonyms. However, there is a need for a publicly available, up-to-date list, and FDA intends to maintain such a list.

VI. Terms That Describe Other Aspects of Food

In the course of the Secretary's labeling initiative, another matter that has increasingly gained the attention of consumers, the food industry, and the agency is the use of terms such as "fresh," "natural," and "organic" on labels or in labeling. These terms are not used to characterize the level of a nutrient in a food but rather to describe other aspects of a food that are

considered desirable. Many comments to the 1989 ANPRM objected to the use of such terms as marketing tools that provide no consistent guidance to the consumer about the nature of the food. Some comments suggested that these terms should be defined by FDA or not permitted.

Because such terms are not used to make nutrient content claims, the 1990 amendments do not require that the Secretary define such terms. However, the agency believes that the misuse of "fresh" and related terms that has occurred in the marketplace necessitates that a definition be established in the labeling regulations to provide a basis for consumers to distinguish foods that have certain desirable attributes from those that do not and to remove any inconsistencies in the use of the term that may remain in the marketplace. The agency announced its intention to take such action with respect to "fresh" in a notice published in the **Federal Register** on February 12, 1991 (56 FR 5894). It also discussed the interim enforcement policy it planned to use until such rulemaking is completed.

FDA is proposing to amend its food labeling regulations to define, and to provide for the appropriate use of, the terms "fresh," "freshly ____," and "fresh frozen" ("frozen fresh") in the labeling of foods. FDA is also addressing the terms "natural" and "organic." However, as explained below, it is not proposing to establish definitions for the latter terms at this time.

A. "Fresh" and Related Terms

1. Use of the Term "Fresh" on Food Labels

a. *Previous FDA findings on use of the terms "fresh" and "fresh frozen" ("frozen fresh").* The agency's longstanding position on the appropriate use of the terms "fresh" and "fresh frozen" is set forth in Compliance Policy Guide (CPG) 7120.06 (Ref. 50). CPG 7120.06 makes two basic points: (1) "fresh" should not be used to describe foods that have been subjected to any form of heat or chemical processing; and (2) "frozen fresh" or "fresh frozen" are examples of terms appropriate for referring to foods that were quickly frozen while still fresh. FDA's position has been and continues to be that use of term "fresh" on foods that have been frozen or subjected to heat or chemical processing (e.g., canning, cooking, baking, pasteurization, smoking, or use of a preservative) is false and misleading.

The agency's position on the use of "fresh" dates back to the 1940s. In TC-71 (February 19, 1940) the agency stated that it would not take exception to such terms as "frozen fresh" on packaged frozen foods, provided that the foods are actually fresh when frozen. In TC-99 (February 21, 1940), FDA stated that the word "fresh" is generally understood by consumers to mean an article of recent origin, and that for butter the word would be appropriate only if the butter had been recently churned. The agency said that "fresh" would not be applicable to butter that had been kept for a length of time, such as in the usual commercial practice of storing butter in cold storage warehouses until it is marketed. In TC-261 (May 7, 1940), FDA stated that the term "fresh tomato juice" should not be applied to the ordinary canned products.

The agency has reiterated its policy over the years. FDA took a consistent position in the findings of fact that it published in the **Federal Register** of October 11, 1963 (28 FR 10900), with the final order establishing definitions and standards of identity for orange juice and various orange juice products, including pasteurized orange juice and orange juice from concentrate. One of the primary reasons for promulgating these standards was the misrepresentation of reconstituted and pasteurized orange juice as "fresh" orange juice. Finding of fact No. 2 stated:

> Fresh orange juice is not a suitable name for the commercially packaged expressed juice of oranges. The housewife who for many years has squeezed oranges knows this juice to be orange juice. The term "fresh" is ambiguous in that it is difficult to determine and to draw the line when a product is fresh and when it is no longer fresh. The use of the term "fresh" on commercially packed orange juice or orange juice products would tend to confuse and mislead consumers.

The findings of fact contain other similar and related comments concerning "fresh." Finding of fact No. 17 stated in part:

> The problem most encountered * * * is the adulteration of orange juice products with water and sugar. The next most frequent problem is misrepresentation of reconstituted orange juice and of pasteurized orange juice as fresh orange juice. The investigation further showed that even managers of retail food stores over the country are confused concerning the identity of various single-strength orange juice products. There is general confusion in the area.

The issuance of standards of identity for various orange juice products was intended, in part, to prescribe specific appropriate names for heat treated and reconstituted orange juice so as to eliminate confusing these products with fresh orange juice.

FDA has also stated in an informal opinion letter (Ref. 50) that irradiated food is a processed food and thus could not appropriately be labeled as "fresh."

b. *Current practices of concern to FDA.* Beginning in the late 1960s FDA received a number of complaints about the deceptive use of the term "fresh" on products (e.g., pasta sauce) that were preserved by heat treatment or products (e.g., fruit juices) that had been concentrated and reconstituted. FDA grew concerned about the proliferation of such misleading label claims and the resultant consumer confusion in the marketplace. In the agency's view, it is important that label statements using the terms "fresh" and "fresh frozen" ("frozen fresh") not convey a misleading impression about the food.

The IOM report (Ref. 5) took a consistent view. It noted that consumers want and expect a product's principal display panel to include short and understandable terms such as "fresh" and "fresh frozen" ("frozen fresh") that describe certain desirable characteristics of the food, because such terms allow them to select quickly foods that they believe are consistent with their dietary concerns. However, the report stated, the lack of uniform and consistent FDA and USDA definitions for these types of terms has led some to conclude that such terms should not be permitted because of the potential for confusion, exaggeration, and deception. Therefore, the IOM report recommended that terms like "fresh" be controlled by narrowing the conditions for their use.

FDA agrees with the recommendations of the IOM report and the general view expressed in many of the comments on the 1989 ANPRM that stronger control of the use of the terms "fresh" and "fresh frozen" ("frozen fresh") is needed so that consumers will not be misled in attempting to make intelligent use of factual information on the food label.

Since 1989, FDA has increased its surveillance of the use of the term "fresh" in the marketplace. In the spring of 1991, the agency instituted a major regulatory initiative against misleading uses of "fresh" on food labels. The agency took formal and informal actions against the use of the term on such products as juice products made from concentrate, juice drinks containing preservatives, and heat processed products such as pasta sauces and caviar. FDA issued letters to several firms citing their misleading use of "fresh" on food labels, warned firms that such misbranded products may be seized by the agency, and has seized some products.

The agency will continue to monitor the use of this term in the marketplace and remains prepared to take action where it encounters the misleading use of the term. However, FDA also believes that the lack of regulations defining "fresh" and "freshly frozen" ("frozen fresh") creates the possibility that these terms will again be abused. Therefore, FDA has tentatively concluded that it is both necessary and desirable to establish definitions by regulation that will standardize the use of these terms on food labels.

2. Proposed Regulation

a. *Legal basis and general provisions.* FDA is proposing to define the terms "fresh" and "fresh frozen" ("frozen fresh") in the labeling of food and to provide for the proper use of these terms. FDA has authority to take these actions under sections 201(n), 403(a)(1), and 701(a) of the act. Section 201(n) of the act allows for the consideration of the extent to which the labeling of a food fails to reveal a material fact in determining whether its labeling is misleading. Section 403(a)(1) of the act states that "A food shall be deemed to be misbranded if its labeling is false or misleading in any particular," and section 701(a) of the act vests the Secretary (and by delegation, FDA) with authority to issue regulations for the efficient enforcement of the act. If this proposal becomes a final rule, foods using these terms will be considered to be misbranded if they are not labeled in accordance with the proposed definitions.

FDA is proposing to redesignate subpart F of part 101 as subpart G and to establish a new subpart F that will contain requirements for claims that are neither nutrient content claims nor health claims. FDA is proposing to define and provide for the use of the terms "fresh," "freshly ____" (the blank to be filled with an appropriate verb such as "prepared," "baked," or "roasted"), and "fresh frozen" in § 101.95. The introductory paragraph of proposed § 101.95 sets out the general requirements for the use of the terms defined in the section, namely that they may be used on the label or in labeling of a food only in conformity with the provisions of the section.

b. *"Fresh," and "Freshly ____."* FDA is proposing to define the terms "fresh" and "freshly ____," to be used in separate contexts: (1) The term "fresh," as defined in proposed § 101.95(a), applies to a raw food that has not been frozen or subjected to any form of thermal processing or any other form of preservation; (2) The term "freshly ____" (e.g., prepared, baked, roasted) in proposed § 101.95(b) applies to a recently produced or prepared food that has not been frozen, or subjected to any form of thermal processing or any other form of preservation, during or subsequent to its manufacture or preparation, excluding a process inherent to the production of the basic product. As discussed below, proposed § 101.95(d) contains provisions for the use of these descriptors in cases that would otherwise be precluded under the definitions in § 101.95 (a) and (b).

FDA believes that consumers generally regard a food in its raw state as being fresh. Proposed § 101.95(a) therefore distinguishes a food in its raw state from the same food that has been processed or preserved for the purpose of defining which is fresh. For example, fish that is caught, cleaned, and displayed for sale under refrigeration may be labeled "fresh." However, if the fish was frozen aboard the fishing vessel, then thawed and prepared for sale in a central facility, it could not be labeled as "fresh" because it has been processed by freezing. A food such as unprocessed juice obtained directly from oranges by squeezing may be labeled as "fresh." However, if the juice is pasteurized, it is not fresh because it has been processed by pasteurization (a thermal process). Similarly, a product made with processed or concentrated ingredients is not "fresh."

Under proposed § 101.95(d)(1), the following conditions would not preclude use of the term "fresh": (1) If an approved wax or coating has been applied to raw produce, (2) if a mild chlorine or mild acid wash has been applied to raw produce, or (3) if raw produce has been treated with approved pesticides after harvest. Although these practices could possibly be viewed as methods of preserving food, they are routine practices in the distribution and handling of raw produce that essentially affect only the food surface and do not appreciably affect the body of the food or alter its raw state. Further, the agency believes that consumers regard such foods as fresh and are not misled when the term is used on these foods.

The agency solicits comments on the use of "fresh" to describe certain raw foods that have been treated with ionizing radiation in accordance with § 179.26 (21 CFR 179.26), specifically those foods for which irradiation at a maximum dose of 1 kiloGray (100 kilorads) is permitted. Currently, § 179.26(b) permits such treatment "for control of *Trichina spiralis* in pork carcasses," "for growth and maturation inhibition of fresh foods," and "for disinfestation of arthropod pests." The agency will determine, based on the comments, whether it should include a provision in § 101.95(d)(1) permitting the term "fresh" to be used on irradiated foods where the irradiation has had little effect on the attributes of the food associated with its raw state. Alternatively, if comments persuade the agency that consumers would be misled by such use of the term "fresh," the agency will consider including a provision in the final rule specifically prohibiting such practices.

Proposed § 101.95(d)(2) provides that refrigeration of a raw food that otherwise meets the definition of "fresh" does not preclude the use of that term. Although refrigeration is a means of preserving food for a finite time, the proposal includes this provision because the agency believes that consumers generally regard refrigerated raw foods as fresh and are not misled when the term is used on such foods.

Proposed § 101.95(b) states conditions for the use of "freshly ____" on labels and in labeling of prepared foods, e.g., soup and bread, as opposed to raw food items. Proposed § 101.95(d)(2) also provides that refrigeration of a food that otherwise meets the definition of "freshly ____" does not preclude the use of the term "freshly ____." In the case of prepared foods, FDA recognizes that recently prepared or produced foods that have not been processed or otherwise preserved are valued by consumers and are generally considered by consumers to be more desirable than comparable foods that have been processed or preserved. Examples of such valued foods would include salads (e.g., bean salad and tuna salad) or soups (e.g., clam chowder) that are prepared in a retail outlet or a central facility, packaged in a consumer package or bulk form without preservatives, and offered quickly for sale without further processing. The agency believes that it is appropriate to label such foods as "freshly prepared" or "freshly made" to emphasize that the food is of recent origin, is not preserved, and has not been processed after preparation. "Prepared" in this context means that the salad or soup was actually formulated from a recipe, versus simply transferring a canned salad to a tray and displaying it for sale in a refrigerated case, or simply heating a canned soup and offering it from a self-service soup bar.

Other examples of foods that meet the proposed definition in § 101.95(b) include: (1) Peanuts that are roasted and sold onsite; (2) shrimp that is steamed at a retail site or at a central facility and quickly offered at retail; and (3)

crabmeat that is steamed or broiled before picking and is sold without preservation. In these cases, the use of other verbs in conjunction with the adverb "freshly" would be appropriate, such as "freshly roasted peanuts," "freshly steamed shrimp," and "freshly picked crabmeat." It should be noted that in all the examples for proposed § 101.95(b), the term "freshly" is an adverb that modifies a verb such as "prepared" or "roasted," and does not describe the food itself as fresh. The agency believes that the proposed terminology is the most appropriate manner for conveying the desirable attributes of recently prepared or produced foods, and thus, it is not proposing to allow for the use of "fresh" to describe the food itself.

Under the proposed definition, recently baked bread, formulated without a chemical preservative, could be labeled as "freshly baked." The fact that the bread was processed by baking does not disqualify it because baking is inherent to the manufacturing of bread. However, if such a product included a chemical preservative, such as a mold growth inhibitor, among its ingredients, it could not be labeled as "freshly baked" because it would be a preserved product. The agency does not believe that the preserved product should bear the same qualitative term, i.e., "freshly baked," as unpreserved bread, because its quality results, in part, from the incorporation of a chemical preservative.

The term "recently" as used in this proposal is a qualitative term whose meaning depends in large degree on the food in question. For example, many consumers would consider a pasta salad to be recently made, and thus "freshly prepared," on the day it was actually prepared on-site or in a central facility. On the other hand, for "freshly roasted" peanuts, consumers would probably consider "recent" to mean that the peanuts are still warm. However, in general, FDA believes that it would not be appropriate for the terms permitted by proposed § 101.95(b) to be used on the label or labeling of a food that is available for sale more than 24 hours after its preparation. FDA has therefore included in proposed § 101.95(d)(3) a provision that states that a food shall not be considered to be recently prepared or made if it is available for sale more than 24 hours after its preparation or production.

The agency's intention in specifying a time period for "recently prepared" is to limit the use of the term "freshly ____" to foods that are qualitatively comparable to foods prepared by consumers for same day consumption. However, the agency realizes that given the variety of foods that are available for sale within a relatively short time after preparation, some foods available for sale more than 24 hours after preparation may merit use of the term "freshly ____." The agency requests comments on this matter. Comments should identify such foods and state why they merit use of the term "freshly ____." If the comments identify such foods, FDA will consider adding provisions to § 101.95(d) that will permit the use of "freshly ____" in the labeling of such foods. Alternatively, the agency would consider specifying a time period other than 24 hours in § 101.95(b) if the comments demonstrate that there are a large number of foods that merit such an exception, and that a more appropriate time period can be included in § 101.95(b).

The proposed definition of "freshly ____" in proposed § 101.95(b) will preclude the use of this term on foods that have been subjected to certain processes and any form of preservation "during or subsequent to" the preparation or production of the food. Thus, the focus of this definition is on the preparation of the product and subsequent treatment of the food item and not on to the ingredients contained in the product. FDA believes that it is common in the marketplace to find prepared foods that are valued for their recent preparation even though they contain processed ingredients, e.g., a pasta salad made with canned tuna. Thus, the agency believes that consumers will not be mislead by permitting such foods to bear terms such as "freshly prepared." However, the agency requests comments concerning whether situations exist in which it would be misleading to label a prepared food containing processed ingredients as "freshly ____." If such cases are identified in the comments, the agency will consider restricting the use of the term to situations where it would not be misleading.

FDA's proposed approach concerning ingredients in a freshly prepared food is generally consistent with the policy of the USDA's Food Safety and Inspection Service (FSIS). FSIS, which regulates meat and poultry based products, permits the use of the term "fresh" when it describes a recently prepared food consisting of ingredients that could not meet its policy criteria (e.g., a ham salad containing cured ham).

c. *"Fresh frozen" and "frozen fresh".* As noted above, it has been the agency's longstanding policy that the term "fresh" should not be used without qualification to describe foods that are frozen or have been frozen. Consistent with this policy, the agency is proposing in § 101.95(c) to define the terms "fresh frozen" and "frozen fresh," when used on the label of a food, to mean a food that is quickly frozen while fresh (i.e., a food that is recently harvested when frozen), by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen quickly, even to the center of the food, and that virtually no deterioration has taken place.

d. *Use of terms in a brand name or as a sensory modifier.* FDA is aware of a number of foods that include as part of the brand or firm name the term "fresh." Brand names, firm names, logos, and mottos are label statements that sometimes make a false or misleading claim and have the potential to mislead. Some manufacturers have claimed that when the term is used as a brand name or with the word "brand" or "style," it is not subject to FDA regulation. Others have sought to insulate their use of the term "fresh" by using it to refer to sensory qualities such as texture, color, flavor, or taste.

The use of this descriptor in conjunction with one of these terms or similar terms is misleading to consumers on the label of a product that is not itself fresh. For example, some traditional canned vegetables have used such labeling in the past, where the product contains ingredients that enable it to undergo a less intense thermal process and to retain a higher level of sensory quality. The agency desires to make it clear that it regards any use of the terms defined in this section to be subject to the requirements of the regulation if the term expressly or implicitly refers to the food. FDA is, therefore, proposing to include in the introductory paragraph in § 101.95 a statement that the requirements of the section pertain to any use of the subject terms that expressly or implicitly refer to the food, on labels or labeling, including use in a brand name and use as a sensory modifier.

e. *Use of fresh ingredients in processed foods.* FDA is also considering whether a processed food made from fresh, as opposed to processed, fruits or vegetables should be permitted (by regulation) to include on the label a factual statement such as "spaghetti sauce—made with fresh mushrooms" FDA requests comments on whether use of the term "fresh" is appropriate in such circumstances.

FDA also requests comments on whether consumers understand such

statements and consider them to be useful in describing a processed product, whether it is important to the consumer to be able to distinguish between processed products made from fresh as opposed to processed (e.g., concentrated and then rehydrated or reconstituted) ingredients, and whether there are other appropriate means for making such distinctions on food labels. In addition, if designation of the ingredient as "fresh" is useful, FDA requests comments on whether the inclusion of blanching as a part of a continuous process at a facility should preclude labeling the ingredient as "fresh." For example, if fresh raw material mushrooms are blanched and then added to the product in a continuous process, should the label be permitted to bear the phrase "made with fresh mushrooms"? FDA will consider the comments it receives and determine whether to include a provision in the final rule addressing use of the term "fresh" to describe ingredients in processed foods.

An issue that has come to the agency's attention in its review of "fresh" claims is the use of remanufactured ingredients. The agency solicits comments on whether the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. For example, would it be useful to consumers for processed products made from remanufactured ingredients to bear a term on its principal display panel such as "made from ____ concentrate," "remanufactured," or "reconstituted?"

If the comments persuade the agency that such a declaration on the product's principal display panel is necessary to not mislead consumers about the nature of a product, the agency will consider including a provision in the final rule requiring such a declaration.

f. *Extended shelf life foods.* Extended shelf life (ESL) is a term that describes a category of foods made possible by relatively recent developments in food processing and packaging technology. Generally, ESL describes a food that is unprocessed or minimally processed (in some cases, the product is cooked just as it would be by a consumer), and thus is not shelf stable, but that is packaged in such a manner so as to maintain its quality for an extended period of time when compared to traditional packaging methods. Such products are often refrigerated (many require refrigeration for safe distribution) and often rely on the use of "barrier" packaging and "modified or controlled atmospheres" in the package to retard aging of the food. For example, one such pasta product packaged in a barrier container with a modified atmosphere, reportedly has a refrigerated shelf life of 34 days (Ref. 52).

FDA notes that ESL do not meet the requirements of § 101.95(b) for the use of the term "freshly ____." However, FDA recognizes that such products may be of a degree of quality similar to that of traditional prepared foods that could appropriately be labeled as "freshly ____." FDA is requesting information on ESL foods that would enable it to determine whether any foods of this type merit use of the term "freshly ____," and if so, what factors about such foods justify the use of the term in a nonmisleading manner. If the comments identify nonmisleading uses of the term "freshly ____" to describe ESL foods, the agency will consider explicitly limiting the proposed definition in § 101.95(b) to foods prepared and packaged by traditional means, and it will consider including provisions in the final rule permitting the use of the term "freshly ____" or other terms to describe foods prepared and packaged using ESL techniques.

B. Natural

The word "natural" is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome. In the past, FDA has not attempted to restrict use of the term "natural" except for added color, synthetic substances, and flavors under § 101.22. In its informal policy (Ref. 53), the agency has considered "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called "natural."

The meaning and use of the term "natural" on the label are of considerable interest to consumers and industry. Data suggest that uses of "natural" claims are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning. For example, two FTC reports (Refs. 54 and 55) cite numerous studies indicating a general lack of consumer understanding and scientific agreement about the meaning of the term.

The term "natural" is used, however, on a variety of products to mean a variety of things. Because of its widespread use, and the evidence that consumers regard many uses of this term as non-informative, the agency is considering establishing a definition for this term. FDA believes that if the term "natural" is adequately defined, the ambiguity surrounding use of the term that results in misleading claims could be abated.

In considering this issue, FDA has reviewed definitions of the term "natural" used by other government agencies, other countries, state governments, and industry. For example, USDA permits the use of the term "natural" on the labeling of meat and poultry products if: (1) They contain no artificial flavor or flavoring, coloring ingredient, chemical preservative, or any other artificial or synthetic ingredient, and (2) they and their ingredients are not more than "minimally processed." "Minimally processed" may include traditional processes such as smoking, roasting, freezing, drying, and fermenting. It may also include those processes that do not fundamentally alter the raw product and that only separate a whole, intact food into component parts such as grinding meat or pressing fruits to produce juices. Solvent extraction, acid hydrolysis, chemical bleaching, and other such relatively complex processes do not meet the criteria for minimal processing, and, thus, if they have occurred, the product would not be allowed by USDA to be labeled as "natural" (Ref. 56).

USDA's policy also provides that all labels of meat and poultry products bearing the term "natural" must be accompanied by a brief statement informing consumers that the product is natural because it contains no artificial ingredients and is only minimally processed. This statement may appear either directly beneath or beside all natural claims or may be placed elsewhere on the principal display panel provided an asterisk is used to tie the explanation to the claim. USDA has approved labels for "All Natural Wingettes" and "All Natural Chili."

Some of the definitions established by other government agencies, other countries, state governments, and industry are more restrictive than the USDA definition, while others are less so. There are numerous inconsistencies among the definitions as well as unanswered questions. Consequently, FDA has concluded that more consumer and industry input is needed before it can develop a definition for "natural." However, the agency notes that after considerable input from various groups, including scientists, consumers, industry, and regulatory professions, the

Federal Trade Commission (FTC) was unable to establish a definition for "natural." (See Refs. 54 and 55 and 48 FR 23270, May 24, 1983—Termination of rulemaking proceeding).

One possible meaning of the term "natural" as it applies to food is the absence of artificial or synthetic ingredients of any kind. This meaning, however, has been degraded by inappropriate use of the term in the marketplace. Should FDA establish a meaningful definition for "natural" so that this term has a common consumer understanding? Because of the multiple and diverse meanings currently in use, establishing a definition for the term "natural" that will be readily accepted and understood will be difficult. The agency is seeking comments on whether it should define this term or should prohibit such claims entirely on the grounds that they are false or misleading.

In reaching a decision on any future FDA course of action, the agency seeks comments on how, or if, it should proceed in developing a definition for the term "natural." FDA is particularly interested in the views of consumers and industry on how "natural food" should be defined. Given past consumer confusion on what "natural" means, FDA seeks comments that provide examples of what a natural food is. In addition, FDA seeks comments on whether a food represented to be natural should be considered to be misbranded under section 403(a) of the act: (1) If it has undergone more than "minimal processing" (the agency also requests comments on what "minimal processing" means), or (2) if it contains any artificial or synthetic ingredients such as food and color additives.

How FDA proceeds will depend largely on response to the agency's concerns regarding a definition of the term "natural" and the identification of a suitable direction that the agency might explore in establishing a definition for such a term.

In addition to information on these broad uses of the term "natural," FDA is also seeking comment on how it distinguishes between artificial and natural flavors in § 101.22. The agency is concerned that its existing definition of "natural flavor" may not be consistent with the current interpretation of "natural" as implying minimal processing. For example, while removing the essential oil from a food is probably well understood to be minimal processing, and the oil is therefore a natural flavor of the food, it is less clear whether hydrolysis or enzymolysis of a food is minimal processing and therefore results in a natural flavor. The agency requests comments with substantiating information to provide a basis for a clearer, more appropriate distinction between natural and artificial flavors.

C. Organic

A review of the comments from consumers to the 1989 ANPRM on the use of the term "organic" demonstrated that consumer perceptions of the term encompass more than is generally intended by the term. Many of the comments suggested that they wanted either:

(1) Organic to mean "pesticide free" (organically grown) food;

(2) Label declaration of any pesticide, growth enhancer, fungicide, chemical, or radiation used; or

(3) At least label declaration of any potentially harmful pesticides and fertilizers used.

On November 28, 1990, Title XXI—Organic Certification, known as the "Organic Foods Production Act of 1990 (OFPA), was enacted as part of the 1990 Farm Bill. The purpose of the statute was:

(1) To establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA stated that to be sold or labeled as an "organically produced" agricultural product, an agricultural product must, with certain exceptions, (1) have been produced and handled without the use of synthetic chemicals, (2) not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding the harvest of the agricultural products, and (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

This statute charges USDA with establishing a certification program for producers and handlers of agricultural products that have been produced using organic methods. In addition, the USDA was instructed to permit each state to implement a State organic certification program for producers and handlers of agricultural products that have been produced using organic methods. The OFPA also established certain requirements under which a processed food could be labeled directly or indirectly as "organically grown."

The OFPA provides that exemptions to certain labeling requirements for processed foods may be made to the extent that the Secretary of Agriculture, in consultation with the National Organic Standards Board and the Secretary of DHHS, determines that they are appropriate.

Because responsibility for regulating use of the term "organic" has been assigned by Congress to USDA, FDA will defer issuing of any regulations governing the term "organic" until USDA has adopted appropriate regulations. At this time, FDA will determine whether any additional regulations governing the term "organic" are necessary.

VII. 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.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.24 that this proposed rule is of a type that does not individually or cumulatively have a significant effect on the human environment. The proposed actions pertaining to food labeling meet the criteria in 21 CFR 25.24(a)(11) for exclusion from preparation of any environmental assessment and an environmental impact statement. The proposed regulations pertaining to petitions for nutrient content claims meet the criteria for exclusion described in 21 CFR 25.24(a)(8). Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Effective Date

FDA is proposing to make these regulations effective 6 months after the publication of a final rule based on this proposal.

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."

X. Comments

Interested persons may, on or before February 25, 1992, 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 for nutrient content claims. 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.

XI. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 101.69 *Petitions for nutrient content claims* relating to submission of petitions to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the Federal Register as part of any final rule that is based on this proposal.

XII. References

The following references have been placed on file 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.

1. DHHS and USDA, "Nutrition and Your Health. Dietary Guidelines for Americans," 1990.

2. "The Surgeon General's Report on Nutrition and Health," DHHS (Public Health Service) Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

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

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

5. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling, Issues and Directions for the 1990's," Washington, DC, National Academy Press, 1990.

6. Crane, N. T., memorandum to file, Modification of USDA's Nutrient Data Base for Standard Reference, Ref. 9, October 16, 1991.

7. Crane, N. T., memorandum to file, Data Analysis No. 1—Nutrient Content on a 100 Gram Basis, October 16, 1991.

8. Crane, N. T., memorandum to file, Data Analysis No. 2—Nutrient Content on a 100 Gram Dry Weight Basis, October 16, 1991.

9. Pennington, "Descriptive Terms for Food Labeling," p. 51, June, 1980, February, 1990.

10. Report of the 4th Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines, Committee on the Nutritional Aspects of Foods Standards, International Union of Nutritional Sciences [illegible], 1989.

11. Market Facts, Inc., "Summary Report, FDA Nutrition Labeling Focus Groups," available from Clinical Nutrition Branch (HFF–265), Division of Nutrition, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, October 1990.

12. Gardner, S., and E. T. Guarino, letter to Fred R. Shank, May 10, 1991.

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15. Levy, A. S., et al. "Nutrition Shelf Labeling and Consumer Purchase Behavior" (in press).

16. Humphrey, H. H. III, letter to Virginia Wilkening, February 12, 1991.

17. Levy, A. S., and J. T. Heimbach, Division of Consumer Studies (HFF–240), Center for Food Safety and Applied Nutrition, Food and Drug Administration, "Recent Public Education Efforts About Health and Diet in the United States," 200 C St. SW., Washington, DC 20204, 1989.

18. National Food Processors Association, "Summary of Findings, Food Labeling and Nutrition * * * What Americans Want," Washington, DC.

19. Tri-Agency Task Group on Nutrition Labeling of Sugars, "Task Group Report on Nutrition Labeling of Sugars," available from the Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, July, 1981.

20. Frattali, V., memorandum to Judith Kraus, August 9, 1988.
21. Kraus, J. to M. Crowe, memorandum of telephone conversation August 11, 1988.
22. Frattali, V., memorandum to Judith Kraus, August 15, 1988.
23. Lake, L. R., letter to J. Radzius, Burditt, Bowles and Radzius, Chartered, August 2, 1989.
24. Franz, M. J., "Relaxing the Rules," Diabetes Forecast, pp. 9–10, June, 1989.
25. Glinsmann, W. H., H. Irausquin, and Y. K. Park, Report from FDA's Sugars Task Force: Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners, *Journal of Nutrition*, Vol. 9, pp. 161–185, 1983.
26. Miller, S. A., letter to Dr. G. Norris Bollenback, The Sugar Association, Inc., September 21, 1979.
27. Quinn, T. M., letter to Mr. Eugene I. Lambert, Covington and Burling, September 10, 1984.
28. Riggins, J. W., letter to Mr. Peri Dutta, North Dakota State Laboratories, July 2, 1985.
29. Riggins, J. W., memorandum to John Bogle, April 27, 1987.
30. Panzica, A., letter to President, R. W. Frookies, Inc., January 3, 1990.
31. Pennington, J. A. T., L. Wisniski, and G. W. Logan, "In-store Nutrition Information Programs," *Journal of Nutrition Education*, Vol. 20, No. 1, pp. 5–10.
32. Department of National Health and Welfare, Canada Food and Drug Regulations with Amendments to May 3, 1990 Part B, Division 24 (B. 24.006).
33. Department of National Health and Welfare, Food and Drug Regulations with amendments to May 3, 1990 Part B, Division 24 (B. 24.004).
34. Buzzard, I. M., letter to Virginia Wilkening, February 12, 1991.
35. Crane, N. T., memorandum to file, Data Analysis No. 3—Distribution of Nutrient Across Food Categories, October 16, 1991.
36. Crane, N. T., memorandum to file, Data Analysis No. 4, Foods with Twenty Percent or More of Reference Value per Service, October 16, 1991.
37. Crane, N. T., memorandum to file, Data Analysis No. 5, 20 percent of reference value per serving, October 16, 1991.
38. Consumer and Corporate Affairs, Canada, Guide for Manufacturers and Advertisers, Hull, Quebec Bureau of Consumer Affairs, 1988:67–69.
39. USDA, "Composition of Foods, Raw, Processed, Prepared," Agriculture Handbook No. 8–1 to 8–16, Human Nutrition Information Service, Washington, DC, 1976–1987.
40. Shank, F. R., letter to Crowley Foods, Inc., October 19, 1989.
41. Crane, N. T., memorandum to file, Data Analysis of the 1988 Food Labeling and Package Survey, October 16, 1991.
42. Crane, N. T., memorandum to file, Analysis of the 1989 N. C. Nielson Co. SCANTRACK Data Base, October 16, 1991.
43. Crane, N. T., memorandum to file, Data Analysis No. 6, Intake vs. Dietary Recommendations, October 15, 1991
44. Food and Drug Administration Health and Diet Survey, 1982
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50. Food and Drug Administration Compliance Policy Guide 7120.06.
51. Holloway, J., letter to Roessler, C., May 31, 1991.
52. "New Ledding Extends Pasta's Freshness, Packaging," p. 138, Vol. 35, No. 13, 1990.
53. Raymond E. Newberry, letter to Clinton K. Davies, PhD, September 29, 1988.
54. Staff Report and Recommendation, Proposed Trade Regulation Rule on Food Advertising, 16 CFR Part 437 Phase 1, United States of America Before Federal Trade Commission, September 25, 1978.
55. Muris, T. J., memorandum to Federal Trade Commission, Subject Food Rule, Phase I, May 17, 1982.
56. USDA, FSIS, Policy Memo 055, November 22, 1982.
57. National Heart, Lung, and Blood Institute, National Cholesterol Education Program, "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," DHHS, Public Health Service, National Institutes of Health, April 7, 1991.
58. Henry, C. B., memorandum to file, Fat and Calories—A Variety of Chocolate Chip Cookies, October 18, 1991.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 105

Dietary foods, Food grades and standards, Food labeling, Infants and children.

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 parts 5, 101, and 105 be amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101–2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1–300ff); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.61 is amended by revising the section heading and by adding a new paragraph (g) to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, health claims, and nutrient content claims and health claims.

* * * * *

(g) The Director and Deputy Director, Center for Food Safety and Applied Nutrition are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of decisions to grant or deny, letters of filing, notices seeking comment, and notices of proposed rulemaking in response to petitions for nutrient content claims and health claims that do not involve controversial issues.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues 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, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.13 is revised to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale.

(b) A claim that expressly or implicitly characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling under § 101.9, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium."

(2) An implied nutrient content claim is any claim that describes the food or

an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran") or that the food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy").

(3) No nutrient content claims may be made on food intended specifically for use by infants and toddlers less than 2 years of age.

(c) Information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(ii) of this section, informing the consumer of such difference (e.g., not for use in cooking).

(2) This disclaimer must be in easily legible print or type and in a size no less than one-half the size of the type of the descriptive term but in no case less than one-sixteenth of an inch in height.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food has been altered compared to other foods of the same type to lower the amount of the nutrient in the food, only foods that have been specially processed, altered, formulated, or reformulated so as to remove the nutrient from the food may bear such a claim (e.g., low sodium potato chips).

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient, when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium free food").

(f) A nutrient content claim shall be in type size and style no larger than that of the statement of identity.

(g) The label or labeling of a food for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than one-half the size of the type of the nutrient content claim but in no case less than one-sixteenth of an inch in height.

(2) The referral statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (see e.g., paragraph (j)(2) of this section or under a regulation in subpart D of this part (see, e.g., §§ 101.54 and 101.62)). If the nutrient content claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information.

(3) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section, if a food contains more than 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium per reference amount customarily consumed, per labeled serving size, or per 100 grams, then that food must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the food as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients," e.g., "See side panel for information about fats and other nutrients."

(i) Except as provided in paragraph (o)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient that implies that the food is high or low in that nutrient only if the food actually meets the definition for either "high" or "low" as defined for the nutrient that the label addresses. Such a claim might be, "contains 100 mg of sodium per serving."

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in reference food. These statements shall be known as "relative claims" and include "reduced," "light" and comparative claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared as specified below to a reference food. Such foods are:

(i) For all relative claims, an industry wide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis of all the foods of the same type as the food for which the claim is made;

(ii) For reduced and comparative claims only, a manufacturer's regular product that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name; or

(iii) For comparative claims only, a food or class of food whose composition is reported in a current valid data base such as U.S. Department of Agriculture's Handbook 8, *Composition of Foods, Raw, Processed, Prepared.*

(2) For foods bearing relative claims:

(i) The label or labeling must bear, immediately adjacent to the claim that is in the most prominent location on the labeling or labeling and in type no less than one-half the size of the type of the claim but no less than one-sixteenth of an inch, the following accompanying information:

(A) The identity of the reference food;

(B) The percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50% less fat," "⅓ fewer calories"), and

(C) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that of the reference food.

(ii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iii) Relative claims for decreased levels of nutrients may be made on the label or in labeling of a food only if the nutrient content for that nutrient differs

from that of the reference food by more than the amount specified in the definition of "low" for that nutrient.

(k) The term "modified" may be used in the statement of identity of a food that bears a comparative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35% less fat than ____" and all other information required in paragraph (j)(2) of this section for comparative claims.

(l) For purposes of making a claim, a "meal-type product" shall be defined as a food that:

(1) Makes a significant contribution to the diet by:

(i) Providing at least 200 calories per serving (container); or

(ii) Weighing at least 6 ounces per serving (container); and

(2) Contains ingredients from 2 or more of the following 4 food groups:

(i) Bread, cereal, rice and pasta group;

(ii) Fruits and vegetables group;

(iii) Milk, yogurt, and cheese group;

(iv) 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. Such representations may be made either by statements, photographs, or vignettes.

(m) Nutrition labeling shall be provided for any food for which a nutrient content claim is made in accordance with §§ 101.9 and 101.36.

(n) Compliance with requirements for nutrient content claim in this section and in regulations in subpart D of this part, will be determined using analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9 of this chapter.

(o) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to October 25, 1989, may continue to be used as part of that brand name, provided they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(2) A soft drink that used the term "diet" as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act.

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under 403(r)(2)(A)(vi) of the act.

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that such claim is exempt from the requirements for disclosure statements in paragraphs (g) and (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C).

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b), (g), and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.50(h).

(8) The terms "sugar free," "sugarless," and "no sugar" may be used on the label and in labeling of chewing gums containing no sucrose provided that when the product is not "low calorie" or "reduced calorie" under § 101.60(b), the label also bear immediately adjacent to the claim each time it is used, the statement "Not a reduced-calorie food," "Not a low calorie food," "Not for weight control," or "Useful Only in Not Promoting Tooth Decay."

5. Subpart D is added to read as follows:

Subpart D—Specific Requirements for Nutrient Content Claims

Sec.

Subpart D—Specific Requirements for Nutrient Content Claims

§ 101.54 Nutrient content claims for "source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in § 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in § 101.9(c)(12)(i), (excluding total carbohydrates and unsaturated fatty aids) may only be made on the label and in 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, § 101.36.

(b) *"High" claims.* (1) The terms "high," "rich in," or "major source of" may be used on the label and in the labeling of a food except meal-type products as defined in § 101.13(l), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed and per labeled serving size.

(2) These terms may be used on the label and in the labeling of a meal-type product as defined in § 101.13(l), provided that it contains per 100 grams (g) of product, an amount of the nutrient that is equal to 20 percent or more of the RDI or DRV.

(c) *"Source" claims.* (1) The terms "source," "good source of," or "important source of" may be used on the label or in the labeling of a food when the food except meal-type products as described in § 101.13(l) contains 10 to 19 percent of the (RDI) or the (DRV) per reference amount customarily consumed and per labeled serving size.

(2) These terms may be used on the label and in the labeling of a meal-type product as defined in § 101.13(l), provided that it contains per 100 g of product, an amount of the nutrient that is equal to 10 to 19 percent of the RDI or DRV.

(d) *"Fiber" claim.* If a nutrient content claim is made with respect to the level

of dietary fiber, that is, that the product is high in fiber, a source of fiber, or that the food contains "more" fiber, and the food is not low in total fat as defined in § 101.62(b)(2), then the label shall disclose the level of total fat per labeled serving. The disclosure shall appear in immediate proximity to such claim and precede the referral statement required in § 101.13(g) (e.g., "Contains [*x amount*] of total fat per serving. See [*appropriate panel*] for nutrition information.")

(e)(1) *"More."* A comparative claim using the term "more" may be used on the label and in the labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food, including meal-type products as defined in § 101.13(l), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) than the reference food that it resembles and for which it substitutes as specified in § 101.13(j)(1)(i), (j)(1)(ii), and (j)(1)(iii);

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV; and quantitative information comparing the level of the nutrient 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 (e.g., "Contains 10% more of the daily value for fiber than white bread. Fiber content of white bread is 1 g per serving; (this product) 3.5 g per serving.")

(2) A comparative claim using the term "more" may be used to describe the level of complex carbohydrates in a food, including meal-type products as defined in § 101.13(l), provided that the food contains at least 4 percent more of the DRV for carbohydrates than the reference food, and the difference between the two foods is only complex carbohydrates as defined in § 101.9(c)(6)(i). The identity of the reference food and quantitative information comparing the level of complex carbohydrates with that of the reference food that it replaces shall be declared in immediate proximity to the most prominent such claim.

(3) A comparative claim using the term "more" may be used to describe the level of unsaturated fat in a food including meal-type products as defined in § 101.13(l) provided that the food contains at least 4 percent more of the DRV for unsaturated fat than the reference food, the level of total fat is not increased, and the level of *trans* fatty acids does not exceed 1 percent of the total fat. The identity of the reference food and quantitative information comparing the level of unsaturated fat with that of the reference food that it replaces shall be declared in immediate proximity to the most prominent such claim.

§ 101.56 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the term "light" or "lite" to describe a food may only be made on the label and in 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 is labeled in accordance with § 101.9 or, where applicable, § 101.36.

(b) The terms "light" or "lite" may be used on the label and in the labeling without further qualification to describe a food, except meal-type products as defined in § 101.13(l), provided that:

(1) The food has at least a ⅓ (33⅓ percent) reduction in the number of calories compared to a reference food as specified in § 101.13(j)(1)(i) with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size;

(2) If the food derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes as specified in § 101.13(j)(1)(i) with a minimum reduction of more than 3 grams (g) per reference amount customarily consumed and per labeled serving size; and

(3) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the calories, and, if appropriate, the fat, were reduced; and quantitative information comparing the level of calories and, if appropriate, fat content, 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, (e.g., "⅓ fewer calories and 50% less fat than our regular cheese cake: lite cheese cake—200 calories, 4 grams fat; regular cheese cake—300 calories, 8 grams fat per serving").

(c) A product, other than a salt substitute, that is low, reduced or otherwise altered in sodium content cannot use the term "light" solely because of this alteration but rather shall use, as appropriate, the term "reduced sodium" or "low sodium."

(d) The term "light" or "lite" may be used to describe a salt substitute if the sodium content of the product has been reduced by at least 50 percent compared to ordinary table salt.

(e) The term "light" or "lite" may not be used to refer to a food that is not reduced in calories by ⅓ and, if applicable, in fat by 50 percent, unless:

(1) It describes some physical or organoleptic attribute of the food such as texture or color and the qualifying information (e.g., "light in color" or "light in texture") so stated clearly conveys the nature of the product; and

(2) The qualifying information is in the same type size, style, color, and prominence as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food (e.g., light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

§ 101.60 Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie content of 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, § 101.36.

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

(i) The food contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to disclose that calories are not usually

present in the food (e.g., "soda water, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," or "low source of calories" "low in calories" may be used on the label and in labeling of foods except meal-type products as defined in § 101.13(1) provided that:

(i) The food does not provide more than 40 calories per reference amount customarily consumed, per labeled serving size, and, except for sugar substitute, per 100 grams (g); and

(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation or reformulation to vary the caloric 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., "celery, a low calorie food").

(3) The terms listed in paragraph (b)(2) of this section may be used on the label or in labeling of meal-type products as defined in § 101.13(1) provided that:

(i) The product contains 105 calories or less per 100 g; and

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

(4) The terms "reduced calorie," "reduced in calories" or "calorie reduced" may be used to describe a food, except mealtype products as defined in § 101.13(1), provided that:

(i) The food has been specifically processed, altered, formulated, or reformulated, to reduce its calorie content by 33⅓ percent or more with a minimum reduction of more than 40 calories 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 identity of the reference food, the percent (or fraction) that the calories have been reduced, and quantitative information comparing the level of the nutrient 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 (e.g., Reduced calorie cupcakes "33⅓% fewer calories than regular cupcakes. Calorie content has been reduced from 150 to 100 calories per serving").

(5) A comparative claim using the term "fewer" may be used on the label or in labeling of a food, including meal type products as defined in § 101.13(1), provided that:

(i) The food contains at least 25 percent fewer calories, with a minimum reduction of more than 40 calories per reference amount customarily consumed and per labeled serving size, than 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 identity of the reference food, the percent (or fraction) that the calories have been reduced, and quantitative information comparing the level of the calories 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 (e.g., "This cheese cake contains 25 percent fewer calories than our regular cheese cake. Calorie content has been lowered from 200 to 150 calories per serving").

(c) *Sugars content claims*—(1) *Use of terms such as "sugars free," "no sugars," or "zero sugars."* Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugars," as indicating that a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a food may not be labeled with such terms unless:

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii)(A), per reference amount customarily consumed and per labeled serving size;

(ii) The food contains no added ingredients that are sugars; and

(iii)(A) it is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), or (b)(4) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie food," "not a low calorie food," or "not for weight control."

(2) The terms "no added sugars," "without added sugars," or "no sugars added" may be used only if:

(i) No amount of sugars as defined in § 101.9(c)(6)(ii)(A) is added during processing or packaging;

(ii) The product does not contain ingredients containing added sugars such as jam, jelly, and concentrated fruit juice;

(iii) The sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes;

(iv) The food that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement indicating that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a food is unsweetened or contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., juices.

(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 sugars per reference amount customarily consumed and per labeled serving size than 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 identity of the reference food, the percent (or fraction) that the sugars have been reduced, and quantitative information comparing the level of the sugars 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 (e.g., "These corn flakes contains 25 percent less sugars than our sugar coated corn flakes. Sugars content has been lowered from 8 g to 6 g per serving").

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) *General requirements.* A claim about the level of sodium 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, § 101.36.

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

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size; and

(ii) The food does not contain any added sodium (sodium chloride) or other ingredient that contains sodium; 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 the sodium content, it is labeled to disclose that sodium is not usually present in the food (e.g., "leaf lettuce, a sodium free food").

(2) The terms "very low sodium," or "very low in sodium," may be used on the label and in labeling of foods, except mealtype products as defined in § 101.13(l) provided that:

(i) The food contains 35 mg or less sodium per reference amount customarily consumed per labeled serving size, and per 100 grams (g) of food; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium 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., "potatoes, a very low sodium food.").

(3) The term "very low sodium," or "very low in sodium," may be used on the label and in labeling of meal-type products as defined in § 101.13(l) provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium 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 "low sodium," or "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in the labeling of foods, except meal-type products as defined in § 101.13(l), provided that:

(i) The food contains 140 mg or less sodium per reference amount customarily consumed, per labeled serving size, and per 100 g; and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium 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., "fresh spinach, a low sodium food").

(5) The terms listed in paragraph (b)(4) of this section may be used on the label and in labeling of meal-type products as defined in § 101.13(l) provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium 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.

(6) The term "reduced sodium," "reduced in sodium," or "sodium reduced" may be used on the label and in labeling, except meal-type products as defined in § 101.13(l) provided that:

(i) The food has been specifically processed, altered, formulated, or reformulated to reduce its sodium content by 50 percent or more with a minimum reduction of more than 140 mg 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 for § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the sodium has been reduced; and quantitative information comparing the level of the sodium 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. (e.g., "reduced sodium—50 percent less sodium than regular peanuts. Sodium content has been reduced from 300 to 150 mg of sodium per serving").

(7) A comparative claim using the term "less" may be used on the label and 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 sodium with a minimum reduction of more than 140 mg per reference amount customarily consumed and per labeled serving size than 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).

(ii) As required in § 101.13(j)(2) for relative claims, the identity of the reference food; the percent (or fraction) that the sodium has been decreased; and clear and concise quantitative information comparing the level of the sodium 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. (e.g., "This tomato soup contains 25% less sodium than our regular tomato soup. Sodium content has been lowered from 500 to 375 mg per serving.")

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted," "no salt," "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of foods only if the food is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if:

(i) No salt is added during processing;

(ii) The food that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the food is not sodium free, such claims are immediately accompanied each time they are used by the statement, "Not a sodium free food" or "Not for control of sodium in the diet."

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not excepted under section 403(r)(5)(A) through (C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) Petitions to be filed under the provisions of section 403(r)(4) of the act shall be submitted in quadruplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other

than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition submitted under section 403(r)(4) of the act, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included in a petition submitted under section 403(r)(4) of the act, the petition shall include a statement regarding each such clinical investigation relied upon in the petition that the study either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in § 10.20(j) of this chapter.

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31.

(i) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition may incorporate it by specific reference to the earlier petition.

(j) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(k) The petition shall include a statement signed by the person responsible for the petition, that to the best of his knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the petition.

(l) All applicable provisions of Part 10—Administrative Practices and Procedures, may be used by the Commissioner of Food and Drugs, the petitioner or any outside party with respect to any agency action on the petition.

(m)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

(Date)
Name of petitioner _____
Post office address _____
Subject of the petition _____
Regulations and Industry Activities Branch (HFF-312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, _____ submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify the level at which the nutrient must be present or what other conditions concerning the food must be met for the use of the term in labels or labeling to be appropriate, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation, supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation under section 403(r)(2)(A)(i) of the act. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. The petition shall include data and information, e.g., surveys to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. Analytical data that shows the amount of the nutrient that is the subject of the claim and that is present in the types of foods for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists (AOAC) methods where available. If no AOAC method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received by the agency. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition), and the petitioner will subsequently be notified of the agency's decision to file or deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Commissioner of Food and Drugs will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (e) of this section.

(4) Within 90 days of the date of filing the Commissioner of Food and Drugs will by letter of notification to the petitioner:

(i) Deny the petition; or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the new term will be

published in the **Federal Register**. The Commissioner of Food and Drugs will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(n)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

(Date)
Name of petitioner ———————
Post office address ———————
Subject of the petition ———————
Regulations and Industry Activities Branch (HFF–312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, _____ submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under section 403(r)(2) of the act).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation under section 403(r)(2)(A)(i) of the act with which the synonymous term is claimed to be consistent. The statement should address why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation, supported by any necessary data, of why use of the proposed term is requested, including an explanation of whether the existing defined term is indequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose. This item shall include data and information, e.g., surveys, to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

C. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner ———————
By ———————
(Indicate authority)

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) that the petition is undergoing agency review (in which case a docket number will be assigned to the petition) and the petitioner will subsequently be notified of the agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or

(ii) that the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and consequently denied, the Commissioner of Food and Drugs will notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of his decision. If the petition is granted the Food and Drug Administration will list, the approved synonymous term in the regulations listing terms permitted for use in nutrient content claims.

(o)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form:

(Date)
Name of petitioner ———————
Post office address ———————
Subject of the petition ———————
Regulations and Industry Activities Branch (HFF–312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
Dear Sirs:

The undersigned, _____ submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brand-name as proposed will not be misleading. It should address in particular what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 403(a) and 201(n) of the act. The statement should provide examples of the types of foods on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food qualifies the food to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation, supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group and should include scientific data sufficient for such purpose.

C. A detailed analysis of the potential effect of the use of the proposed brand name on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet. If the branded product is intended for a specific group within the population, the analysis should specifically address the dietary practices of such group, and should include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner ———————
By ———————

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition); or

(ii) That the petition is incomplete, e.g., one that lacks any of the data required by this part, one that states such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Commissioner of Food and Drugs will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (e) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently returned to the petitioner), the Commissioner of Food and Drugs will:

(i) Notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified; or

(ii) Deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition. Should the Commissioner of Food and Drugs not notify the petitioner of his decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of such fact.

6. Subpart F is redesignated as Subpart G and new Subpart F is added to read as follows:

SUBPART F—SPECIFIC REQUIREMENTS FOR CLAIMS THAT ARE NEITHER NUTRIENT CONTENT CLAIMS OR HEALTH CLAIMS

§ 101.95 "Fresh", "freshly," "fresh frozen", "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food only in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier.

(a) The term "fresh," which may be used only on the label of a raw food, means that the food has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (d) of this section.

(b) The term "freshly ____" (the blank being filled with an appropriate verb, e.g., "prepared," "baked," "roasted"), which may be used on the label of a prepared or produced food, means that the food is recently made or prepared and has not been frozen, or subjected to any form of thermal processing, or any other form of preservation (except as provided in paragraph (d) of this section) during or subsequent to its manufacture or preparation, except a process inherent to the production of the basic food.

(c) The terms "fresh frozen" and "frozen fresh," when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). "Quickly frozen" means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(b) Provisions and restrictions. (1) The addition of approved waxes or coatings, the post-harvest use of approved pesticides, or the application of a mild chlorine wash or mild acid wash on raw produce, does not preclude the food from use of the term "fresh."

(2) A food meeting the definition in paragraph (a) or (b) of this section that is refrigerated, is not precluded from use of "fresh" and "freshly prepared," as provided by this section.

(3) A food shall not be considered to be recently prepared or made if it is available for sale more than 24 hours after its preparation or production.

PART 105—FOODS FOR SPECIAL DIETARY USE

7. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 350, 371, 376).

8. Section 105.66 is revised to read as follows:

§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.30 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie" foods and other comparative claims.* A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraph (e)(2) of this section, and in § 101.13(o)(2) of this chapter for soft drinks, a food, including a formulated meal replacement, or other food that is represented to be of special dietary use as a whole meal, may be labeled with the terms "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading, and the food is labeled "low calorie" or "reduced calorie" or bears a comparative claim of special dietary usefulness in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms

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.

[FR Doc. 91-27150 Filed 11-26-91; 8:45 am]

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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)