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Part IV—Continued

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Food Labeling; General Provisions; Nutrition Labeling; Label Format; Nutrient content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 101

[Docket Nos. 91N-0384 and 84N-0153]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to: (1) Provide definitions for specific nutrient content claims using the terms "free," "low," "lean," "extra lean," "good source," "high," "reduced," "light" or "lite," "less," "fewer," and "more" and provide for their use on the food label; (2) provide for the use of implied nutrient content claims; (3) define and provide for the use of the term "fresh;" and (4) address the use of the terms "natural" and "organic." This action is part of the food labeling initiative of the Secretary of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: February 14, 1994, except §§ 101.10 and 101.13(q)(5) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on February 14, 1995.

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SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposed rule (entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" hereinafter referred to as the general principles proposal) to: (1) Define nutrient content claims (also known as descriptors) and to provide for their use on foods labels; (2) define specific nutrient content claims that include the terms "free," "low," "source," "reduced," "light" or "lite," and "high"; (3) provide for comparative claims using the terms "less," "fewer," and "more"; (4) set forth specific requirements for sodium and calorie claims; (5) establish procedures for the submission and review of petitions regarding the use of nutrient content claims; (6) revise § 105.66 (21 CFR 105.66), to solely cover foods for special dietary use in reducing or maintaining body weight; (7) establish criteria for the appropriate use of the term "fresh;" and (8) address the use of the term "natural." A document correcting various editorial errors in that proposed rule was published in the **Federal Register** of March 6, 1992 (57 FR 8189).

In the same issue of the **Federal Register** (56 FR 60478), FDA also published a proposed rule (entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol." A document correcting various editorial errors in the fat/cholesterol proposal was also published in the **Federal Register** of March 6, 1992 (57 FR 8177). The agency published the fat/cholesterol proposal as a separate document from the general principles proposal, even though it had based the two documents on the same statutory provisions, because it had published a tentative final rule on cholesterol content claims in the **Federal Register** of July 19, 1990 (55 FR 29456). FDA included proposed definitions for fat and fatty acid content claims in the fat/cholesterol proposal because of the interrelationship among these nutrients and cholesterol in the etiology of cardiovascular disease.

Also in the same issue of the **Federal Register** (56 FR 60507), FDA published a proposed rule (entitled "Food Labeling: 'Cholesterol Free,' 'Low Cholesterol,' and '——— Percent Fat Free' Claims") to define "cholesterol free" and "low cholesterol" and to provide for the proper use of these terms and the term "——— percent fat free." The proposed rule was intended to ensure on an interim basis that these terms are not used in a manner that is misleading to consumers.

The general principles proposal (56 FR 60421) and the fat/cholesterol proposal (56 FR 60478) were issued as part of the agency's food label reform initiative and in response to the 1990 amendments (Pub. L. 101-535). The food label reform began in 1989 when FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative concerning the use of food labeling as a means for promoting sound nutrition. The following year (November 8, 1990), the President signed the 1990 amendments into law. This legislation clarified and strengthened FDA's legal authority to require nutrition labeling on foods and to establish those circumstances whereby claims can be made about nutrients in foods. Now as FDA prepares to implement the new regulations, the agency reiterates that the 1990 amendments have three basic objectives. They are. (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods. With these goals in mind, the agency believes that the new regulations will reestablish the credibility of the food label.

With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) which 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 the nutrition labeling, unless such claim is made in accordance with section 403(r)(2).

The agency received over 1,800 comments in response to the general principles proposal, and 500 comments in response to the fat/cholesterol proposal. Each comment addressed one or more of the provisions in these proposals. The comments were from a variety of sources including consumers, health care professionals, trade organizations, manufacturers, consumer advocacy organizations, foreign governments, and State and local governments. Many of the comments generally agreed with one or more provisions of the proposal, without providing other grounds for support other than those provided by FDA in the preamble to the proposal. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative and will be addressed in those final documents, while other comments addressed issues

outside the scope of the proposal and will not be discussed here.

A number of comments to the general principles and fat/cholesterol proposals suggested modifications in, or were opposed to, various provisions of the proposals. Because the general principles governing both documents are identical, and because the issues raised in comments responding to the two proposals are similar, FDA has chosen to address the comments on, and to establish regulations based on, both proposals in this single document. The agency will summarize the issues raised in the comments and address them in this document.

The agency also notes that it received about 125 comments on the tentative final rule on cholesterol content claims after the closing date for comments of August 20, 1990. These comments were not addressed in the fat/cholesterol proposal. However, the agency has reviewed these comments and is also responding to them in this final rule.

As for the third proposal on cholesterol claims and "——— percent fat free," FDA has concluded that this final rule will provide adequate assurance to consumers that these terms are not used in a misleading manner. Therefore, the agency is announcing that it is withdrawing this proposal. Comments that were submitted on this proposal (Docket No. 84N-153A) have been considered in the development of this final rule. They will be addressed with the other comments on the general principles proposal and the fat/cholesterol proposal in this final rule.

B. Foods for Special Dietary Use

In 1978, FDA promulgated regulations in § 105.66 pertaining to the use of the terms "low calorie" and "reduced calorie" on foods represented as or purporting to be for special dietary use in the maintenance or reduction of caloric intake or body weight. Under the 1990 amendments, FDA is defining the terms "low" and "reduced" as nutrient content claims that identify the level of a nutrient in a food intended for consumption by the general population and is adopting specific definitions for the terms "low calorie" and "reduced calorie." To reflect these actions, the agency is revising § 105.66 to delete the provisions that define "low calorie" and "reduced calorie." Because § 105.66 was adopted under the authority of section 403(j) of the act, these revisions must be made in accordance with the formal rulemaking procedures in section 701(e) of the act (21 U.S.C. 371(e)). Under these procedures, there is an opportunity to object to a final rule and to request a public hearing based upon such objection. Such an opportunity is not provided as part of the notice-and-comment rulemaking procedures that are appropriate for most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments. Therefore, for administrative convenience, FDA is publishing the final rule amending § 105.66 elsewhere in this issue of the **Federal Register.**

II. General Principles for Nutrient Content Claims

A. Legal Basis

FDA has the authority to issue this final rule regarding nutrient content claims under sections 201(n) (21 U.S.C. 321(n)), 403(a), 403(r), and 701(a) of the act. These sections authorize the agency to adopt regulations that prohibit labeling that: (1) Is false or misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from use of the food, or (2) uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

B. Scope

Section 403(r)(1)(A) of the act provides that claims, either expressed or implied, that characterize the level of a nutrient which is of a type required to be declared in nutrition labeling may not be made on the label or in labeling of any food intended for human consumption that is offered for sale unless the claim is made in accordance with section 403(r)(2). In the general principles proposal, the agency proposed to incorporate this general statutory requirement into proposed § 101.13(a) and (b) and to establish a new § 101.13 and the applicable regulations in part 101, subpart D (21 CFR part 101) as the provisions governing nutrient content claims.

1. One comment stated that the claims that are subject to the proposed regulations, which implement section 403(r)(1)(A) of the act, are appropriately called "nutrient descriptors," not "nutrient content" claims as proposed by FDA. The comment pointed out that the statutory language of the 1990 amendments does not include the phrase "nutrient content" claim. It stated that the words in section 403(r)(1)(A) of the act refer to a covered claim as a claim that "characterizes the level of any nutrient * * *." The comment's purpose in contrasting the wording of the proposal and that of the statute is to limit the applicability of the regulation to claims about the level of a nutrient and to exclude statements about amounts of nutrients. The comment stated that simple factual information about the nutrient content of a food, for which no characterizing claims are made, is explicitly excluded from regulation under section 403(r)(1)(A) of the act. It said that the last sentence in section 403(r)(1) of the act provides that a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving, or 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C, or 50 milligrams (mg) of sodium—is not a claim characterizing the level of the nutrient. The comment requested that to assure that the regulations for section 403(r)(1)(A) of the act claims are not misunderstood to extend to nutrient statements that do not "characterize the level of a nutrient," all references to "nutrient content" claims be redesignated to "nutrient descriptors" or "nutrient descriptor claims."

The agency advises that while it can agree that the terms "nutrient descriptor" and "nutrient descriptor claims" may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The distribution the comment draws between "nutrient descriptors" and "nutrient content" claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term "nutrition content claim" to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes "a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *." FDA stated in the general principles proposal (56 FR 60421 at 60424), that 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 (136 Congressional Record H5841 (July 30, 1990)). In addition, section 403(r)(2)(E) of the act specifically exempts from the limitations on claims established in section 403(r)(2)(A)(i) through (r)(2)(A)(v), "a statement in the label or labeling of food which describes the percentage of vitamins and minerals in

the food which describes the percentage of such vitamins and minerals recommended for daily consumption by the Secretary." If such declarations as "10 percent of the U.S. RDA for vitamin C" were not within the scope of section 403(r)(1)(A) of the act, there would have been no need for Congress to provide a specific exemption for such claims. Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations "shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act." Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food. Thus, FDA's use of the term "nutrient content claims" is fully consistent with the act.

2. In proposed § 101.13(b)(3), FDA stated that no nutrient content claims could be made on foods specifically intended for infants and children less than 2 years of age.[1] A few comments stated that the prohibition was inconsistent with the overall intent of the 1990 amendments, which is to avoid consumer confusion by providing relevant and useful information to consumers by which they can make informed food choices. The comments said that such a prohibition would unfairly restrict nutrient content claims on foods primarily intended for infants and children less than two years of age while allowing such claims on products that, though aimed primarily at adults and older children, are actively promoted either on the label or in the advertising as being for use by infants or children less than 2 years of age. Although the comments recognized the validity of this prohibition with respect to certain nutrients, they requested that the agency provide an exception from this general prohibition for claims about other nutrients. Specifically, the comments requested changes that would, among other things, allow "no salt added" and "no sugar added" claims, permit "high protein cereal" to be so labeled, allow the percentage of the Reference Daily Intake (RDI) of a vitamin or mineral to be stated on the principle display panel (PDP), allow claims about fortification of the product with vitamins and minerals, and allow products to be labeled with a statement of identity that includes an ingredient that is a standardized food whose name includes a claim (e.g., "juice with low fat yogurt") without the normal referral statements required for nutrient content claims. The comments maintained that these exceptions would place infant foods on a par with foods intended for the general population that are promoted for infants and children less than 2 years of age and would allow continuation of the long standing practice of providing information relevant to the perceived special nutritional needs of this group.

The comments added that permitting "no sugar added" and "no salt added" claims on these foods is consistent with recent research that shows that sugar and salt are not necessary for a baby's palate, and that feeding sweetened or salted foods to infants can enhance their preference for such foods which is carried into adult eating patterns. Such "no salt added" and "no sugar added" claims, the comments said, would also allow manufacturers to highlight products that are consistent with dietary recommendations for infants and children less than 2 years of age provided over the past 11 years by health authorities, including the American Academy of Pediatrics, the U.S. Surgeon General, and U.S. Department of Agriculture (USDA)/FDA Dietary Guidelines.

In response to the comments, FDA has reconsidered the propriety of nutrient content claims on foods specifically intended for infants and children less than 2 years of age. The agency now believes that the complete prohibition of nutrient content claims on foods for infants and children less than 2 years of age may have been overly broad. Although current dietary recommendations for Americans do not include infants and children less than 2 years of age, there is no basis in the 1990 amendments to limit nutrient content claims to only foods intended for the population over the age of 2. In addition, the agency cannot discount the possibility that information may be developed that will allow the agency to define specific claims on the level of a nutrient in the food that are appropriate for foods for infants and children less than 2 years of age. Such claims are subject to the requirements of section 403(r) of the act.

Accordingly, the agency has revised new § 101.13(b)(3) to state that no nutrient content claims may be made on foods for infants and children less than 2 years of age unless a regulation specifically authorizing such a claim has been established in part 101, subpart D, among certain other parts of the regulations. Interested persons may submit a petition under new § 101.69 with appropriate information that would provide a basis on which the agency could determine that a specific nutrient content claim would be appropriate for foods for infants and children less than 2 years of age.

The agency also notes that it can permit, by regulation under section 403(j) of the act, claims that are made because of the special dietary usefulness of the food. The agency intends to use its authority under section 403(j) and (r) of the act to regulate foods for infants and children less than 2 years of age. In evaluating a petition for the use of a claim, it will determine under which authority of the act the claim is appropriately regulated. Accordingly, the agency is including in new § 101.13(b)(3) a reference to regulations in part 105 among those regulations that permit claims on foods for infants and children less than 2 years of age. In addition, in the general principles proposal, FDA stated that the regulations in part 107, issued under the authority of section 412 of the act (21 U.S.C. 350), permit certain nutrient content claims on infant formulas. For clarity, FDA has also included part 107 among the regulations permitting claims in new § 101.13(b)(3).

The comments that requested permission to make certain claims did not provide, nor has the agency developed, a sufficient basis on which to conclude that any of the nutrient content claims that FDA is defining, or any other claims, are appropriate for food specifically intended for infants and children less than 2 years of age. Although the agency is not prohibiting the statement of identity, "juice with low fat yogurt" because low fat yogurt is a standardized food and the statement of identity accurately characterizes the product, the agency notes that the other statements about the fat content of a product would be inappropriate on a food intended for infants and children less than 2 years of age. Such a food would be inconsistent with the guidance provided by various health authorities, which was noted in the general principles proposal and

[1] The agency notes that in the comments on the mandatory nutrition labeling proposal, one comment stated that the term "toddler" was improperly used. In the final rule for mandatory nutrition labeling, the agency agrees with this comment and is replacing the term "toddler" with the phrase "children less than 2 years of age". The term "toddler" was also used throughout the nutrient content claims proposal. Therefore, for clarity and consistency, the agency is using the phrase "children less than two years of age" in lieu of the term "toddler" in this final rule.

published in a report by the National Heart, Lung, and Blood Institute, National Cholesterol Education Program (NCEP) (Ref. 1), that fat and cholesterol should not be restricted in the diets of infants.

The agency has also considered the request to authorize the use of "no sugar added" and "no salt added" claims on foods specifically intended for infants and children less than 2 years of age. The terms "no sugar added" and "no salt added" have been defined as nutrient content claims for adult foods in §§ 101.60(c)(2) and 101.61(c)(2) and imply that the food is either "low" or "reduced" in calories or sodium, respectively However, because dietary guidelines urging Americans to moderate their intake of sodium and salt are specifically for adults and children over 2 years of age, claims on foods intended specifically for infants and children less than 2 years of age are not appropriate. Therefore, the agency is not granting this request.

However, terms "unsweetened" and "unsalted" can be viewed differently. In the general principles proposal (56 FR 60421 at 60437), the agency cited the September 22, 1978, final rule on label statements for special dietary foods (43 FR 43238). In that final rule, FDA concluded that the term "unsweetened" was a factual statement about an organoleptic property of a food. The general principles proposal stated that the agency was not aware of any reason to change this view. Although the agency did not propose in the general principles proposal to define the terms "unsweetened" for foods intended specifically for infants and children less than 2 years of age the agency considers that this statement on baby food, as on adult food, is not intended as a nutrient content claim but as a taste claim. As such it is consistent with the recommendations of the American Academy of Pediatrics (Ref. 33) and the Surgeon General's report (Ref. 4) that sugar should be added sparingly, if at all, to foods prepared for normal infants. Consequently, the agency believes that highlighting that a food is unsweetened may provide useful information about the organoleptic properties of the food. Accordingly, the agency is adding foods intended specifically for infants and children less than 2 years of age to the exceptions provided in § 101.60(c)(3) for the term "unsweetened" as a factual statement.

Similarly, the agency believes that a statement that the food is "unsalted" on foods for infants and children less than 2 years of age can also be viewed as a statement about the organoleptic properties of the food. This term is also consistent with the recommendation from the same health authorities, noted in the comments, that, similar to sweetness, a salty taste is not necessary for an infant's palate. The agency recognizes that although the word "sweet" is used exclusively to identify a taste, the word "salt" may be associated with the level of a nutrient or with the taste of a food. However, consistent with the use of the word "unsweetened" as a statement of taste, the agency is permitting the term "unsalted" to be used on foods intended exclusively for infants and children less than 2 years of age. The agency is providing in § 101.61(c)(3) that "unsalted" may be used on these foods provided that it refers only to the taste of the food and is not otherwise false and misleading.

Finally, in keeping with section 403(r)(2)(E) of the act as amended, which permits, without further definition, label statements that describe the percentage of vitamins and minerals in the food relative to the RDI, the agency concludes that it is appropriate to permit statements of this type on foods intended specifically for infants and children less than 2 years of age. Elsewhere in this issue of the **Federal Register**, FDA is listing values that may be used as RDI's specifically for infants and for children under 4 years of age. These reference amounts provide an appropriate basis for label statements on foods intended specifically for infants and children less than 2 years of age that describe the percentage of vitamins and minerals relative to the RDI. Accordingly, the agency is clarifying its intentions by amending new § 101.13(q)(3) to specifically include foods for infants and children less than 2 years of age among those that may bear a percent RDI statement.

The agency has not prohibited claims on foods that are promoted for infants and children under the age of 2 but that are intended primarily for adults and older children. However, the agency cautions that any nutrient content claims made on such products in association with a statement about use of the food for infants and children under the age of 2 would be misleading under section 403(r) of the act unless such claim has specifically been permitted for such a population by regulation.

C. Labeling Mechanics

The 1990 amendments do not include specific limits on the prominence of nutrient content claims. However, FDA did propose certain requirements on how claims are to be presented. In the general principles proposal (56 FR 60421 at 60424), FDA proposed to require in § 101.13(f) that a nutrient content claim be, in type size and style, no larger than the statement of identity. The agency stated that this proposed requirement would ensure that descriptors are not given undue prominence. The agency proposed this requirement under section 403(f) of the act and under its general authority under section 403(r). 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.

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, a statement referring the consumer to the nutrition label (i.e., "See ———— for nutrition information"). FDA proposed to incorporate this requirement in § 101.13(g).

Section 403(r)(2)(B) of the act requires that the referral statement appear prominently, but it does not contain specific requirements such as to type size or style. However, section 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act require 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." 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 adjacent to one another, the agency tentatively concluded that these statements should be of the same type size. Therefore, the agency proposed in § 101.13(g)(1) that the referral statement be in type one-half that of the claim, but in no case less than one-sixteenth of an inch, consistent with other minimum type size requirements for mandatory label information.

3. Many comments stated that no type size requirements for either nutrient content claims or referral statements (other than those specifically included in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv)) are mandated by the 1990 amendments, and that the agency should not impose requirements beyond those included in these amendments.

While the 1990 amendments do not specify type size requirements for nutrient content claims or for the

referral statement, the act must be read as a whole. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. FDA has, therefore, included those prominence requirements in these regulations that it finds necessary to ensure that this requirement is satisfied with respect to the information required under the 1990 amendments.

1. Relationship of size of nutrient content claim to statement of identity

4. Some comments suggested that the type size for claims be limited to a size no larger than the most prominent type size on the PDP. Some comments suggested that the type size should not exceed either the size of, or one-half the size of, the largest type or brand name. Some of these comments stated that these alternatives will allow manufacturers more flexibility and be more in line with the Executive Order 12291. Several comments stated that there is no reason to connect type size of the nutrient content claim to that of the statement of identity because if the nutrient content claim is disproportionately large, the statement of identity as well as other mandatory information on the PDP, such as net quantity of contents, will be so obscured or small as to violate existing section 403(f) of the act.

The agency rejects these comments. The nutrient content claim and the statement of identity are two of the most important pieces of information on the PDP. Given the limited amount of space on the PDP, the agency finds that it is necessary to link the size of the two pieces of information, so that manufacturers, can, and will, give appropriate prominence to each of them in planning their labels. The options suggested by the comments to unlink the size of the nutrient content claim from the statement of identity could result in a claim being unduly prominent. It would not be consistent with the goal of adopting regulations for the efficient enforcement of the act if the agency's regulations created a situation in which violations of the act were likely to develop. Thus, the agency rejects those options. However, the agency does agree that more flexibility with respect to the size of the nutrient content claim is appropriate.

5. Several comments stated that claims should have maximum prominence and be permitted to be of a type size greater than the statement of identity, especially when the claim is included in a brand name, since claims both provide important information to the consumer and serve to draw consumer attention to a specific product among other similar products. Several comments stated that the claim should not be more than twice the size of the statement of identity to provide for flexibility in communicating the claim effectively. Some comments stated that this alternative will allow manufacturers more flexibility and be more in line with the Executive Order 12291.

FDA recognizes the concerns expressed in these comments. FDA has reconsidered the proposed limit on type size for nutrient content claims and concludes that the proposed limit may unduly restrict the effectiveness of claims. FDA is concerned that, as a result, the incentives for manufacturers to innovate and improve their food products may be reduced. As some comments pointed out, style and format play important roles in effective marketing which is important not only in selling the product but in bringing the healthful attributes of the product to consumers' attention. The alternative presented in the comments of limiting the claim to not more than twice the size of the statement of identity provides for the flexibility requested to further the effectiveness of claims, while ensuring a certain proportionality of these two important pieces of information on the PDP. Therefore, the agency is revising new § 101.13(f) to require that the claim be no larger than two times the statement of identity.

2. Referral statements

6. Several comments stated that referral statements are redundant if the claim appears on the information panel with complete nutrition information. Other comments stated that these statements contribute to label clutter and cause the PDP to look like an information panel.

In response to the first group of comments, the agency points out that under proposed § 101.13(g)(2), a referral statement is not required when a claim appears on the information panel. More importantly, the requirement for a referral statement when a claim is made is statutory. Section 403(r)(2)(B) of the act specifically provides that the label contain this statement prominently and in immediate proximity to the nutrient content claim. Although the referral statement does add to the information in the PDP, this statement is necessary to ensure that consumers fully understand the nutrient content claim that is being made.

7. Several comments stated that referral statements, if required at all, should be one-half the size of the claim. Other comments stated that if a minimum type size requirement is necessary for the referral statement, FDA should specify only a minimum type size of one-sixteenth of an inch, which is the minimum type size prescribed for most mandatory information on a food label. Other comments suggested that referral statements if required at all, should be a minimum of one-sixteenth of an inch, or be of a minimum type size consistent with that required for the net quantity of contents statement in § 101.105(i) (which varies from one-sixteenth of an inch to one-quarter of an inch depending upon the area of the PDP), because this standard would assure a proportionality to the other printed material on the label.

The agency has considered these comments on the minimum type size of the referral statement. FDA agrees that it is not necessary to link the type size of the referral statement to that of the claim (as the proposal does). Such a requirement could contribute to label clutter. However, FDA does not agree that specifying only a minimum type size of one-sixteenth of an inch for the referral statement will assure adequate prominence for that statement, particularly on packages where the area of the PDP is large, and the claim is in large letters. Rather, FDA agrees that the requirements of section 403(f) and (r)(2)(b) of the act will be satisfied if the referral statement is presented in a type size consistent with the minimum type size requirements for the net quantity of contents declaration, which are linked to the area of the PDP. The proportionality between the size of the referral statement and the size of the label will ensure that the referral statement is presented with appropriate prominence.

However, FDA does not wish to inadvertently establish minimum type sizes for nutrient content claims. When the claim is less than twice what the minimum size of the referral statement would be given the size of the label and § 101.105(i), FDA believes that the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. The agency believes that this approach to the type size requirement for the referral statement provides additional flexibility to firms in utilizing label space but still ensures adequate prominence for this statement.

Therefore, FDA is revising the referral statement requirement in new § 101.13(g)(1) to provide that the type

size of the referral statement be no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

8. Several comments requested that FDA provide that the referral statement on labels bearing a nutrient content claim become optional after 2 years. The comments argued that after 2 years, consumers will have learned that information supporting the claim is elsewhere on the label.

Section 403(r)(2)(B) of the act does not provide any authority for the agency to make such a modification to the requirement for the referral statement. Therefore, the agency rejects this request.

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," i.e., a disclosure referral statement. FDA referred to this level as the "disclosure level" in the general principles proposal (56 FR 60425). In proposed § 101.13(h), FDA defined such levels for fat, saturated fat, cholesterol, and sodium, based upon an approach that considered dietary recommendations for these nutrients, the number of servings of food in a day, and available information on food composition. The proposed provision set out the required contents of the referral statement that would result (56 FR 60421 at 60425).

9. Several comments supported the disclosure level concept. However, others expressed the view that the concept places emphasis upon a single food rather than on the total diet, with the result that a food is perceived by consumers as being "good food" or "bad food," based upon the presence or absence of a disclosure referral statement.

The disclosure statement is required under section 403(r)(2)(B)(ii) of the act, and the disclosure provision in this final rule is consistent with that requirement. However, FDA disagrees with the assertion that the presence of a disclosure statement on a food label will lead consumers to perceive that the labeled food is "bad," or that the absence of a disclosure statement on a food label will be perceived as "good." The disclosure statement specifically directs the consumer to the information panel for information about other nutrients in the food in addition to the nutrient for which disclosure is triggered, e.g., "See side panel for information about fats and other nutrients." Thus, consumers' attention will be directed to the nutrition label, and they will be able to utilize the information therein, not just the disclosure statement, as a basis for making a purchase decision about the food. The disclosure statement is not intended to serve as a primary basis for making a purchase decision. However, if a nutrient content claim is made, the label must provide the consumer with the facts that bear on the advantages asserted by the claim and with sufficient information to understand how the product fits into a total dietary regime.

10. Several comments noted that in the preamble of the general principles proposal (56 FR 60421 at 60425), the agency stated that "there are no generally recognized levels at which food components such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease," and that a similar statement appears in the preamble of the November 27, 1991, proposed rule entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537 at 60543). Based on these statements, the comments reasoned, the agency would not be able to make the analysis required in section 403(r)(2)(B)(ii) of the act for including a disclosure statement in the referral statement.

The agency disagrees with the comments. Although the agency stated in the proposal 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," and thus "if FDA were to attempt to set these (disclosure) levels on an individual food basis, it would not be possible to do so," the agency also specifically noted that the act directs the agency to take into account the significance of the food in the total daily diet when making its analysis for when a disclosure statement is required.

The analysis that the agency performed in arriving at the circumstances where a disclosure statement is required was based upon dietary guidelines, taking into account the significance of the food in the total daily diet. The analysis utilized the agency's proposed Daily Reference Value's (DRV's) for total fat, saturated fat, cholesterol, and sodium and estimates of the amounts of these nutrients in foods and the number of servings of food consumed in a day. Therefore, although the disclosure levels are applied to individual foods, the basis of their derivation is the total dietary intake of nutrients that may pose an increased risk of diet-related disease, and the difficulty in maintaining healthy dietary practice that is created if these nutrients are consumed in particular foods at levels that exceed those established as disclosure levels. Thus, the agency concludes that its statements in the proposal did not preclude it from performing this analysis, and that it performed its analysis in a manner consistent with the statute's guidance.

11. Some comments asserted that consumers should be warned if the level of certain nutrients poses an increased risk of disease, irrespective of whether a nutrient content claim is made.

The agency disagrees with these comments. Although section 403(r)(2)(B)(ii) of the act mandates that the agency require that referral statements identify particular nutrients in certain circumstances where health or nutrient claims are made, the act does not direct the agency to require the identification of such nutrients in instances where a claim is not made.

Under sections 201(n), 403(a), and 701(a) of the act, the agency could require the identification of nutrients that are present at levels that increase the risk of a disease or health-related condition in the absence of a claim. However, in the absence of a nutrient content claim, there would be no basis to conclude that consumption of the food would receive any particular emphasis as part of the total daily diet, and thus there would be no particular basis for concern, and hence for a warning, about the levels of fat, saturated fat, cholesterol, or sodium in the food. Only when the significance of the food in the total daily diet is highlighted, as it is when a nutrient content claim is made, does the level of these other nutrients become material not only for purposes of section 403(r)(2)(B)(ii) of the act but also for sections 201(n) and 403(a) of the act.

12. One comment expressed concern that the agency's establishment of disclosure levels will be an open invitation for product liability suits for all products exceeding the threshold amounts.

As stated above, the agency believes 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." The

disclosure levels are not tied to concerns about consuming the individual food but to concerns that claims can mislead consumers about the significance of the food in the total daily diet, and that rather than facilitating compliance with dietary guidelines (see H. Rept. 101–538, 101st Cong., 2d sess. (October 1990)), such claims could make compliance with such guidelines more difficult if certain relevant information is not brought to the consumer's attention. The disclosure levels should be understood in this way. The agency wishes to make clear, however, as stated in the final rule on health claims, published elsewhere in this issue of the **Federal Register**, that foods that contain nutrients at levels that exceed the disclosure level are not unsafe, will not cause a diet related disease, and are not dangerous or "bad" foods.

13. Several comments suggested that levels other than 15 percent of the DRV should be used as the threshold level for disclosure statements. Some comments stated that a 20 percent level should be used because it is consistent with the definitions of "more" and "high" and supportable on the basis of estimates of food consumption. Another comment suggested a 7 1/2 percent level specifically for fat and saturated fat, believing that 15 percent is too high for these nutrients. Similar comments pertaining to a disqualifying level for a nutrient for a health claim in response to the November 27, 1991, proposal on "Labeling; General Requirements for Health Claims for Food," were received by the agency.

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. The agency is, therefore, adopting the same levels for the individual nutrients for both types of claims. The agency is modifying the disclosure levels in new § 101.13(h)(1) and the disqualifying levels in new § 101.14(a)(5) to 20 percent of the DRV. The rationale for increasing these levels to 20 percent of the DRV is given in the final rule on general requirements for health claims for food, which is published elsewhere in this issue of the **Federal Register**, and is incorporated herein. Therefore, the disclosure levels in new § 101.13(h) are being revised to 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 mg of cholesterol and 480 mg of sodium per reference amount customarily consumed (hereinafter referred to as "reference amount"), per labeled serving size or for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must have water added to them prior to typical consumption, the 50 g criterion applies to the "as prepared" form) (see also discussion in section III.A.1.b. of this document).

14. Several comments opposed the proposed requirement of § 101.13(h) that if a food contains more than the specified amounts of fat, saturated fat, cholesterol, or sodium per reference amount, per labeled serving size, or per 100 g, then the referral statement must include a disclosure statement. The comments stated that "per 100 g" unfairly discriminates against foods with standard serving sizes of less than 100 g, e.g., cheese, crackers, cookies, margarine, and butter. The comments further stated that the 100-g criterion makes little sense and should be eliminated.

The agency considered these comments and continues to believe that a weight-based criterion, in addition to the per reference amount and per labeled serving size criteria, is needed as a criterion for disclosure levels to ensure that if a claim is made for a food that is dense in fat, saturated fat, cholesterol, or sodium, the claim will not be misleading in light of the levels of fat, saturated fat, cholesterol, or sodium in the food. Therefore, the agency is retaining a weight-based criterion for disclosure levels in the final rule.

However, the agency agrees that the 100-g criterion is too restrictive and is modifying the criterion applied to disclosure levels in new § 101.13(h) and disqualifying levels in new § 101.14 to a weight-based criterion of 50 g that is applicable only to foods with reference amounts of 30 g or less or 2 tablespoons or less (see also discussion in section III.A.1. of this document). The rationale for this modification is fully set forth in the final rule on general requirements for health claims for food, published elsewhere in this issue of the **Federal Register** and is incorporated herein.

15. One comment contended that there is not an appropriate scientific basis for establishing a disclosure level for sodium.

The agency rejects the comment's assertion that the scientific evidence is not sufficient to support the establishment of a disclosure level for sodium. In the general requirements for health claims for food document and in the sodium/hypertension health claims document published elsewhere in this issue of the **Federal Register**, FDA responds to comments that assert that identifying sodium as a disqualifying nutrient for health claims is inappropriate and to comments that the scientific evidence relating sodium to hypertension is insufficient. Those responses are incorporated herein. The agency notes that the evidence from clinical trials supports that high sodium intake is related to high blood pressure, that the evidence from human observational studies is generally consistent and supportive, that the long-term prospective study data are sometimes inconclusive and sometimes supportive, and that there is significant scientific agreement among experts that this relationship exists. The agency concludes that the scientific basis is sufficient, and that sodium reduction is likely to benefit a significant portion of the general population.

However, as explained in the general requirements for health claims in food document published elsewhere in this issue of the **Federal Register**, in response to comments FDA is increasing the disqualifying/disclosure level to 20 percent of the DRV, as compared to 15 percent as proposed, and thus the level will be 480 mg per serving as compared with the proposed level of 360 mg.

E. Amount and Percentage of Nutrient Content Claims

In the general principles proposal (56 FR 60421 at 60426), FDA proposed to regulate the use of statements of amount (e.g., contains 2 g of fat) or that use a percentage (e.g., less than 1 percent fat) to describe the level of a nutrient in a food. The agency proposed in § 101.13(i) that foods bearing statements about the amount or percentage of a nutrient in food must meet the definition for "low" in the case of fat, saturated fat, sodium, and calories and "high" for fiber, vitamins, minerals, and other nutrients for which the term is defined.

16. Some comments expressed the view that statements regarding the amount and percentage of nutrients in food are confusing, deceptive, and misleading to most consumers and should not be permitted. One comment suggested that studies are needed to ascertain consumer perceptions in this area, and that amount or percentage labeling statements are not necessary on foods.

The agency is not persuaded that studies are needed to ascertain how these statements are understood by the consumer, or that it is necessary to ban these statements. The agency believes that statements concerning the amount and percentage of nutrients in food can provide useful information to consumers and flexibility to the food manufacturer in stating the nutritional attributes of a food. However, FDA recognizes that these statements can be

misleading. Therefore, FDA has carefully prescribed the circumstances in which such statements may be used in new § 101.13(i).

17. One comment stated that the 1990 amendments do not require FDA to limit amount or percentage statements about nutrient claims in the manner that the agency has proposed.

The 1990 amendments provide, in section 3(b)(1)(A)(iv), that FDA shall permit statements describing the amount and percentage of nutrients in food if they are not misleading, and if they are consistent with the terms defined by the agency. As discussed in the general principles proposal (56 FR 60421 at 60426), the legislative history of the 1990 amendments contemplates that the agency would define the circumstances by regulation "under which statements disclosing the amount and percentage of nutrients in food will be permitted" (136 Congressional Record, H5841–2 (July 30, 1990)). This portion of the legislative history states that "amount and percentage statements must be consistent with the terms that the Secretary has defined under section 403(r)(2)(A)(i) of the act [definition of descriptive terms] and they may not be misleading under section 403(a) in the current law." Thus, the agency believes that regulations to ensure that these statements will not be used in a misleading manner are consistent with the 1990 amendments. Therefore, the agency concludes that, consistent with the intent of the 1990 amendments, regulations controlling the use of label statements that state the amount or percentage of a nutrient in a food are appropriate.

18. Several comments suggested that amount and percentage disclosure statements should be permitted without restriction if the statement is accompanied by appropriate explanatory information, and as long as the statements are not misleading. Additionally, the comments implied that the agency should not prohibit or restrict the use of claims that convey the amount and percentage of nutrients in food because this information can direct consumers to the favorable characteristics of a food and allow consumers to compare food products within the same product line.

Other comments stated that foods should not be required to comply with such strict requirements before they can use amount and percentage statements. These comments contended that the agency has ample authority to regulate amount and percentage statements under section 403(a) of the act.

FDA finds that some restrictions on amount and percent claims are necessary. FDA advises that numerous consumer complaints, comments on a 1989 ANPRM on food labeling (54 FR 32610, August 8, 1989), and comments on the general principles and fat/cholesterol proposals about misuse of label statements such as "—— percent fat free" have persuaded the agency that, in many cases, statements regarding the amount and percentage of nutrients in food have been misleading. Moreover, section 3(b)(1)(A)(iv) of the 1990 amendments prescribes specific conditions in which such claims may be made. Therefore, FDA believes that it is necessary to limit the use of such statements in a manner that ensures that they will not mislead consumers, and that, if they implicitly characterize the level of a nutrient, they are consistent with the terms defined under section 403(r)(2)(A)(i) of the act. If amount and percentage statements are to be limited in this manner, the circumstances in which they can be used must be specifically presented. Thus, the agency concludes that, consistent with the 1990 amendments, it is necessary to limit by regulation the use of label statements that state the amount or percentage of a nutrient in a food. Therefore, as discussed in response to the next comment, the final regulation will include a provision in new § 101.13(i) limiting the use of such statements.

19. Many comments requested that FDA consider revisions in the provisions for amount and percent statements in the final rule. Some comments stated that the agency should not prohibit the use of amount and percentage statements on foods that do not meet the definition for "low" or "high" for a particular nutrient. One comment argued that, as proposed, this regulation would deprive consumers of useful information, hinder consumers from making informed food choices, and prohibit consumers from quickly differentiating between similar foods within the same product category. A similar comment suggested that FDA should permit the use of amount and percentage statements on foods where the value in the factual statement does not exceed the proposed nutrient claim disclosure level for single foods.

A few comments asserted that amount and percentage labeling statements should be permitted on foods that qualify for a "source" claim. Another comment suggested that FDA should permit the use of amount and percentage statements on foods that qualify for a "reduced" claim.

Some comments suggested that FDA should permit the use of amount and percentage statements to convey information regarding the calorie content per serving of food, consistent with the number of calories that appear on the nutrition panel. Other comments suggested that it is customary for consumers to refer to calorie information when selecting foods, and, therefore, the use of amount and percentage statements to describe this information should be permitted in the final regulation.

A few comments suggested that amount and percentage statements about the sodium content of a food provides factual information to consumers and should be permitted. Another comment stated that very few foods could convey amount and percentage statements for sodium under the proposed provisions.

These comments have convinced the agency to reconsider the proposed provisions for statements concerning the amount and percentage of nutrients in foods. The agency believes that statements relating the amount and percentage of nutrients in foods are generally useful to consumers for such purposes as pointing out the level of a nutrient in the food and facilitating comparisons between foods. The proposed provisions for amount and percentage statements would have limited the use of these statements to only foods that are "low" or "high" in the particular nutrient. FDA believes that the provisions in the proposal were too restrictive because they would deny consumers the use of such statements to evaluate many foods. FDA has considered how to permit statements of amount and percent that implicitly characterize the level of a nutrient (e.g., "less than 10 grams of fat") in a manner that benefits consumers and also satisfies the requirements of the statute. FDA believes that these conditions are met when such amount and percentage statements about a nutrient are made on foods that meet the criteria for any nutrient content claim, including relative claims, for the nutrient. Such amount and percentage statements are useful in helping consumers identify foods that facilitate conformance to current dietary guidelines. This includes foods that are a "good source of" or foods "low" or "high" in a nutrient as well as, foods that are alternatives to other reference foods (e.g., foods that are "reduced" in a nutrient.

Thus the final rule has been revised in new § 101.13(i)(1) to provide that a statement of percent and amount may be contained on the label or in the labeling of a food that meets the definition for a claim (as defined in part 101, subpart D) for the nutrient that the label addresses.

The agency also believes that a statement about the amount and percentage of nutrients that implicitly characterize the level of the nutrient can provide useful information to consumers even if the food does not meet the criteria for a claim, provided the statement does not misleadingly imply that a food contains a small or large amount of a nutrient and makes clear whether the food meets one of the nutrient content claims that the agency is defining. In circumstances in which a food does not meet the criteria for a claim, an amount or percentage statement that implicitly characterizes the level of a nutrient, appearing by itself might be misinterpreted. Thus, the statement must be accompanied by a disclaimer such as "less than 10 grams of fat, not a low fat food" or "only 200 mg of sodium per serving, not a low sodium food." The disclaimer will not only make the claim not misleading, as required by section 3(b)(1)(A)(iv) of the 1990 amendments, it will also provide the means by which the amount or percentage can be declared consistently with section 403(r)(2)(A)(i) of the act by affirmatively stating that the amount does not meet the relevant definition.

To provide for statements about the amount or percentage of a nutrient in a food that implicitly characterize the level of the nutrient under these circumstances, FDA is adding new § 101.13(i)(2) to allow for the use of amount and percentage statements when the level of the nutrient does not meet the definition for a claim if a disclaimer accompanies the claim.

This revision also includes provisions for the location and type size of the disclaimer statement that require that the disclaimer be in easily legible print or type and in a size no less than required by § 101.105(i) for net quantity of contents except where the size of the claim is less than two times the size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch. This approach has been fully discussed in response to comment 7 of this document.

Because these revisions permit the use of amount and percentage statements where a food qualifies for all relative claims, and not just "high" or "low," the agency is deleting from new § 101.13(i) the phrase that refers to these statements as implying that a food is "high or low" in a nutrient and is inserting language that states that these statements imply that the food "contains a large or small amount" of that nutrient

In addition, based on the comments and its review of the 1990 amendments, FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement "100 calories" or "5 grams of fat" on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling. Therefore, FDA is providing in new § 101.13(i)(3) that an absolute statement of amount may be made without a disclaimer if "[t]he statement does not in any way implicitly characterize the level of the nutrient in the food, and it is not false, or misleading in any respect."

Finally, the agency is advising in new § 101.13(i)(4), for clarification, that amount and percentage statements made on labels or in labeling as "—— percent fat free" are not subject to the provisions of that paragraph. These statements are regulated separately under new § 101.62(b)(6). The agency believes this clarification is necessary because the preamble discussion in the general principles proposal supporting § 101.13(i) cited "—— percent fat free" as an example of a claim subject to section 3(b)(1)(A)(iv) of the 1990 amendments. While this example is appropriate, the agency is making it clear that the actual regulations governing "—— percent fat free" statements are provided in new § 101.62(b)(6) because those provisions differ from those of new § 101.13(i). The provisions for "—— percent fat free" statements are discussed below in the preamble section III.B.c.vi. [on Percent Fat Free] of this document.

F. Nutrition Labeling Required When a Nutrient Content Claim is Made

In the general principles proposal, the agency proposed (56 FR 60421 at 60426) in § 101.13(m) (redesignated as § 101.13(n) in this final rule) 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 proposed § 101.9 or, if applicable, proposed § 101.36.

20. The majority of comments addressing this issue favored the proposed requirement. One comment was concerned that requiring nutrition labeling on all foods bearing a claim will confuse consumers rather than empower them to make informed dietary selections.

The agency disagrees with the latter comment. Nutrition labeling is necessary when a claim is made to ensure that other important nutritional aspects of the food are presented along with that aspect highlighted by the claim. This fact is recognized in section 403(r)(2)(B) of the act, which requires that any nutrient content claim be accompanied by a statement referring the consumer to the nutrition label. Thus, nutrition labeling in the labeling of a food that bears a claim will assist consumers in making informed dietary selections because it provides them with additional important information about a food.

However, the Dietary Supplement Act of 1992 imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting § 101.36 and has modified § 101.13(n) to reflect this fact. The agency has also added a reference to § 101.10 to cover the situation in which a nutrient content claim is made for restaurant food (see section IV. of this document).

G. Analytical Methodology

In the general principles proposal (56 FR 60421 at 60428), the agency proposed in § 101.13(n) (redesignated as new § 101.13(o) in this final rule) to determine compliance with the requirements for nutrient content claims using the analytical methodology prescribed for determining compliance with nutrition labeling in proposed § 101.9.

21. A comment expressed the view that specifying methods such as official Association of Official Analytical Chemists (AOAC International) methods for the verification of nutrient claims is a barrier to innovation. The comment suggested that FDA should specify that appropriate valid methods may be used for determining nutrient content. The comment noted that if the manufacturer uses a nonofficial method, the manufacturer should have the burden of substantiating the validity of the method that is used.

FDA notes that new § 101.9(g), as amended by the mandatory nutrition labeling document published elsewhere in this issue of the **Federal Register**, states that, unless otherwise specified, compliance with nutrition labeling will be determined using methods validated by AOAC International. That regulation also states that if no "official" analytical method is available or appropriate, other reliable and appropriate analytical procedures may be used.

An AOAC International Task Force on Nutrient Labeling Methods has

considered the adequacy of AOAC International methods to meet nutritional labeling needs. The task force judged adequacy on the basis of a survey of nutrient method users and on the basis of the collaboratively validated and officially approved status of methods in the AOAC International Official Methods of Analysis. The methods judged to be adequate relative to the regulations and to reflect current analytical definitions are listed in *The Referee* 16:7–12 (1992) (Ref. 2).

Section 101.9(g) sets out the methods that the agency will use for compliance determinations. Manufacturers may use nonofficial methods of analysis to establish nutrient content label values, but in doing so, they should ensure the validity of their methods with respect to applicability, specificity, sensitivity, accuracy, precision, and detectability. If they fail to do so, and their methods produce significantly different results than the official method, their label may subject them to regulatory action. Reliable and appropriate alternative analytical methods may be submitted to FDA for a review of their acceptability.

Thus, by referencing new § 101.9, new § 101.13(o) does not preclude a manufacturer from using alternative analytical methods for determining nutrient content label values. No amendment of the regulation is necessary to comply with the comment's suggestion.

Analytical methodology is more extensively discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**.

H. Exemptions

This section addresses provisions in the general principles proposal for certain exemptions from the requirements for nutrient content claims: (1) Claims in a brand name; (2) "diet" soft drinks; (3) certain infant formulas; and (4) standards of identity. Other exemption provisions are addressed in the sections of this document pertaining to scope, restaurant foods, sugar free, and petitions. FDA advises that the exemption provisions proposed as § 101.13(o) have been redesignated as new § 101.13(q) in this final rule.

1. Claims in a brand name

Under section 403(r)(2)(C) of the act, manufacturers may continue to use brand names that include nutrient content claims that have not been defined by regulation, as long as those claims appeared as part of a brand name before October 25, 1989, and are not false or misleading under section 403(a). 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.

To implement this provision of the act, the agency proposed § 101.13(o)(1) (redesignated as § 101.13(q)(1)), which 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 that they are not false or misleading under section 403(a) of the act.

22. Several comments stated that allowing some products to continue to use a nutrient content claim in a brand name while precluding others on the basis of a date (October 25, 1989) is not justified, even if it is legally sustainable. Further, some comments contended that some nonexempt products could have an equivalent or superior nutritional profile. Other comments stated that the agency should broaden the exemption to include some claims in brand names appearing after October 25, 1989, without requiring a petition or other administrative process.

The agency advises that section 403(r)(2)(C) of the act grants the agency authority to exempt only those claims in the brand names of products bearing such claims before October 25, 1989, unless the brand name contains a term defined by the Secretary under section 403(r)(2)(A)(i) or is false or misleading. While some nonexempt foods may have an equivalent or superior nutrition profile, such foods are not recognized by the statute as exempt from the section 403(r)(2)(A) of the act. Thus, the agency is obligated by the statute's language to subject nonexempt foods to the general requirements of section 403(r)(2)(A) of the act that claims contained in a brand name be defined by regulation or by an approved brand name petition submission.

23. Several comments stated that claims in brand names should be restricted to terms that have been defined by FDA, so that claims appearing before October 25, 1989, will be consistent with claims in brand names appearing after that date. The comments stated that requiring claims to be consistent will facilitate the education of the public, while allowing some claims to be exempt will create multiple meanings for the same term depending on whether it appeared on a label before or after October 25, 1989. The comments stated further that such an exemption would likely lead to nonuniformity in the marketplace and consequent consumer confusion. One of these comments stated that FDA lacked the resources necessary to provide exemptions for some products while enforcing regulations on others.

A clarification of the 1990 amendments' provisions concerning exemptions is necessary. For a claim in a brand name to remain exempt from the act's requirements, that claim would have to be, of necessity, one that has not been defined by the agency by regulation. Thus, after the effective date of section 403(r)(1)(A) of the act, that claim could not be used on food products that were not on the market before October 25, 1989. Therefore, while an undefined term may have inconsistent meanings in brand names of food products that were on the market before October 25, 1989, it will not have multiple meanings depending on whether it appeared on a food label before or after October 25, 1989, as the comment stated. Until the claim is defined, it can not be used at all on post-October 25, 1989, products or anywhere but in the brand name of pre-October 25, 1989, products. Once it is defined, it can only be used in accordance with that definition.

The agency agrees that the establishment of definitions that state clear and consistent meanings for nutrient content claims will facilitate consumer understanding of those claims. Toward this end, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will govern as many of the types of claims that frequently appear in brand names as is possible.

However, the agency notes that because numerous types of claims appear as part of brand names, this final rule will not likely define all of the claims that may be expressed or implied as part of a brand name. The agency expects that some of these claims will continue to be used under the exemption granted in section 403(r)(2)(C) of the act. In this regard, after these regulations become effective, FDA will monitor claims used in brand names that remain exempt, and if there is evidence that use of undefined claims could result in consumer confusion or misleading labeling, the agency will consider defining terms for such claims on its own initiative.

FDA believes that defining such claims will further the statute's goal of providing consistent nutrition information on food labels and will encourage competition in the marketplace by making the terms available for products not eligible for the exemption. The agency does not

agree with the comment that stated that FDA lacks the resources necessary to enforce a regime in which some products are subject to exemptions while others are not. The agency does not expect a significant added burden to be placed upon its resources if some claims in a brand name remain exempt, since exempt status does not flow from agency action or approval but is granted by the statute if the claim appeared in a brand name of a food product before October 25, 1989.

24. Some of the comments requested that FDA either define terms that are implied nutrient content claims used in brand names by regulation, to provide for their use under section 403(r)(2)(A) of the act, or regulate their use on a case by case basis under the general misbranding provisions of the act.

The agency agrees in principle with this comment's suggestion that it should define terms used as part of a brand name that may express or imply a nutrient content claim. As noted in the response to the previous comment, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will permit, to the extent feasible at this time, as many as possible of the types of claims that frequently appear in brand names.

However, as also noted above, the provisions in this final rule will not likely define all claims made as part of a brand name. With regard to any claim not defined by the agency, the alternatives provided by the statute are that either the claim is exempt, or it must be the subject of a brand name petition that is granted by the agency. There is no provision in the statute for nondefined terms used in claims to be evaluated under the broad misbranding provisions of the act, other than that which states that exempt claims in brand names (i.e., claims that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989; see discussion in comment 25 of this document) must not be misleading under section 403(a) of the act. Therefore the agency rejects the suggestion that it either define all the terms or regulate their use on a case by case basis under the provisions of the act that prohibit false or misleading labeling.

25. Several comments stated that proposed § 101.13(o)(1) should be revised to clearly state that the exemption applies only to terms used in brand names used on specific and discrete food products before October 25, 1989, and not to products introduced after that date. These comments stated that the statutory exemption in section 403(r)(2)(C) of the act is triggered on a product-by-product basis, i.e., "such brand name" must have been in use on "such food" before October 25, 1989, for the exemption to apply. Some of these comments stated that an across-the-board exemption to a particular brand name would give an unfair competitive advantage to manufacturers who happened, before October 25, 1989, to have used an expressed or implied nutrient content claim in a brand name.

Other comments disagreed, arguing that product line extensions of qualifying brand names should also be exempted from the requirements for nutrient content claims because it would be unfair to exclude new products from bearing the same claim in the brand name until a petition for the use of the claim in the brand name is approved. Some comments stated that the 1990 amendments are ambiguous regarding whether the exemption provision for brand names applies to specific products bearing the brand name or to the brand name itself. These comments stated that this provision should be interpreted broadly because: (1) Laws afford special protection from government interference to trademark brand names; (2) a broad interpretation would be in accordance with Executive Order 12630, which directs that agency actions for the protection of public health and safety should be designed to advance significantly the health and safety purpose and be no greater in scope than is necessary to achieve that purpose and (3) a broad interpretation would be consistent with the President's "Memorandum For Certain Department and Agency Heads" on reducing the burden of government regulation (Ref. 3).

The agency does not believe the 1990 amendments are ambiguous on this issue because the statutory language, specifically the requirement that "* * * such brand name was in use on such food," limits the scope of the exemption to specific foods bearing the claim in the brand name. Thus, the agency does not agree with the comments that asserted that the agency should apply the exemption to line extension products.

The agency agrees with the comment that the final rule should be revised to clarify the scope of the exemption for brand names, and therefore it is revising the first sentence of new § 101.13(q)(1) to read:

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

26. One comment requested clarification as to whether the exemption for claims in brand names in use before October 25, 1989, applies to the type size of the claim on the label as well as to the claim itself. Several comments stated that referral statements should not be required for claims that are made as part of a brand name. Several comments stated that brand name claims should be required to bear referral statements, particularly if accompanied by a claim that uses a defined term.

Section 403(r)(2)(C) of the act exempts certain claims contained in a brand name from the requirements of section 403(r)(2)(A). This exemption covers all the requirements in section 403(r)(2)(A) of the act , including the disclosure requirements in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv) as well as the accompanying type size requirements. Claims in brand names are not exempted however from section 403(r)(2)(B) or (f). Therefore, such claims are not exempt from the type size requirement in new § 101.13(f) or from the referral statement requirements in new § 101.13(g) and (h). FDA is adding a sentence to new § 101.13(q)(1) to make this clear.

27. Several comments requested that FDA adopt a policy whereby enforcement action will not be taken against products bearing an expressed or implied claim in a brand name that is the subject of a petition until the agency has ruled on the use of the claim.

The agency disagrees with these comments. The statute establishes a petition process for new nutrient content claims, including use of an implied claim in a brand name. See section 403(r)(4)(A) of the act. The latter type of petition is deemed to be granted if the agency does not act on it in 100 days (section 403(r)(4)(A)(iii) of the act). It would make little sense for Congress to have included a petition process with such tight timeframes if it intended that a claim could appear while the petition for such claim is under agency review. Therefore, the agency denies this request.

28. Several comments stated that no nutrient content claim used before October 25, 1989, in a brand name should be permitted regardless of whether or not it has been defined, but provided no supporting rationale for this position.

Because these comments are inconsistent with section 403(r)(2)(C) of

the act, and in the absence of any information to support the position they advance, FDA is rejecting them.

29. Several comments stated that the agency should allow the use of undefined claims in a brand name that were not in use before October 25, 1989 if the claim is accompanied by clarifying information.

The agency disagrees with these comments. The course of action advocated by these comments would nullify the explicit provisions of the statute that require that any claim in a brand name that is not exempt under section 403(r)(2)(C) of the act be used only in accordance with a definition established by the agency, or after the agency has granted a petition for the claim (section 403(r)(1)(A) and (r)(2)(A)). While such information may cure a misbranding under section 403(a) of the act, it would not be consistent with section 403(r). Therefore the agency denies the comment's request that it allow the use of undefined nonexempt claims in a brand name if accompanied by qualifying information.

2. "Diet" soft drinks

Section 403(r)(2)(D) of the act exempts use of the term "diet" on soft drinks from the requirement that a term may be used only in accordance with the definitions established by FDA, provided that its use meets certain conditions: (1) The claim must be contained in the brand name of such soft drink; (2) the brand name must have been in use on the soft drink before October 25, 1989; and (3) the use of the term "diet" must have been in conformity with § 105.66. In accordance with these conditions, the agency proposed 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.

30. Several comments requested clarification that the exemption for a claim that uses the term "diet" in the brand name of a soft drink does not preclude line extensions, e.g., new flavors for the brand after October 25, 1989.

For the reason discussed in comment 25 of this document, the statutory exemption for claims using the term "diet" in the brand name of a soft drink does not extend beyond discrete products that were available before October 25, 1989. However, the agency is continuing to define the term "diet" in its regulations, specifically in § 105.66, as discussed in the general principles proposal (56 FR 60421 at 60457). Thus, if the use of the term "diet" in the brand name of a soft drink is in conformity with § 105.66, it may be used on a soft drink product whether or not that product was available before October 25, 1989. The agency is unaware of any instances whereby line extensions for "diet" soft drinks would not be in conformity with § 105.66, and no such instances were presented in the comments. For clarity, the agency is specifying in new § 101.13(q)(2) that soft drinks marked after October 25, 1989, may use the word "diet" provided they are in compliance with current § 105.66.

31. Several comments requested clarification that claims that use the term "diet" in the brand name of a soft drink are exempt from the requirement in section 403(r)(2)(B) of the act that nutrient content claims be accompanied by the referral statement. These comments further stated that the exemption applies to all of the requirements imposed by section 403(r)(2) of the act.

The agency agrees with the comments that section 403(r)(2)(D) of the act exempts a soft drink bearing the term "diet" as part of the brand name from all provisions of section 403(r)(2), including the requirement that a referral statement accompany the claim.

3. Infant formulas and medical foods

Section 403(r)(5)(A) of the act states that section 403(r) does not apply to infant formulas subject to section 412(h) of the act or to medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)). Section 412(h) of the act 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. Section 5(b)(3) of the Orphan Drug Act defines the term "medical food" as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that 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 presented its views on what constitutes a medical food in its supplementary proposal on mandatory nutrition labeling (56 FR 60366 at 60377). Accordingly, the agency proposed in § 101.13(o)(4) to reflect these provisions of the act.

32. Several comments pointed to the fact that the agency already permits, under § 107.10(b)(4) (21 CFR 107.10(b)(4)) which was issued under authority of sections 412 and 403 of the act, the labels of certain infant formula products to bear statements such as "with added iron" (see 56 FR 60366 at 60378). These comments requested that the agency revise proposed § 101.13(o)(4) to state explicitly that claims permitted by part 107 (21 CFR part 107) can continue to be made without respect to the requirements of part 101 for infant formulas for normal full term infants, as long as the claims comply with the requirements of part 107. One comment stated that the infant formula regulations ensure FDA oversight for these foods, making additional restrictions unnecessary. These comments stated that such a revision would make it clear that claims permitted under part 107 are not subject to the regulations established under the 1990 amendments.

Under section 403(r)(5)(A) of the act, section 403(r) applies to all infant formulas except infant formula that are exempt under section 412(h) of the act. Under section 403(r)(2)(A)(i) of the act, a claim that characterizes the level of a nutrient in a food may be made only if it uses terms that are defined by regulation by the Secretary (and FDA, by delegation). Thus, while the terms used on infant formula are subject to a nutrient content claims regime, claims made on infant formula in accordance with part 107 are in compliance with that regime because they use terms defined in the regulations of the agency. To reflect this fact, FDA has added references to part 107 in new § 101.13(b) and (b)(3).

33. One comment requested that nutrition information in the form of publications and promotional materials provided to pediatricians concerning infant formula products for normal full-term infants be exempt from the labeling requirements of this final rule.

The agency advises that to the extent that nutrition information in any form, including publications and promotional materials of the type described, is labeling, it must comply with all applicable requirements of the act and their implementing regulations in this final rule. Further, FDA does not have authority to exempt any food labels or labeling from the requirements of the act. Labeling on infant formula products for normal full-term infants is not exempted by the 1990 amendments from the act's requirements for nutrient content claims. Therefore, the labeling for these foods must comply with the requirements in this final rule.

4. 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 (21 U.S.C. 341) shall not be subject to section 403(r)(2)(A)(i) or (r)(2)(B). 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. However, in the general principles proposal (56 FR 60421 at 60429), FDA reviewed the legislative history of this provision, which makes clear that Congress did not intend section 403(r)(5)(C) of the act to imply, in any way, that 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 (see H. Rept. 101–538, 101st Cong., 2d sess. 22 (1990)).

Accordingly, the agency proposed 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 proposed § 101.13(b),(g), and (h) or to the definitions of part 101, subpart D.

34. Several comments disagreed that nutrient content claims that are part of the common or usual name of a food that was subject to a standard of identity on November 8, 1990, should be exempt from having to comply with the definitions for such claims established by the agency. These comments stated that consumers may be confused by inconsistent meanings of the same term in standardized versus nonstandardized foods because many consumers do not know the difference between standardized and nonstandardized foods. Additionally, these comments stated that it was unfair to exempt standardized foods from the general requirements for nutrient content claims.

Section 403(r)(5)(C) of the act specifically exempts nutrient content claims that were part of the common or usual name of a food subject to a standard of identity on November 8, 1990, from the requirement that terms used to make claims comply with definitions established by regulation. Because this exemption is statutory, the agency must make it available to foods that meet the criteria for the exemption. Therefore FDA is retaining new § 101.13(q)(6) as proposed. The agency more fully discusses this exemption in the document addressing labeling requirements for foods named by use of a nutrient content claim and a standardized term published elsewhere in this issue of the **Federal Register**.

5. Other

35. The agency determined in the final regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, that bottled water is not exempt from nutrition labeling unless it contains insignificant amounts of nutrients. Similarly, label statements on bottled water that make claims about nutrients of the type required to be declared in nutrition labeling are nutrient content claims requiring definition under section 403(r) of the act. In this regard, the proposal asked for comment as to how to decide what constitutes a nutrient content claim (56 FR 60421 at 60424). Comments on this issue have led FDA to conclude that fluoride is a special nutrient that warrants different labeling requirements than other nutrients.

Many public drinking water systems add fluoride to drinking water to help reduce dental caries. In addition, the Surgeon General has supported this practice (Ref. 4). However, there are concerns that fluoride levels in drinking water not be too high. The Environmental Protection Agency has established primary and secondary drinking water standards for fluoride (51 FR 11396, April 2, 1986) and FDA has proposed to revise its quality standard for fluoride in bottled water accordingly (53 FR 36036, September 16, 1988). Therefore, FDA believes that while the presence of fluoride in bottled water is of interest to consumers and its declaration should not be prohibited, the agency does not wish to encourage unnecessary addition of fluoride to bottled water. The agency is concerned that if terms like "good source of fluoride" or "high in fluoride" were permitted, they might encourage such additions.

Consequently, the agency has not defined a nutrient content claim for fluoride. Instead, it has provided that a statement indicating the presence of added fluoride may be used, but the claim may not include a description of the level of fluoride present. FDA has provided in new § 101.13(q)(8) that bottled water containing added fluoride may state that fact on the label or in labeling using the term "fluoridated," "fluoride added," or "with added fluoride."

III. Definition of Terms

A. General Approach

1. Criteria for definitions of terms

a. Serving size to evaluate nutrient content claims

In a proposal addressing food labeling and serving sizes that was published in the **Federal Register** on November 27, 1991 (56 FR 60394), FDA proposed among other things to: (1) Define serving and portion size on the basis of the amount of food customarily consumed per eating occasion, (2) establish reference amounts (reference amounts customarily consumed) per eating occasion for 131 food product categories, and (3) provide criteria for determining labeled serving sizes from reference amounts. In § 101.12(g), FDA proposed that if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), then both the reference amount and the serving size declared on the product label are to be used in determining whether the product meets the criteria for a nutrient content claim.

The agency also discussed this requirement in the general principles proposal (56 FR 60421 at 60430), stating that it believed it would be misleading to make a claim on a product that met the criteria for a claim on a reference amount basis but that did not qualify for the claim on the basis of the labeled serving size, i.e., the entire container. The agency noted, however, that this approach created situations in which a product in one size container would be eligible to bear a claim, while the same product in a different size container would not be eligible. In the serving size proposal (56 FR 60394 at 60413), FDA discussed another approach to eligibility for a claim based solely on the reference amount plus a disclaimer on the label and solicited comments on both options.

36. Most comments addressing this issue, including several industry comments, supported FDA's proposal for basing claims on both the reference amount and the labeled serving size. However, several comments from industry, trade associations, and a few professionals objected to requiring both the reference amount and the labeled serving size. These comments stated that claim evaluations should be based solely on the reference amount. The comments argued that claims should reflect true characteristics of the product, and that a product that qualifies for the claim should be able to bear the claim on all container sizes. They argued that inconsistency from

container to container in the use of claims on the same product in different sized containers would be confusing to consumers.

These comments and FDA's responses are fully discussed in the final rule on serving sizes, elsewhere in this issue of the Federal Register. As explained in that document, the agency has been persuaded to reconsider its proposal and has concluded in that final rule to base eligibility for a claim solely on the reference amount and to require a disclaimer when the amount of the nutrient contained in the labeled serving size does not meet the maximum or minimum amount criterion in the definition for the nutrient content claim for that nutrient. The disclaimer that follows the claim will inform consumers of the basis on which the product qualifies for the claim. Therefore, the possibility of misleading the consumer is reduced. The agency believes that this approach resolves the objections raised in the comments. Further, under this approach the claim would reflect true characteristics of the product, not the container size, and may be less confusing to consumers.

Accordingly, in the final rule FDA is revising all of the provisions for specific nutrient content claims that, as proposed, would have required foods bearing claims to meet both a per reference amount criterion and a per labeled serving size criterion. These sections, as revised, now require that the food only meet a per reference amount criterion.

FDA is also codifying the requirements for the disclaimer in the final rule in new § 101.13(p). New § 101.13(p)(1) states:

> The reference amount set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount, and the amount of the nutrient contained in the label serving size does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 mL (8 fl oz)").

Further, new § 101.13(p)(2) provides that the criteria for the claim must appear immediately adjacent to the most prominent claim in easily legible print or type and in a size no less than that required by § 101.15(i) for net quantity of contents except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement should be no less than one-half the size of the claim but not smaller than one-sixteenth inch. This provision ensures that the disclaimer will have appropriate placement on the label and that its prominence will be consistent with other required supporting statements (e.g., referral statements).

b. Criterion based on a designated weight

In the general principles and fat/cholesterol proposals, FDA proposed in §§ 101.60, 101.61, and 101.62 that the definition of certain terms (e.g., "low" for calories, fat, sodium, and cholesterol and "very low" for sodium) be based on the following criteria: (1) The amount of nutrient per reference amount (reference amount), (2) the amount of nutrient per labeled serving size, and (3) the amount of nutrient per 100 g of food. The weight-based criterion (i.e., per 100 g of food) required that the maximum amount of the nutrient allowed per serving also be the maximum amount of the nutrient contained in 100 g of the food (e.g., for "low fat," 3 g or less of fat per serving and 3 g or less of fat per 100 g).

In the general principles proposal (56 FR 60421 at 60430), FDA stated that without the weight-based criterion, "low" claims would be allowed on certain foods that are dense in a nutrient on a weight basis yet still qualify for a "low" claim because of their small serving size. For example, without the weight-based criterion, butter and some margarines could make "low sodium" claims, although they contain as much as 900 mg sodium per 100 g of food. In addition to stating the misleading nature of such claims, FDA expressed concern that nutrient dense foods with small serving sizes may be consumed frequently throughout the day and ultimately make substantial contributions to the diet despite their "low" claims. Thus, FDA proposed the weight-based criterion to prevent misleading "low" claims on certain nutrient dense foods. FDA further stated that such claims may be counterproductive relative to educating consumers about the nutrient quality of foods.

37. Many comments requested that the agency delete the weight-based criterion from the final rule. The comments cited various reasons for this request. One of these comments stated that the weight-based criterion would eliminate important foods from the diet of persons advised by medical personnel to "watch" a particular nutrient and suggested that such persons might not eat particular foods if such foods were not labeled as "low" in that nutrient. The comment maintained that foods that do not meet the agency's proposed criteria for "low" can still be included in a healthy diet.

The agency realizes that some foods that do not meet its criteria for "low" can be included in a diet that meets current guidelines. The agency notes that the proposed definition of "low" is designed to allow a consumer to meet current dietary recommendations while selecting a variety of foods, including some that are "low" in a nutrient such as fat, and some that are not "low." Thus, FDA disagrees with the essential point of this comment, that it should not include a weight-based criterion for "low" claims because some foods that do not meet the criteria for "low" can be included in a diet that meets current guidelines. The agency believes that a weight-based criterion is a necessary criterion for the definition of "low" to prevent misleading claims on certain nutrient dense foods.

38. Some comments argued that the need for the criterion was eliminated or diminished by FDA regulations that would require serving sizes to reflect amounts customarily consumed and would require the listing of both serving size and nutrient content on the nutrition label. One of these comments further stated that if there were still problems with certain nutrient dense foods qualifying for "low" claims, then the reference amount might be adjusted to solve these problems.

FDA considered the comments suggesting that the weight-based criterion could be deleted because serving sizes will be based on amounts customarily consumed. However, the agency rejects this suggestion because basing eligibility for a claim on serving size alone would mean that certain foods with small serving sizes that have a substantial amount of a particular nutrient on a per weight basis could make "low" claims. For example, the agency conducted an analysis to assess the effect of deleting the weight-based criterion using food composition data of USDA (Ref. 5) in conjunction with the reference amounts in FDA's final rule on serving sizes. The analysis showed that without a weight-based criterion, products such as sugar, grated parmesan cheese, and 25 percent fat cream could be labeled as "low calorie;" evaporated whole milk, nondairy creamer, green and ripe olives, and whipped dessert toppings as "low fat;" salted peanuts, butter, margarine, mayonnaise, ripe olives and mustard as "low sodium;" and grated parmesan cheese and regular mayonnaise as "low cholesterol" (Ref. 6). "Low" claims on these foods are contrary to recommendations made in the "Nutrition and Your Health: Dietary

Guidelines for Americans," issued jointly by the U.S. Department of Health and Human Services and USDA (Ref. 7) and would mislead and confuse the consumer.

Furthermore, "low" claims may promote increased consumption of such foods and thus, result in dietary practices even more inconsistent with dietary guidelines. For example, "low calorie" claims could appear on the labels of granulated sugar and brown sugar, although the guidelines state that sugars and the many foods that contain them in large amounts should be used in moderation by most healthy people and used sparingly by people with low calorie needs. A "low fat" claim could be made on evaporated whole milk, although the guidelines promote the consumption of skim or low fat milk to help obtain a diet low in fat. In addition, "low sodium" claims could be made on ripe olives, mayonnaise, and mustard, although the guidelines identify olives, salad dressing, and condiments such as mustard as foods that contain considerable amount of sodium. Further, "low sodium" claims could be made on some salted snacks, although the guidelines recommend that salted snacks be consumed sparingly. Consumer confidence in the validity of nutrient content claims would likely be undermined by "low" claims on foods that are clearly not "low" in certain nutrients but could make a claim because the established serving size is so small. For these reasons, FDA has concluded that the weight-based criterion should not be eliminated.

Furthermore, the agency rejects the suggestion made in one comment to adjust reference amounts (serving size) to prevent claims on nutrient dense foods. The agency does not have the authority to do so. Section 403(q)(1)(A)(i) of the act states that the serving size is an amount that is customarily consumed. Therefore, FDA concludes that a weight-based criterion is the best way to address the problem that it has identified.

39. Several comments stated that the weight-based criterion should be deleted because: (1) The 100 g amount is not based on amounts of foods customarily consumed; (2) consumers do not make food choices based on 100 g of food; (3) some foods now labeled as "low sodium" may no longer be permitted to use that term; and (4) not all food products with similar amounts of a nutrient per serving would be permitted to bear "low" claims.

As discussed in the general principles proposal (56 FR 60421), the 100-g criterion is a criterion that reflects nutrient density. As such, it is not intended to reflect an amount of food customarily consumed. FDA finds no reason to conclude that this criterion will confuse consumers because it is not disclosed to the consumer. Additionally, the agency is not persuaded that consumers will be confused if some products currently using terms such as "low sodium" no longer qualify because of the additional criterion. Rather, the agency believes that consumers expect changes in claims on products to result from the implementation of the 1990 amendments.

Further, FDA does not believe that consumers will be confused if all food products with similar amounts of nutrients per serving did not bear "low" claims because consumers will likely recognize certain foods as being nutrient dense and others as not being nutrient dense. On the contrary, consumer confusion is likely to result if "low" claims appear on foods that are generally known to contain considerable amounts of the subject nutrient on a weight basis.

40. Several comments opposed to the weight-based criterion also disagreed with the statement in the general principles proposal (56 FR 60421 at 60431) that some nutrient dense foods with small serving sizes may be consumed frequently throughout the day. These comments said there was no evidence that these foods are overconsumed, nor was there evidence that they are consumed more than food products with larger serving sizes. A few of these comments stated that consumer education efforts could address any problems with these foods including their possible overconsumption.

FDA has reconsidered whether nutrient dense foods with small serving sizes will be frequently consumed, and the importance of this issue in justifying a weight-based criterion. The agency acknowledges the difficulty in providing persuasive evidence that many nutrient dense products may be frequently consumed, in part because of certain limitations in the available food consumption estimates. However, the agency believes that "low" claims on certain nutrient dense foods with small serving sizes, such as those cited in comment 38 of this document, may promote increased consumption of these foods, and when considered in the context of the total diet, such consumption would be inconsistent with current dietary recommendations. Therefore, the agency believes that "low" claims on these foods will be misleading to consumers.

Further, it would be inappropriate for the agency to use consumer education to promote the acceptance of labeling claims that it regards as misleading because such an approach would undermine the provision of the act that directs the agency to establish regulations to prevent false and misleading label declarations. Therefore, the agency rejects the suggestion that it abandon the weight-based criterion in favor of efforts to educate consumers about "low" claims for nutrient dense foods.

41. Other comments opposed to the proposed weight-based criterion asserted that it will act as a disincentive to manufacturers to produce healthier food products if they could not use claims such as "low" on the label. One of these comments said that manufacturers will have difficulty reformulating some products to meet the weight-based criterion, while another said that the inability to advertise a healthier product could lead to a manufacturer's shifting the emphasis from reducing fat or salt to adding fat or salt for better taste.

FDA examined the extent to which a weight-based criterion would be a disincentive to manufacturers to produce healthier products. The agency acknowledges that an overly restrictive weight-based criterion would limit the number of products that could be reformulated to qualify for "low" claims. However, the agency disagrees that manufacturers are likely to resort to adding fat or salt if they are unable to make "low" claims, because the manufacturer would still have available comparative claims such as "less" to publicize nutritional improvements in products. Therefore, FDA rejects these comments.

42. Several comments were opposed to the weight-based criterion because of the number and type of food products that would be precluded from bearing claims by this criterion. Some of the food products cited by the comments included certain dry food products (e.g., dry hot cereals and dehydrated soups); some types of bread, pasta, crackers, and other cereal grain products; snack products and cookies; lower fat cheeses and other dairy products; lower fat salad dressings; spice blends and seasoning blends; and sauces, margarine, butter, and oils. One comment said that it would make it almost impossible for products whose reference amount was less than 100 g to qualify for certain nutrient content claims, while other comments said that the criterion discriminates against food with small serving sizes and nutrient-dense foods. Other comments said that this criterion

diminished the distinction between the terms "low" and "free" and was unfair to low moisture foods.

FDA considered the comments that said that the weight-based criterion should be deleted because of the number and types of food products that would be precluded from bearing claims. The agency disagrees with the comment that the proposed criterion would make it almost impossible for products with a reference amount of less than 100 g to qualify for certain content claims. Many products with reference amounts under 100 g would qualify for "low" claims under FDA's proposed criterion (e.g., many vegetable products, dried fruit, legumes, some gravies and sauces, some fish products, several cereal grain and pasta products, and a number of breakfast cereals could make "low fat" claims) (Ref. 8).

FDA also considered the comments that said that the proposed weight-based criterion discriminates against foods with small serving sizes and nutrient dense foods, but concluded that a weight-based criterion is needed to prevent nutrient dense foods with small serving sizes from making misleading claims. Further, the agency disagrees that the revised weight-based criterion would diminish the distinction between "low" and "free" claims. The agency has provided clearly distinctive definitions for these two nutrient content claims.

43. At least two comments suggested alternative criteria that would incorporate the frequency of consumption of a food. One comment suggested that nutrient dense foods with small serving sizes should be prevented from making "low" claims only if they are consumed many times during the day. Another comment proposed that foods be required to meet the criteria for "low" claims based both on levels per reference amount and per total daily intake (i.e., reference amount times average number of servings per consumer per day). The daily number of servings would be derived from national food consumption surveys. This comment acknowledged that a major disadvantage to this approach would be the complexity of determining the figures.

The agency agrees that an approach that considers frequency of consumption would be complex. FDA rejects this approach principally because it does not adequately address the agency's concerns with regard to nutrient dense foods with small serving sizes. The agency believes that the suggested approach would not effectively control misleading claims on nutrient dense foods with small serving sizes because it does not provide any means of dealing with the likely effect of the appearance of the claim on the food. In other words, it would make little sense for the agency to allow a claim based on current consumption levels, but then to move to withdraw the authorization for the claim as soon as new consumption information appears showing that there is increased consumption of the food in response to the claim, and that consumption is inconsistent with dietary guidelines. A weight-based criterion will ensure that increased consumption of the food will still be consistent with dietary guidelines.

44. One comment suggested, as an alternative to the weight-based criterion, that food products that may have significantly different serving sizes because of different uses be required to meet the "low" level based on all of the respective reference amounts. The comment stated that one-third of all nondairy creamers are consumed with cereal in place of milk, and thus the reference amount used as a basis for claims should reflect this use. This comment also suggested as an alternative to the weight-based criterion that food products that have small serving sizes be required to meet a lower nutrient level per serving to make a claim. For example, for foods with a one ounce reference amount or less, fat content could not exceed 2 g per reference amount.

The agency rejects these suggestions because the first has only limited application, and the second is not an effective alternative in preventing misleading claims. With regard to the first suggestion, most nutrient dense foods with small serving sizes (e.g., butter) would be subject to only one reference amount. The second suggested alternative would not prevent "low fat" claims on foods such as grated parmesan cheese and whipped dessert toppings (Ref. 9), and, as discussed in comment 38 of this document, such claims would be misleading.

45. Some comments suggested applying a weight-based criterion only to foods with small serving sizes. One comment suggested that the agency develop a provision to cover foods that weigh 40 g or less per serving and contain more than 5 calories per g. Another comment suggested that the proposed weight-based criterion only be applied to foods with reference amounts 15 g or less or 2 tablespoons or less and that are consumed frequently throughout the day. Other comments suggested that certain nutrient content claims be prohibited on specific categories of foods with very small serving sizes or prohibited on foods with less than a minimum serving size that contained more than a certain amount of fat on a dry weight basis. One comment suggested that a minimal serving size for specific nutrient content claims be established such as one tablespoon.

The agency has carefully considered the suggestions raised in the comments that a weight-based criterion apply only to foods with small serving sizes. Because the intent of the agency is to prevent misleading claims on nutrient dense foods that have small serving sizes, the agency has concluded that narrowing the scope of the provision such that it only applies to foods with small serving sizes adequately addresses its concern of misleading claims on nutrient dense foods with small servings. Moreover, the agency has concluded that with appropriate provisions applicable only to foods with small serving sizes, misleading claims on nutrient dense foods can be prevented. However, the alternatives suggested in the comments were not the most effective options in preventing such claims. For example, with the first alternative suggested by the comments, green olives with about 13 g of fat per 100 g could qualify as "low fat" and 25 percent fat cream with about 240 calories per 100 g as "low calorie" (Ref. 10). With the second suggested alternative, salted peanuts with about 430 mg sodium per 100 g could qualify as "low sodium" (Ref. 10).

The agency considered, however, that if the second suggested alternative was modified to apply to foods with reference amounts of 30 g or less or 2 tablespoon or less, and the concept of frequency of consumption was deleted, then the proposed weight-based criterion applied to such foods would prevent inappropriate claims (Ref. 6). In addition, this criterion would permit more foods that are promoted in dietary guidelines to make "low" claims than FDA's proposed criterion. For example, breads and pastas that qualified on a per serving basis could make "low" claims. Accordingly, in the final rule, the agency is including a weight-based criterion for "low" claims only for those foods that have reference amounts of 30 g or less or 2 tablespoons or less. As discussed below, in comment 48 of this document, the agency is also persuaded to adopt a less restrictive weight-based criterion.

46. At least two comments suggested as an alternative that foods with small serving sizes be required to have a qualifying statement such as "low fat per one tablespoon" or "low fat when consumed in a 1-ounce serving." One

comment suggested that this qualifying statement only be required for foods that exceeded FDA's proposed per 100-g criterion. These comments said that the disclosure would alert people to the possibility that the product would no longer be "low fat" if a larger serving were consumed and would educate consumers who did not know that nutrient content claims are dependent on serving sizes.

This alternative would permit claims on all foods meeting the per serving criterion and would provide additional clarification of the claim to the consumer. However, the agency is not persuaded to adopt this alternative because the agency believes that even with the additional disclosure, such claims may confuse the consumer if the food product contains considerable amounts of the nutrient on a weight basis.

47. A few comments suggested as an alternative that all food products that meet the per serving criterion for a claim also be required to meet a caloric density criterion. Reasons cited in support of a caloric density criterion were that it would prevent nutrient dense foods with small serving sizes from making misleading claims, would allow products of widely differing serving sizes and calorie levels to be assessed fairly, and would eliminate inequities of the proposed 100-g criterion that favored hydrated products. One comment recommended that "low fat" foods not contain more than 15 g of fat per 100 g on a dry weight basis, which is equivalent to about 30 percent of calories from fat. Another comment recommended that instead of a weight-based criterion, a criterion of less than 45 percent of calories from fat should be applied to the "low fat" definition.

Disadvantages to a caloric density approach were also cited in comments. They included the potential for: (1) Manufacturer misuse such as increasing the fat/calorie content of a product to obtain a lower level of a particular nutrient (e.g., a lower sodium or cholesterol level) on a per calorie basis, and (2) manufacturer disincentive to produce "lower calorie" foods because, with the caloric density approach, the levels of problem nutrients would be higher compared to the higher calorie version of the product.

Other comments suggested that a weight-based criterion be based on nutrient levels per 100 calories or nutrient levels per 117.5 calories. The latter caloric level was derived by dividing the agency's proposed reference daily caloric intake of 2,350 calories by the agency's estimate of 20 servings of food being consumed in a day. The comment stated that this caloric level would be tied to average daily consumption, whereas 100 g has no relation to daily food consumption.

The agency has considered the appropriateness of applying a caloric density criterion for "low" claims for fat, cholesterol, and sodium. The agency acknowledges that it proposed this type of approach for a weight-based criterion for saturated fat in order to provide "low" claims for saturated fat on certain fats and oils (e.g., canola oil) because all fats and oils would exceed a weight-based criterion based on 100 g.

The agency is concerned, however, that the caloric density approach would permit misleading "low" claims for cholesterol and sodium. For example, if the criterion was that a food could have no more than proposed nutrient levels per 117.5 calories, then butter with about 800 mg of sodium per 100 g could qualify for a "low sodium" claim and grated parmesan cheese with about 80 mg of cholesterol per 100 g for a "low cholesterol" claim (Ref. 11). The agency also agrees with comments that the caloric density approach could encourage the development of higher fat, higher calorie products in order to make "low sodium" and "low cholesterol" claims. Thus, this approach would be inconsistent with national dietary goals of lowering fat intake (Refs. 4, 7, and 12).

The agency also considered whether this type of criterion might be applied to fat but not to sodium and cholesterol. However, if a criterion such as less than 30 percent calories from fat were used, then low calorie, high moisture products such as ready-to-serve gazpacho soup may not qualify for a "low fat" claim (Ref. 11), even though a serving of a cup might contain only 2 g of fat and be consistent with foods promoted in dietary guidelines. In addition, the agency does not believe that there is a sufficient basis to justify a higher level such as no more than 45 percent calories from fat, as suggested by one of the comments. Furthermore, national goals that target nutrient intake as a percentage of calories focus on the total diet, not on the percentage of calories in individual foods (Refs. 4, 7, and 12). Accordingly, the agency rejects a criterion based on caloric density for claims for nutrients other than saturated fat.

46. Several comments suggested as an alternative that FDA use a less restrictive weight-based criterion. Variants of this alternative were to use: (1) The disclosure/disqualifying levels per 100 g, (2) proposed levels per 30 g (one ounce), or (3) proposed levels per 50 g. One of these comments further stated that the use of the proposed levels per 30 g would be more closely tied to reference amounts and would allow truthful nutrient claims on the majority of foods, while preventing claims on nutrient dense foods with small serving sizes. This comment cited as a disadvantage, however, that this approach would still be arbitrary and not related to how consumers actually eat foods.

Another comment supported the use of proposed levels per 50 g because it would allow more grain products to qualify as "low fat." In addition, the comment stated that a per 50-g criterion would prevent higher fat crackers and cookies and other high fat foods with small serving sizes from making "low fat" claims. This comment further stated that the per 50-g criterion would allow more products to qualify for "low sodium" and "low cholesterol" claims and would result in more flexibility for manufacturers and more choices for consumers.

FDA considered the options presented in the comments for a less restrictive weight-based criterion. Upon reconsideration, the agency acknowledges that the level it proposed, per 100 g, is too restrictive. While the proposed criterion would have prevented "low" claims on certain nutrient dense foods, it also would have prevented some breads and other cereal grain products for which increased consumption is recommended in national dietary guidance from qualifying for "low" claims (Ref. 7). FDA has thus rejected maintaining the weight-based criterion as proposed.

The agency disagrees that a main reason for selecting a weight-based criterion should be the relationship of per 100 g, per 50 g, or per 30 g to the amounts of foods consumers actually eat. The criterion serves only as a measure of nutrient density. The reference amount reflects what consumers actually eat. However, FDA notes that a criterion based on proposed levels per 50 g or per 30 g would be more compatible with consumption amounts than per 100 g for individual foods, although 50 g or 30 g amounts would still be substantially greater than the reference amounts for some food products such as minor condiments.

While the agency acknowledges that the proposed criterion of 100 g is too restrictive, FDA is concerned that the alternative suggestions of applying the proposed disqualifying levels per 100 g (e.g., 11.5 g per 100 g for fat) or proposed levels per 30 g (e.g., 3 g per 30 g for fat, which is about 10 g per 100 g) could still result in misleading claims

even if the weight-based criterion is applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less. For example, with either of these criteria, evaporated whole milk and liquid nondairy creamers could still make "low fat" claims, and regular cream cheese could still make a "low sodium" claim (Ref. 6). In addition, the use of the per 30-g criterion when applied to foods with these reference amounts (i.e., 30 g or less or 2 tablespoons or less) could result in misleading "low calorie" claims on products such as half-and-half, olives, and maraschino cherries. Accordingly, FDA has not adopted these alternatives.

The agency also considered the alternative suggested in the comment of using proposed levels per 50 g. If a 50-g criterion was applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less, then all of the products cited above as inappropriate for "low" claims would be prevented from making misleading "low" claims (Ref. 6). In addition, compared with FDA's proposed per 100-g criterion, the per 50-g criterion would permit more foods for which increased consumption is recommended in current dietary guidelines to make "low" claims. For example, more breakfast cereals and snacks such as pretzels and air popped popcorn could make "low fat" claims.

The agency concludes that the use of a per 50-g criterion when applied to foods with reference amounts of 30 g or less or 2 tablespoons or less minimizes confusing or misleading claims while maximizing appropriate "low" claims consistent with dietary guidance. Accordingly, the agency is revising relevant paragraphs of new §§ 101.60, 101.61, and 101.62 to provide for a weight-based criterion for these foods be based on nutrient levels per 50 g of food for "low" claims. The agency is also revising new § 101.61(b)(2) to require that the per 50-g criterion apply to "very low sodium" claims.

49. One comment stated that a weight-based density criterion would be unduly restrictive to dry products such as dehydrated soups and dry hot cereals that require water to be added and that would qualify based on an "as prepared" form but not on the "as purchased" form. This comment suggested that a criterion based on the hydrated product would be more equitable for foods that must have water added to them before typical consumption.

The agency points out that the weight-based criterion in the final rule does not apply to dehydrated soups or dry hot cereals because their reference amounts exceed the specified reference amounts to which the weight-based criterion applies. However, the agency agrees with the comment that the weight-based criterion should be applicable to the "as prepared" form when the product purchased is dehydrated, because the reference amount of the product, as well as any accompanying nutritional information, is based on the hydrated form of the food. Thus, the agency concludes that it would be inconsistent to require that a weight-based criterion be based on the dehydrated form when all other accompanying information is based on the "as prepared" or hydrated form. Thus, the agency supports this recommendation for its limited application to dehydrated products with reference amounts of 30 g or less or 2 tablespoons or less. Accordingly, FDA is also revising the above cited sections by inserting "For dehydrated foods that are typically consumed when rehydrated with only water, the per 50-g criterion refers to the as prepared form," to allow products that must have water added to them before typical consumption to make a claim if the "as prepared" hydrated form meets the per 50-g criterion.

2. Need for consistency of terms and limited number of terms

As discussed in the general principles proposal (56 FR 60431), the agency's approach to developing a system of nutrient content claims emphasizes three objectives: (1) Consistency among definitions, (2) claims that are in keeping with public health goals, and (3) claims that can be used by consumers to maintain healthy dietary practices.

The agency also noted that it has followed an approach that will limit the number of defined terms. This approach is consistent with that advocated in the Report of the "Fourth Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines," Committee on the Nutritional Aspects of Food Standards, International Union of Nutritional Sciences (IUNS) (Ref. 13), which states 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.

Alternatively, the agency noted that some have argued that establishing flexible provisions for the use of terms will facilitate consumer understanding by better attracting attention to the message being delivered about the food. In addition, the agency noted that some have suggested that defining more terms or providing greater flexibility for the use of various terms to convey nutritional information encourages competition among products and fosters nutritional improvement in products. The agency specifically requested comments on how it can balance the goals of consumer understanding and competition (56 FR 60421 at 60431).

50. Some comments did not agree with the objective of maintaining consistency among the definitions. One comment stated that consumers will not be confused by the use of nonconsistent terms. One comment stated that because the proposed definitions for absolute nutrient content claims such as "low" and "high" are based on uniform standards that apply across all food groups, many foods that can help consumers improve their diets will not meet the standards in these definitions.

It is important for effective consumer education to establish consistent definitions for descriptive terms whenever possible to limit the possibility of consumer confusion. Thus, FDA has not made changes in its regulations in response to these comments. However, should a situation arise in which a flexible approach to defining a term would promote public health goals or assist consumers in maintaining healthy dietary practices, the agency will consider adopting such an approach. In implementing the provisions of the act on nutrient content claims (e.g., through the petition process), the agency intends not to inhibit useful and informative competition in the marketplace, so long as it is still consistent with the three objectives stated above.

3. Synonyms

Section 3(b)(1)(A)(ix) of the 1990 amendments provides that regulations for nutrient content claims may also include similar terms that are commonly understood to have the same meaning.

To implement these provisions, the agency requested in the general principles proposal (56 FR 60421 at 60431) comments on a list of synonyms suggested by the Grocery Manufacturers of America (GMA), for the terms "no," "very low," "low," "significant," "high," and "very high." The agency also requested comments on a report by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS'), entitled, "Nutrition Labeling Issues and Directions for the 1990's" (the IOM report) (Ref. 14) addressing concerns that a proliferation of synonyms on food labels will be confusing to consumers

who may believe that there are differences among the terms. Further, the agency requested comments on the use of synonyms for the nutrient content claims "free," "low," "high," and "source."

Section 403(r)(4)(A)(ii) of the act grants to any person the right to petition the Secretary (and FDA, by delegation) 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).

51. Several comments stated that it is important to limit the number of synonyms, while some comments advocated that FDA ban the use of all synonyms. The comments argued that the 1990 amendments do not require synonyms, that the use of synonyms does not contribute to improved public health, and that synonyms are used by companies only to gain a competitive edge.

Some comments suggested that all synonyms put forward by GMA should be accepted. The comments generally contended that synonyms are necessary to allow manufacturers greater flexibility; that there are many truthful and informative synonyms for the basic descriptors FDA is defining; that all terms will carry some defined meaning; that use of multiple synonyms will encourage competition among products; and that as long as there is a single definition for a term and its synonyms, consumers will not be confused.

A few comments stated that FDA should permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining the intended meaning. The comments argued that this approach would increase consumer understanding and confidence, without discouraging manufacturers' flexibility.

Another comment stated that qualitative research is needed to assess consumer understanding of descriptors before the publication of final regulations, and if such testing is not possible, definitions and synonyms should be tentative for 2 years and then reassessed.

FDA notes that many comments advocated either an extremely open or extremely restrictive approach to synonyms. However, FDA has not taken either of these positions. Because a goal of the 1990 amendments is to make nutrition information on the label or labeling of foods available in a form that consumers can use to follow dietary guidelines (H. Rept. 101–538, supra, 10), and the act envisions that synonyms for defined terms can be an appropriate means to communicate such information, the agency will evaluate synonyms according to the standard in the 1990 amendments, i.e., that the term is commonly understood to have the same meaning as a defined term. In doing so, FDA intends to be open to considering terms that meet this standard. However, FDA does not intend to permit any synonym that it believes would be unclear in meaning to consumers with respect to characterizing the level of a nutrient in a food. For instance, FDA does not consider the term "smidgen" to be commonly understood to mean "very low" in describing the level of a nutrient. Similarly, FDA does not consider the term "loaded" to be commonly understood to mean "high."

FDA disagrees with the comments that suggested that the terms and synonyms being established in this final rule should be permitted on a tentative basis for 2 years. FDA has sought to select terms and synonyms that are familiar to consumers. The standardization of these terms by regulation and the availability of nutrition labeling in conjunction with the claims, coupled with consumer education, will promote consumer understanding of their meaning. Thus, FDA believes that consumers will be able to use the terms and synonyms that it is defining to make informed dietary choices. Further, through petitions and rulemaking, FDA can change, add, or delete synonyms as new terms come to have established meanings or problems with defined terms become apparent.

FDA also disagrees with the suggestion that it permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining its intended meaning, because the act requires that terms (including synonyms) used to characterize the level of a nutrient in a food be either defined by the agency or approved by the agency in response to a petition. There is no provision in the act that allows for the use of undefined synonyms in the absence of action by the agency.

In this document, FDA has considered various synonyms that have been suggested in the comments. The issues considered by the agency and its conclusions regarding specific synonymous terms are discussed in detail in the relevant sections of this document.

B. Terms Describing the Level of a Nutrient

1. Free

In the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "free" for total fat, cholesterol, sodium, sugars, and calories. FDA also proposed to define the terms "no," "zero," "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for the term "free." The agency specifically requested comments on whether consumers commonly understand the meaning of all these terms to be, and whether the terms are in fact, synonymous.

In arriving at the proposed definition for "free" for each nutrient, 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. The agency noted, however, that some manufacturers may add very small amounts of certain nutrients to aid in the manufacturing process for some products. FDA proposed not to allow use of the term "free" on such products, even if the products met the quantitative criteria for use of the term. However, the agency requested comments on whether "free" claims should be allowed on these products if they provide an appropriate disclosure statement and also on what such a disclosure statement should be.

FDA also proposed that "free" claims used on foods that are inherently free of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. Synonyms. A number of comments addressed synonyms proposed by FDA for "free" in the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478). Many of these comments supported the use of synonyms for "free." Several comments agreed specifically with one or more of FDA's proposed synonyms for "free" such as "no" or "zero." One comment provided data showing that "free" and "no" are synonymous terms. Another comment provided data that "free" and "without" are synonymous terms.

52. At least one comment (a Ph.D. thesis) requested that the term "without" be a synonym for "free." The comment presented data in support of its request. This investigation (Ref. 15) was conducted at the University of South Dakota using 192 undergraduate students. The students' perceived notions of the amount of calories, fat, and cholesterol relative to 12 nutrient content claims terms were examined. The results demonstrated statistically that the participants perceived that "without" and "free" have the same meaning.

FDA agrees with this comment. The data presented, along with FDA's previous approval of the claim "without added salt," persuade the agency that "'without' should be a synonym for 'free'." Accordingly, the agency is revising new § 101.60(b)(1) on calories, new § 101.60(c)(1) on sugar, new § 101.61(b)(1) on sodium, new § 101.62(b)(1) on fat, new § 101.62(c)(1) on saturated fat, and new § 101.62(d)(1) on cholesterol, to allow "without" to be a synonym for "free."

53. One comment maintained that manufacturers are likely to abuse the terms "free" and "no."

FDA believes that most manufacturers will comply with the requirements of these regulations. However, manufacturers who violate the requirements for these definitions will be dealt with by appropriate regulatory action.

54. One comment suggested that "free" be used where there is an absence of a nutrient, and that a phrase such as "very small amount of" be used where the food contains very small amounts of a nutrient, even if the amount of the nutrient present is physiologically insignificant.

FDA rejects this suggestion. As discussed in the general principles proposal (56 FR 60421 at 60432), FDA believes that it is appropriate to apply the term "free" to a nutrient when a food contains that nutrient in a dietetically trivial or physiologically inconsequential amount, even though the nutrient is present at a level at or near its reliable limit of quantitation. With modern analytical methods, the level at which the presence of a nutrient may be quantified is becoming increasingly smaller. For example, there are almost no foods that can be said to be truly sodium free, yet the level of sodium present in some foods has no impact on the diet. Furthermore, the additional term would likely cause consumer confusion because it is ambiguous and would not be clearly distinguishable from "free" in a meaningful way.

55. One comment stated its support for the use of the word "none." Another comment suggested that "none" be used instead of "free" but gave no reason for this suggestion.

The comment did not provide sufficient supporting information to persuade the agency that consumers commonly understand "none" to have the same meaning as "free." Therefore, FDA is not providing for the use of "none" as a synonym for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of this term as prescribed in new § 101.69.

56. Several comments supported the synonyms for "free" that contain "source of" language (i.e., "trivial source of," "negligible source of," "dietarily insignificant source of"). One comment stated that the de minimis nutrient threshold levels encompassed by such phrases are of no public health concern. Several comments disliked these proposed synonyms. Some of these comments asserted that these phrases could be confusing or misleading to consumers. One comment pointed out that the inclusion of the word "source" in some of the synonyms for "free" could confuse consumers because the agency had given another meaning to this word in the general principles proposal.

In this final rule, as explained later in this document, FDA is changing the descriptive term "source" to "good source" to clarify its meaning and relative position in the hierarchy of descriptive terms. As a result, FDA does not believe that the use of the words "———— source of" in some synonyms for "free" will be confusing to consumers. Therefore, FDA is maintaining the position that it took in the general principles proposal (56 FR 60421 at 60434) that the terms "trivial source of," "negligible source of," and "dietarily insignificant source of" are suitable synonyms for "free," provided that they are used on the labels or in labeling of foods in accordance with the agency's definition.

57. Another comment stated that, unlike "no" and "zero," which are absolute terms, the terms containing the language "———— source of" could be misinterpreted.

FDA acknowledges that "free," "no," and "zero" are absolute terms that are synonymous to one another in their meaning. However, FDA also believes that the "———— source of" terms that it has listed as synonyms of "free" are appropriate for use on the food label and consistent with the agency's definition for "free" because they express that the nutrient is present at or near the reliable limit of detection and thus at a dietetically trivial or physiologically inconsequential level. Therefore, FDA concludes that no change is warranted in response to this comment.

58. One comment objected to the use of the phrases "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for "free" because such phrases equate the presence of trivial amounts of a nutrient with the absence of a nutrient. The comment asserted that people can experience life-threatening reactions to "trivial" amounts of substances.

FDA does not agree that these phrases are inappropriate as synonyms for the "free" nutrient content claims that are being defined in this final rule. As explained above, FDA defined the term "free" based on a dietarily insignificant amount of the nutrient in question, and these terms are consistent with that definition.

Further, FDA advises that the nutrient content claims that it is defining in this final rule provide consumers with information about nutrients in a food, and not about substances in foods that consumers may need to avoid because of allergies or intolerances. A consumer should read the ingredient list on the food label to determine whether a food contains a substance he or she needs to avoid.

59. Several comments suggested that FDA include the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary isignificance," "trivial amount of," and "meaningless" as synonyms for "free."

These comments did not provide sufficient supporting information to persuade the agency that consumers commonly understand the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary insignificance," "trivial amount of," and "meaningless" to have the same meaning as "free." Therefore, FDA is not providing for the use of any of these terms as synonyms for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in new § 101.69 of this final rule.

60. Some comments suggested that variations in spelling be allowed for descriptors and their synonyms.

Although FDA has not specifically provided for variations in the spelling of various descriptive terms or their synonyms, except for "light" ("lite"), the agency believes that reasonable variations in the spelling of these terms would be acceptable, provided that these variations are not misleading to consumers. However, should the agency encounter terms that use questionable variations in spelling, it will evaluate these variations on a case-by-case basis to determine whether they comply with section 403(a) and (r) of the act.

b. Statutory limitations on circumstances in which an absence ("free") claim may be made. The 1990 amendments describe the circumstances in which claims that state the absence of a nutrient may be made on a food. Section 403(r)(2)(A)(ii)(I) and (r)(2)(A)(ii)(II) of the act, respectively,

provide that a claim may not state the absence of a nutrient unless: (1) The nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary (and FDA, by delegation), or (2) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices, and the statement discloses that the nutrient is not usually present in food.

i. Substitute foods. In the general principles proposal (56 FR 60421 at 60432), FDA proposed to define when one food may be considered to substitute for another to eliminate any confusion that may arise over this issue. In § 101.13(d), FDA proposed that a substitute food is one that is used interchangeably with another food that it resembles in its physical, organoleptic, and functional characteristics, and that it is not nutritionally inferior to that food unless it is labeled as an "imitation." The agency also proposed in § 101.13(d)(1) that a food that does not possess the same characteristics as the food for which it substitutes must declare the difference on its label or in its labeling, adjacent to the most prominent claim. FDA also proposed in § 101.13(d)(2) that any declaration (i.e., disclaimer) made regarding the different characteristics of the substitute food should be in easily legible print or type, no less than one-half the size of the descriptive term.

The agency also stated in the proposal that it believes that identifying imitation foods that meet nutrient content claim definitions may provide a benefit to the consumer, even though they are nutritionally inferior. Therefore, FDA tentatively concluded that such foods should be allowed to bear nutrient content claims, as long as they are appropriately labeled.

61. A few comments agreed with FDA's proposed definition for substitute foods. Some of the supporting comments stated that regulations governing the use of substitute foods are necessary to avoid misleading consumers who are not aware of the dissimilarities between an original food and a food that serves as a substitute food. However, one comment stated that the agency lacks the legal basis to prescribe the use of disclosure statements on substitute foods as extensive as that proposed by the agency. This comment suggested that a disclaimer statement should not be required on substitute foods, and that the required statement is excessive and will result in a label that is confusing to consumers.

The agency disagrees with the comment that FDA has no legal basis to require disclaimer statements on substitute foods. As the agency stated in the proposal (56 FR 60421 at 60432), section 201(n) of the act provides that food labeling is misleading, and thus the food is misbranded under section 403(a) of the act, if it fails to disclose facts material to the consequences of the use of the food. For example, if a food has different performance characteristics than the food for which it substitutes, this fact must be disclosed in conjunction with the claim that draws a connection between the two foods. Under sections 201(n), 403(a), and 701(a) of the act, the agency has the authority to require disclaimer statements when these statements are necessary to disclose material facts.

The agency also disagrees with the contention that disclaimer statements will confuse consumers. The agency believes that this information is of value to consumers because it informs them about important aspects of the food that otherwise would not be evident.

62. Some comments addressed specific aspects of disclaimer statements. One comment that opposed the agency's proposed definition for a substitute food stated that the proposal is overly broad, and that FDA should limit the disclosure requirements to differences that materially limit the uses of a substitute food when compared to the food it resembles.

The agency has reconsidered its proposed requirements for disclaimer statements. FDA believes that "differences in performance characteristics" between a substitute food and an original food may include minor differences that consumers would consider relatively unimportant for that food (e.g., a different freezing point for a nonfat thousand island dressing substitute). The agency believes that such differences are significant only when they materially limit the use of the food compared to the use of the original food (e.g., "not recommended for frying"). FDA concludes that when the differences between the substitute food and the original food do not limit the use of the substitute, they need not be disclosed because they would not be considered to be material facts that relate to the consequences of the use of the food. Therefore, the agency is revising new § 101.13(d)(1) to state, that:

If there is a difference in performance characteristics that materially limits the use of the food, 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)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

Furthermore, to ensure that the disclaimer is presented with appropriate prominence, consistent with the requirements for other required supplementary information (e.g., referral statements), the agency is revising new § 101.13(d)(2) to read:

This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch.

63. A few comments stated that "shelf life" should be deleted from the definition because future developments may result in superior substitute foods with a longer shelf life.

The agency rejects this comment. The agency believes that, for two foods to be considered to be used interchangeably, they should generally resemble each other with respect to shelf life. However, the agency points out that the definition does not require that the substitute possess the same shelf life characteristics as the original food. As revised, the regulation would only require disclosure of the shelf life of the substitute food if that information is a material fact, as discussed in the previous comment.

64. One comment requested that FDA provide clarification in the final rule that differences in shelf life can be disclosed through code dates or freshness guarantee statements.

When shelf life information is required under the revised provisions, it would be appropriate to disclose the information through code dates or freshness guarantee statements if this information is presented in a readily understandable manner, in accord with the other requirements for disclaimers.

65. One comment suggested that any differences in performance characteristics associated with substitute foods should be located in the bottom 30 percent of the PDP as provided for in proposed § 101.67(b). This comment argued that proposed § 101.13(d)(1) should be revised to conform to that provision.

FDA rejects this comment. The agency believes that the disclaimer should be adjacent to the most prominent claim as it proposed because of the importance of the information. Further, the agency also notes that in the final rule on the use of nutrient content claims for butter, which appears elsewhere in this issue of the **Federal Register**, it is revising new

§ 101.67 to be consistent with new § 101.13(d)(1).

66. One comment argued that the dietary, health, and economic consequences regarding the use of substitute foods have not been addressed. This comment stated that the nutritional science associated with substitute foods is insufficient to fully determine whether they should be considered equivalent to traditional foods.

FDA is not authorized under the act to judge the dietary, health, or economic consequences of the use of substitute foods. Under section 403(r)(2)(A) of the act, foods that substitute for other foods must satisfy certain requirements if they are to bear nutrient content claims that highlight differences between them and the foods for which they substitute (see, e.g., section 403(r)(2)(A)(ii)(I) of the act). By issuing these labeling provisions for substitute foods, FDA has not judged that substitute foods are equivalent to traditional foods. These provisions are intended to ensure that material differences between the use of the substitute food and the use of the original food are conspicuously stated on the label or labeling of the food, so that consumers can make fully informed judgments about their value and their usefulness in maintaining healthy dietary practices.

67. A few comments expressed the view that consumers may not understand the difference between substitute foods and imitation foods. One of these comments suggested that data should be used to evaluate consumer perception on the differences between these terms.

FDA is not aware of any consumer confusion from the use of the terms "substitute" and "imitation" on food labels, nor did these comments provide any information to show that such confusion exists. Imitation foods are a subgroup of substitute foods. Under § 101.13(e), imitation foods are defined as being nutritionally inferior to the foods for which they substitute and that they resemble. FDA believes that the labeling requirements for substitute, and imitation foods will enable consumers to understand the nature of each of these types of foods. Therefore, FDA is making no change in response to these comments.

ii. Foods inherently free of a nutrient. In the general principles proposal (56 FR 60421 at 60433), the agency proposed for calories in § 101.60(b)(1)(ii) and sodium in § 101.61(b)(1)(iii) that if a food is inherently free of the nutrient, without the benefit of special processing, alteration, formulation, or reformulation to lower the content of that nutrient, a "free" claim on such food must refer to all foods of that type and not to a particular brand. In the fat/cholesterol proposal, the agency proposed a similar requirement for foods inherently cholesterol free (proposed § 101.62(d)(1)(i)(D) and (d)(1)(ii)(E)) or fat free (proposed § 101.62(b)(1)(iii)).

FDA proposed to establish this approach as a general requirement for nutrient content claims for "free" and claims for "low" in § 101.13(e)(2). Conversely, the agency provided in proposed § 101.13(e)(1) that, if a food has been processed, altered, formulated, or reformulated to remove the nutrient from the food, it may appropriately bear the terms "free" or "low" before the name of the food. FDA specifically requested comments on the proposed provision allowing "free" or "low" claims on foods that do not usually contain, or are usually low in, a nutrient.

68. A few comments stated that the agency should not allow use of the statement "————, a (nutrient) free food," on processed foods that do not normally contain the nutrient. These comments contended that this approach would eliminate the use of claims where the only benefit is to the manufacturer.

The agency rejects this comment. The agency believes, as stated in the proposal (56 FR 60421 at 60433), that highlighting that a food is free of a nutrient can help consumers to maintain healthy dietary practices whether the food is inherently free of that nutrient or is processed to be that way. Further, FDA believes that when a food is inherently free of a nutrient as a result of how it has been formulated, the disclosure "————, a (nutrient) free food" is necessary to prevent "(nutrient) free" claims from being misleading.

69. One comment argued that FDA should consider use of the term "naturally low in fat" instead of "————, a fat free food." Another comment preferred more flexibility in the wording of nutrient qualifiers (e.g., "as always, sodium free" or "naturally sodium free").

FDA points out that new § 101.13(e)(2) does not dictate the precise wording that manufacturers are to use to advise consumers that the food inherently meets the criteria and to clearly refer to all foods of that type. Therefore, the agency believes that the regulation contains sufficient flexibility with respect to the wording of the required qualifier. FDA will assess qualifying statements used on labels to determine whether the wording used meets the requirements of the regulations and take action on those that do not. Clearly, all such possible qualifiers do not meet the regulatory criteria. For example, FDA believes that the term "always" as used in the disclosure statement suggested by the comment does not clearly indicate that all foods of that type are also free of the nutrient. Thus, it may be interpreted to mean that only that brand of the food is free of the nutrient, and, as such, the claim is misleading.

70. Some comments opposed use of the statement "a fat free food" on foods that are inherently fat free. These comments stated that foods naturally "fat free" are placed at a disadvantage as compared to foods that have been modified to lower their fat level. One comment suggested that use of the term "fat free" instead of "————, a fat free food" should be appropriate on foods that are inherently fat free.

The agency disagrees with these comments. FDA continues to believe that when a "fat free" claim is made on foods that are inherently free of that nutrient, the claim is misleading unless it is accompanied by a statement that all foods of that type are inherently fat free. Thus, the agency is not providing for the use of "fat free" without the disclaimer on foods that are inherently fat free.

71. One comment requested clarification of proposed § 101.13(e)(1). The comment noted that the language of that section allows only those foods that are formulated, reformulated, specially processed, or altered to remove a nutrient from the product to bear the claim "free" or "low" before the name of the food, without the generic statement that all foods of that type are "free" of, or "low" in, that nutrient. The comment asserted that it is not clear whether a food that has been formulated to not include a nutrient that could be present in the food would be allowed to bear a claim addressed by proposed § 101.13(e)(1). For example, potato chips, fried in vegetable oil are free of cholesterol because the oil is cholesterol free, while potato chips fried in lard are not cholesterol free because of the cholesterol introduced by the lard. The comment emphasized that such foods are not "inherently free" of a nutrient but have instead been formulated so that the nutrient is not added. The comment recommended that the agency allow the terms "free" and "low" to be used on such products.

FDA agrees that there is a need for clarification in proposed § 101.13(e)(1) to allow for the use of "free" and "low" claims on foods that are formulated in such a way that certain nutrients that may be present in the food are not added to the product. The agency

believes that formulating a food in a way that precludes certain nutrients from being added to the food is equivalent to processing a food such that the nutrient is removed from the product. Thus FDA has modified new § 101.13(e)(1) to state:

> Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food may bear such a claim (e.g., "low sodium potato chips").

FDA believes that this amendment will alleviate any confusion concerning the appropriate use of "free" and "low" claims.

72. A few comments suggested that FDA should expand its criteria for claims regarding the absence of a nutrient to encompass foods produced by modern advances in technology, e.g., biotechnology, horticulture, or crop selection.

FDA's criteria for nutrient content claims apply to all foods. The agency is not aware of special needs with respect to foods of the types mentioned in the comment and cannot conclude at this time that special provisions in the regulations are needed for these foods.

c. Specific definitions

i. Sodium free and terms related to salt

73. Several comments objected to the provision in proposed § 101.61(b)(1)(ii) that a food containing added salt (sodium chloride) or any ingredient that contains sodium cannot be labeled "sodium free," even though it still contains 5 mg or less of sodium per serving. One of these comments stated that "free" terms should be based solely on the analytical definition, and that consumer education programs should be set up to explain the definitions. Other comments agreed that the food should not contain any added sodium chloride but believed that disallowing ingredients containing sodium was unnecessary and overly restrictive. A trade association for the cracker industry said that for years "sodium free" crackers have been used at hospitals for patients on sodium-restricted diets. Because these crackers are made with enriched wheat flour that naturally contains trivial amounts of sodium, they could not continue to be marketed as "sodium free" under the proposed rule. This comment requested that proposed § 101.61(b)(1)(ii) be entirely eliminated or modified to allow a "sodium free" claim when a food has ingredients that contain naturally occurring sodium.

Alternatively, some comments totally supported the proposed rule. They agreed that the listing of salt as an ingredient of a product bearing a "sodium free" claim is confusing, and, therefore, its addition should be disallowed. Other comments suggested that the confusion could be eliminated if the label of such a product explained that the product contains a trivial amount of sodium. Most of these comments preferred that such a disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of sodium chloride or ingredients that contain sodium to foods that bear a "sodium free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be eliminated, and that a disclosure statement be required to avoid consumer confusion about the quantity of sodium in the food. The agency is persuaded that it is the listing of salt (sodium chloride) or related substances that are generally understood by consumers to contain sodium (e.g., baking soda or ingredients with sodium as part of their common or usual name such as sodium ascorbate) that creates the confusion. Accordingly, the agency is revising new § 101.61(b)(1)(ii) to require that the listing of these ingredients in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement is to read: "adds a trivial amount of sodium," "adds a negligible amount of sodium," or "adds a dietarily insignificant amount of sodium." The agency concludes that ingredients that may contain trivial amounts of sodium, such as enriched flour used in making crackers, do not contribute to consumer confusion and, thus, do not need a disclosure statement.

74. One comment requested that any label on which the term "sodium free" appears be required to include the disclosure, "contains less than 5 mg of sodium per serving." This comment stated this disclosure would alert consumers to the possible presence of a dietarily insignificant amount of sodium, and, thus, an ingredient list that includes a sodium-containing compound would no longer be a potential source of confusion.

The agency disagrees with this recommendation because it believes that requiring a disclosure with all "sodium free" claims is not necessary and would add to label clutter. In the document on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is concluding that less than 5 mg of sodium is a dietarily insignificant amount and may be declared as "0" in the nutrition label. The agency sees no reason to take a different position with respect to the nutrient content claim. Disclosing the quantitative amount of sodium on a label that bears a "sodium free" claim and declares "0" sodium in the nutrition label would only create consumer confusion. Accordingly, the agency is not revising new § 101.61(b)(1) to require the requested disclosure.

75. A few comments requested that products not meeting the "sodium free" definition because they contain 5 mg or more of naturally occurring sodium should be allowed to use the claim "unsalted" ("without added salt," "no salt added") without having to disclose "not a sodium free food." One comment stated that there is virtually no risk that a consumer would associate "unsalted" as being synonymous with "sodium free." Another comment requested that the term "unsalted" be a synonym for "salt free" foods. Other comments disagreed and supported the requirement for a disclosure.

The term "unsalted" ("without added salt" or "no salt added") on a food that is not sodium free and that does not disclose that it is "not a sodium free food" could mislead consumers, as explained in the proposed rule (56 FR 60435). The comments presented no evidence that consumers would not be confused by this claim without the disclosure. Therefore, the agency is not persuaded to change its position on the need for the disclosure. However, to reduce the amount of information required on the principal display panel, the agency will allow this disclaimer to be placed in the information panel. The referral statement required by section 403(r)(2)(5) of the act will refer the consumer's attention to the information panel. This statement will ensure that this material fact is brought to the consumer's attention through a statement made in conjunction with the claim. Accordingly, the agency is changing the required location of this disclosure in § 101.61(c)(2)(iii).

Furthermore, the agency does not agree that the term "unsalted" should be used as a synonym for the term "salt free." To confine "unsalted" claims only to foods that meet the "sodium free" definition, including foods bearing a "salt free" claim would be overly restrictive. The agency is denying this request.

76. One comment stated that for over 25 years, cracker manufacturers have been making crackers with no surface

salt that are described on their labels as "Unsalted Tops * * * Crackers." These crackers are made with sodium chloride and baking soda and have never claimed to be low or reduced in sodium. The comment says that these products meet the desire of some consumers for crackers that taste less salty. The comment asked whether this name can continue to be used in light of proposed § 101.61(c)(2)(i), which specifies that the term "unsalted" may only be used on a food label if no salt is added to the food during processing. It requested that the rule be modified to allow for the use of the name "Unsalted Tops * * * Crackers" as well as other names in which the term "unsalted" is qualified and does not refer to the entire food.

The use of the term "unsalted," as it appears in the name "Unsalted Tops * * * Crackers," modifies the word "tops." When used in this context, "unsalted" does not refer to the salt content of the entire food. For this reason, the agency does not consider this use of the term "unsalted" to be subject to the requirements of new § 101.61 and does not believe that this rule needs to be modified to allow for the use of this name or other names in which the term "unsalted" is qualified in this manner. Accordingly, the agency has not revised the definition of "unsalted."

77. One comment stated that it is misleading for plain corn to claim "no added salt" when frozen corn does not have added salt.

In the absence of details in the comment, the agency presumes that this comment is referring to canned corn by the term "plain corn." The agency has a food standard (§ 155.130) for canned corn that permits salt as an optional ingredient and understands that salt is usually added to this product. The agency believes that if no salt is added to canned corn, the food that it resembles and for which it substitutes is canned corn, not frozen corn. Therefore, the agency concludes that it is not misleading for the product to bear the claim "no added salt."

ii. Sugar free. 78. At least one comment recommended that FDA define the term "sucrose free" instead of "sugars free."

The agency disagrees. Sucrose is only one of the sugars found in foods. For this reason, the agency believes that the term "sucrose free" would mislead consumers into believing that the food is free of all sugars. Accordingly, the agency is not defining "sucrose free."

79. At least one comment recommended that FDA define the term "no refined sugar."

The agency is not accepting these comments. The agency is concerned that consumers would be misled into believing that a food containing no refined sugar is better than a food containing refined sugar. The dietary guidelines (Ref. 7) advise Americans to consume sugars in moderation. Consumers need to understand that it is the amount of dietary sugar, not whether or not it is refined, that is important in following the guidelines. Accordingly, the agency is not defining the term "no refined sugar."

80. A couple of comments requested that the term "sugar free" be used instead of the term "sugars free." One comment said that the term "sugar free" would be in harmony with the term permitted in Canada and other countries. Another comment stated that although the term "sugars free" is technically correct, it is unfamiliar and will confuse the majority of consumers. The comment expressed doubt that consumers understand or care about FDA's reasons for proposing "sugars free" and believed that only a few consumers would notice that the listing in the nutrition label is for "sugars," not "sugar."

The agency is persuaded, based on the arguments made by the comments, that the term "sugars free" may be confusing to consumers. Accordingly, the agency is defining the term as "sugar free" in § 101.60(c)(1). The agency points out that this section provides that a food label may bear this claim if the food contains less than 0.5 g of sugars, as defined in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register** (redesignated from § 101.9(c)(6)(ii)(A) in the proposal). FDA proposed to define "sugars" as the sum of all free mono- and oligosaccharides through four saccharide units and their derivatives (such as sugar alcohols). However, as discussed in the final rule on nutrition labeling, in response to comments, the agency is changing the definition to include only mono- and disaccharides. Thus, the term "sugar free" refers to less than 0.5 g of mono- and disaccharides.

81. At least one comment requested that FDA define "sugar free" as free of all simple sugars.

FDA disagrees with this comment. As explained in the above section, the agency is defining "sugar free" as less than 0.5 g of sugars, that is mono- and disaccharides. FDA believes that this terminology is more precise than the term "simple sugars."

82. Numerous comments requested that the term "sugar free" be allowed to describe foods containing sugar alcohols (polyols). These comments suggested that FDA either should exclude sugar alcohols from the definition of "sugars" or should broaden the exemption in proposed § 101.13(o)(8) that allows the term "sugar free" on the label of chewing gums that contain sugar alcohols. The comments requested that foods containing sugar alcohols, such as soft candies, hard candies, breath mints, lozenges, and sodas, be included in the exemption. Alternatively, a few comments stated that allowing the claim "sugar free" on chewing gums would be confusing to consumers if sugar alcohols are included in the definition of sugars. One of these comments proposed that the claim on chewing gums should be "contains sugar alcohols" rather that "sugar free." Other comments suggested that the claim on chewing gums as well as other foods containing sugar alcohols should be "sugarless" to avoid confusion with foods meeting the definition of "sugar free." They believed that this term should be allowed only for foods that typically contain sugar, are modified to contain only sugar alcohols, and do not contain other carbohydrates.

The agency has reconsidered this issue and is persuaded that the term "sugar free" should be allowed to describe foods containing sugar alcohols. As described above, the agency is changing the definition of sugars to include only mono- and disaccharides. Thus, sugar alcohols are no longer included in this definition. A food containing sugar alcohols may bear a "sugar free" claim as long as it meets the requirements in new § 101.60(c)(1) for "sugar free" and in new § 101.9(c)(6)(iii) that polyol content be disclosed, as discussed in the final rule on nutrition labeling published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is deleting proposed § 101.13(o)(8) because the exemption that is provided is no longer needed.

83. Numerous comments supported the statement "useful only in not promoting tooth decay" in proposed § 101.13(o)(8), to continue to allow on the label of chewing gums that claim to be "sugar free." Many of the comments requested that the statement be allowed on the labels of other foods containing sugar alcohols that claim to be "sugar free." One comment suggested that FDA should revise the definition of "sugars" to exclude sugar alcohols and revise proposed § 101.60(c)(1)(iii)(B) to allow the requested statement to accompany "sugar free" claims. This provision, as proposed, would require either the statement "not a reduced calorie food," "not a low calorie food," or "not for

weight control." Other comments suggested that FDA should broaden the exemption in proposed § 101.13(o)(8) to allow the requested statement to appear on other foods. Alternatively, at least one comment suggested only the statements "not a reduced calorie food" and "not a low (free) calorie food" are appropriate. The comment specifically suggested that FDA should disallow the statement "useful only in prevention of tooth decay" with "sugar free" claims. This comment also implied that FDA should disallow the statement "not for weight control" with "sugar free."

The agency has reviewed these comments and has determined that there is no compelling reason to disallow the statement "not for weight control." However, the agency has concluded that the statement "useful only in not promoting tooth decay" should not be allowed because it is an unauthorized health claim. In the general principles proposal (56 FR 60437), the agency stated that it intended to reevaluate the usefulness of chewing gums sweetened with sugar alcohols in not promoting tooth decay. The agency acknowledged that the data supporting the claim were over 20 years old and requested new data. The agency received data in response to the request and will make a determination on the validity of this claim in accordance with the final rule on health messages published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is not revising § 101.60(c)(1)(iii)(B) to allow the statement "useful only in not promoting tooth decay" to appear with "sugar free" claims.

The agency is deleting the exemption in proposed § 101.13(o)(8) that would have allowed a "sugar free" claim on chewing gums containing sugar alcohols and the statement about not promoting tooth decay. As explained above, this exemption is no longer needed because the agency has decided not to define sugar alcohols as "sugars."

84. Many comments requested that FDA revise proposed § 101.13(o)(8) to allow the statement "Toothfriendly" to accompany "sugar free" claims on the label of chewing gums in place of the statement "useful only in not promoting tooth decay." In addition, these comments requested that such statements may be accompanied by a pictogram of a smiling tooth. These comments stated that the term "Toothfriendly" is more readily understood by consumers with limited reading and vocabulary skills. One comment said the "Toothfriendly" dental education programs have been successfully promoted in several European countries by "Toothfriendly Sweets International," a nonprofit organization dedicated to promoting dental health. The agency received at least one comment opposing the term "Toothfriendly." The comment contended that the "Toothfriendly" program is just another third party endorsement program similar to those the agency has considered in the past. It stated that the claim is unsupported by any evidence and would promote the consumption of foods that are completely without nutritive benefit.

The agency is denying this request because it believes that the statement "Toothfriendly" accompanied by a pictogram of a smiling tooth is an implied health claim that, unless a regulation is established, is unauthorized (see section 403(r)(1)(B) of the act). As discussed in the previous comment, the agency has not made a determination that chewing gums sweetened with sugar alcohols are useful in not promoting tooth decay.

85. A few comments stated that the definition of "sugar free" should be less than 4 g per serving. They said that they selected this value because it is the dietary requirement for diabetics. Another comment requested that the term "sugar free" be accompanied by the statement: "For use in diabetic meal plans. Not a reduced calorie food (if appropriate)."

The agency does not agree that "sugar free" should be less than 4 g of sugars per serving as explained in the general principles proposal (56 FR 60421 at 60436). The agency emphasized there that the definitions of nutrient content claims do not specifically address issues related to diabetes management practices, and that diabetes management should not be based solely on the consumption of "sugar free" foods. Rather, diet planning for diabetics should encompass the entire diet and be supervised by a trained professional. The agency notes that the American Diabetes Association (ADA) submitted a comment that expressed strong support for defining "sugar free" at less than 0.5 g per serving. It stated that the amount of sucrose or other sweeteners in their recipes should not be used in the context of support for defining this claim. Accordingly, the agency is not defining "sugar free" as less than 4 g per serving. Consistent with this policy on "sugar free," the agency also denies the request that "sugar free" claims be accompanied by the statement, "For use in diabetic meal plans. Not a reduced calorie food."

86. A couple of comments objected to the provision in proposed § 101.60(c)(1)(ii) that a food containing added ingredients that are sugars cannot be labeled "sugar free," even though it still contains less than 0.5 g of sugars. One comment stated that FDA should not distinguish between trivial amounts present naturally, and those present because they were added. Other comments supported the proposal. They agreed that the listing of a sugar, for example, as an ingredient of a product bearing a "sugar free" claim is confusing and misleading. One comment expressed concern that the agency is allowing ingredients containing sugars, such as fruit juices, to sweeten foods that bear a "sugar free" claim. Other comments suggested that the confusion could be eliminated if the label of a "sugar free" food that has ingredients containing sugars disclose that the amount of sugar is trivial. Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of ingredients that are sugars to foods that bear a "sugar free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be revised and that a disclosure statement be required to avoid consumer confusion about the quantity of sugar in the food. The agency believes that it is the listing of sugar or ingredients that are generally known to contain sugars that creates the confusion. Accordingly, the agency is revising new § 101.60(c)(1)(ii) to require that the food contain no ingredient that is a sugar, or that is generally understood by consumers to be a sugar, unless the listing of the ingredient in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar."

iii. "No added sugar," and "unsweetened"/"no added sweeteners". In the general principles proposal (56 FR 60421 at 60437), FDA proposed in § 101.60(c)(2) to permit the use of the terms "no added sugars," "without added sugars," or "no sugars added" (revised in this final rule to state "no added sugar," "without added sugar," or "no sugar added" as discussed in the section on "Sugar Free"). The agency said, however, that to use the claim five conditions must be met: (1) No amount of sugars, as defined in proposed § 101.9(c)(6)(ii)(A) (redesignated as § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling publishe' elsewhere in this issue of the **Federal Register**), is added during processing c

packaging; (2) the product does not contain ingredients that contain added sugars; (3) the sugars content has not been increased above the amount naturally present in the ingredients 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 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.

The intent of the agency in defining these terms was to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation," consistent with the definition for "sugars" that FDA is adopting in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling. In implementing the guidelines, the purpose of the "no added sugar" claim is to present consumers with information that allows them to differentiate between similar foods that would normally be expected to contain added sugars, with respect to the presence or absence of added sugars. Therefore, the "no added sugar" claim is not appropriate to describe foods that do not normally contain added sugars. In such cases, proposed § 101.60(c)(3) would provide for the use of a factual statement that the food is unsweetened, or that it contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., fruit juices, without requiring that the food meet the definition for "sugar free."

87. Some comments addressed use of the "no added sugar" terms on foods containing fruit juice as an ingredient. One comment interpreted the proposal as providing that modified juice products and juice products that function as sweeteners are not to be considered as added sugars. The comment specifically requested that FDA clarify its position on this matter. Another comment stated that the use of fruit juices as sweetening agents caused problems for diabetics and suggested that the five requirements listed in new § 101.60(c)(2) for a "no added sugar" claim should be supplemented by a sixth criterion: That a food does not contain sugars in the form of fruit juice, fruit concentrate, applesauce, or dried fruit.

The agency advises that the purpose of a "no added sugar" claim is to identify a food that differs from a similar food because it does not contain the added sugars that would normally be present in the other food. For this provision to be of practical benefit to consumers, it must preclude use of the claim on a food where the sugars that are normally added are replaced with an ingredient that contains sugars that functionally substitute for the added sugars. Thus, the agency concludes that the use of any ingredient that contains sugars, including fruit juice and modified or concentrated fruit juice, for the purpose of substituting for sugars that would normally be added to a food precludes the use of the "no added sugar" nutrient content claim. To avoid misinterpretation of the regulation on this matter, FDA is revising new § 101.60(c)(2)(i) to state: "No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging."

88. One comment interpreted proposed § 101.60(c)(2) to mean that a "no added sugar" claim would not be precluded on a product such as an all-fruit spread if that product does not contain sugar-sweetened ingredients.

FDA advises that to qualify for a "no added sugar" claim, the ingredients in the all-fruit spread could not include any ingredient that meets the agency's definition of "sugars" (new § 101.9(c)(6)(ii)), or any ingredient that contains sugars that functionally substitute for added sugars (e.g., fruit juice) (new § 101.60(c)(2)(i)), nor any ingredient that contains added sugars (e.g., concentrated fruit juice) (new § 101.60(c)(2)(ii)).

89. A comment recommended that foods that contain only indigenous sugars, but not including sugars present in concentrated or otherwise altered ingredients or products, be exempt from the requirement for disclaimer and referral statements. This comment stated that a statement such as "no added sugar" is less a nutrient content claim than an assurance that the sweetness characteristics of a product are not derived from added processed sugars, such as sucrose or high fructose corn syrup, and that this information is essential to diabetics that have been instructed by a physician to seek out foods that do not have added processed sugar but instead are fruit juice based.

The comment suggested that the required disclaimer indicating that a food is not "low" or "reduced" in calories may be misleading to consumers, causing unjust alarm that a juice product is high in calories and unhealthy. As an alternative to the disclaimer, the comment favored a qualifying statement for foods sweetened with concentrated juices, such as "sweetened with concentrated grape juice."

A similar comment requested that FDA exempt pure fruit juices from the provisions of proposed § 101.60(c)(2) or revise this section by deleting proposed § 101.60(c)(2)(iv) and (c)(2)(v) (i.e., the requirements that the food that the product resembles and for which it substitutes normally contains added sugars, and that the product bear a disclaimer statement that it is not low calorie or calorie reduced and that directs the consumer's attention to the nutrition panel). The comment stated that a "no added sugar" claim on fruit juices had been used for many years without consumer confusion, that it helped to increase consumer awareness of the added sugars in flavored drinks, and that products that are pure juices do not contain added sugars. The comment also stated that consumers regard the terms "no added sweeteners" and "no added sugar" as synonymous, and that they do not regard juices as low or reduced calorie products.

The agency disagrees with the fundamental position of these comments that a special allowance for the "no added sugar" claim should be made when the sugars added to a food are inherent to the ingredient through which they are added. As discussed in comment 79 in section III.B.c.ii. of this document, the agency believes that it is misleading to imply that a food that contains inherent sugars is nutritionally superior to a food that contains refined sugars. Thus, the labeling of a product sweetened with juice concentrate, though it bears a factual statement identifying the source of the sweetener, would be misleading if it included the statement "no added sugar." The agency concludes that granting the allowances that these comments seek would permit the use of "no added sugar" in a manner that is inconsistent with the purpose of this claim, i.e., to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation." Thus, FDA is not making any changes in response to these comments.

90. One comment expressed concern that the addition of concentrated juice to unconcentrated apple juice for the purpose of achieving uniformity in the finished juice may preclude the use of the term "no sugar added."

The agency advises that the addition of a concentrate of the same juice to achieve uniformity would not, in itself, preclude the use of a "no sugar added" claim, provided, the other conditions for the claim are met. (See also the document on ingredient labeling

published elsewhere in this issue of the **Federal Register**.) If a concentrate of another juice were added for the purpose of increasing the sugar content of the finished juice, the product could not bear a "no sugar added" claim.

91. One comment sought assurance that fruit juice from concentrate that has been reconstituted to normal strength would be able to make a "no sugar added" claim.

The agency advises that the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a "no added sugar" claim; however, the other conditions for the claim must still be met.

92. Several comments requested confirmation that fruits packed in fruit juice would be able to make a "no sugar added" claim under the provisions of proposed § 101.60(c)(2). One of the comments stated that the Brix of the juice would not be above that of the fruit itself, and another noted that no refined sugars would be used in the product but only fruit juices or concentrated fruit juice.

The agency concludes that juice-packed fruits that contain juice with the same sugars content as the single strength juice of the fruit would qualify for a "no sugar added" claim, provided that the other conditions for the claim are met. This food meets the criteria for the claim in § 101.60(c)(2). If these same fruits were packed in syrup or in juice concentrate, they would not qualify for this claim under § 101.60(c)(2)(ii) because syrup and juice concentrate are ingredients that contain added sugars.

93. One comment stated that if enzymes are used primarily for flavor or texture development, or for reasons other than to intentionally alter the sugars content of a product, then the food should be permitted to bear a "no sugar added" claim. The comment maintained that although such enzymatic processes may result in a slight increase in the sugar content of the product, the increase would not necessarily alter the sweetness profile of the product. The comment expressed the view that the agency's limitation in proposed § 101.60(c)(2)(iii) for "no sugar added" for such foods is overly restrictive and not in the best interest of consumers.

The agency agrees that proposed § 101.60(c)(2)(iii) should not preclude the use of enzymes or other processes where the intended functional effect of the process is not to increase the sugars content of a food, even though an increase in sugars that is functionally insignificant does occur. FDA concludes that such a prohibition would be overly restrictive and without benefit to consumers seeking to moderate their sugars intake because any increase in the sugars content of a food from such processes would be of little, if any, consequence in the total diet. Accordingly, FDA has revised new § 101.60(c)(2)(iii) in the final rule to state:

> The sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results.

iv. Calorie free. 94. The agency received a few comments on the term "calorie free." These comments supported the proposed definition of less than 5 calories per serving. One comment preferred that the definition be less than 2.5 calories but did not object to the proposed definition.

Based on these comments, the agency concludes that no change in the definition of "calorie free" is necessary.

95. One comment requested that soda water not be used as an example of a "calorie free" food because some consumers may conclude that all diet soft drinks are "calorie free" foods.

To avoid confusion, the agency is revising new § 101.60(b)(1)(ii) to read: (e.g., "cider vinegar, a calorie free food").

v. Fat free. 96. Most of the comments on the definition of the term "fat free" supported the proposed definition of less than 0.5 g of fat per serving. A few comments disagreed with less than 0.5 g. Some of these comments stated that "fat free" should be zero fat, while at least one comment suggested that the definition should be 0.5 g or less of fat.

The agency points out that zero fat is not an option as a limit because it is analytically impossible to measure. The proposed definition of less than 0.5 g of fat is appropriate because it is the reliable limit of detection of fat in all types of foods, and thus analytically it equates to zero. Furthermore, 0.5 g of fat is low enough compared to the DRV for fat, which the agency is establishing at 65 g (§ 101.9(c)(9)), to be considered dietarily and physiologically insignificant. For example, a person consuming 10 servings per day of "fat free" foods would consume less than 5 g of fat from these sources.

The agency is not including 0.5 g in the definition because the comment that suggested this change provided no compelling reason for it. Less than 0.5 g of fat is consistent with the way "free" terms have been defined by FDA in the past and with the way the agency is defining other "free" terms in this final regulation. Accordingly, the agency has not revised this definition.

97. At least one comment suggested that "fat free" be defined in terms of the fat content per serving and per 100 g of the food. The comment noted that the density criterion would prevent foods with small serving sizes, such as crackers, from making a "fat free" claim.

The agency is not persuaded that a second criterion based on the amount of fat per 100 g is necessary for the definition of "fat free." The first criterion of less than 0.5 g of fat requires that the food contain such a trivial level of fat that even frequent consumption of foods that bear a "fat free" claim would not affect in any meaningful way the overall fat level in the diet. Accordingly, the agency has not revised the definition of "fat free." This conclusion applies equally to all of the "free" claims that are being defined.

98. A few comments recommended that "fat free" be defined solely on the basis of less than 0.5 g per 100 g.

FDA considered this approach of defining nutrient content claims solely on the amount of a nutrient in a specified weight 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. In addition, it allows consumers a means to more readily compare very dissimilar foods. However, FDA does not believe that this approach alone is appropriate for defining nutrient content claims. Foods are consumed in various amounts depending upon their nature and use in the diet. The agency believes that nutrient content claims could be misleading and not useful to consumers when expressed solely in terms of 100 g of food because this approach does not reflect amounts customarily consumed for all foods. For this reason, FDA did not take this approach in defining the term "fat free." Accordingly, the agency is not revising the definition of "fat free" in this manner.

99. Several comments objected to the provision in proposed § 101.62(b)(1)(ii) that a food containing added fat cannot be called "fat free," even though it still contains less than 0.5 g of fat per serving. One comment stated that "the agency should not speak of good faith or bad; it is simply a matter of definition and materiality." It contended that whether the fat is inherent or added should not be relevant as long as the amount present is less than 0.5 g. Comments stated that this provision would deprive consumers of the benefit of many innovative, nutritious products and argued that it would discriminate

against foods in certain categories based on dietarily insignificant amounts of fat. For example, less than 0.5 g of fat is added to some salad dressings that would otherwise meet the definition of "fat free." Furthermore, one comment noted that the proposed rule may be difficult to enforce since fat that is inherent cannot be distinguished from added fat.

Alternatively, many comments supported the proposal. They agreed that the listing of soybean oil, for example, as an ingredient of products bearing "fat free" claims is confusing and misleading. One comment said that "fat free" is a misnomer if fat has been added to the food. A few of these comments believed that even the addition of ingredients containing fat, such as nuts, should be disallowed. Other comments suggested that the confusion could be eliminated if the label of products containing any ingredient that contains fat were required to bear a disclosure statement, such as, "soybean oil (trivial source of fat)." Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of fat to foods that bear the claim "fat free" and is persuaded that it is unduly restrictive. The agency has decided to revise new § 101.62(b)(1)(ii) in the same way that is has revised § 101.60(c)(1)(ii) on "sugar free" claims and § 101.61(b)(1)(ii) on "sodium free" claims because the same considerations apply with respect to each of these claims. The agency believes that it is the listing of fats or ingredients that are generally understood by consumers to contain fat (i.e., nuts) in the ingredient statement that creates the confusion, and that a disclosure statement about the amount of fat in the food will eliminate that confusion. Accordingly, the agency is revising new § 101.62(b)(1)(ii) in the final rule to require that the listing of fats or ingredients that are understood to contain fat in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat."

vi. "Percent fat free" claims. FDA proposed several provisions in the fat/cholesterol proposal (56 FR 60478) regulating the use of "percent fat free" claims to ensure that the consumer is not misled by these claims, and that, as the claim implies, the food does in fact contain only a small amount of fat Specifically, FDA proposed in § 101.62(b)(6)(i) to require that "percent fat free" claims can only be made: (1) For "low fat" foods (i.e., foods containing 3 g or less of fat per serving and per 100 g of food) or (2) for "low fat" meal-type products (i.e., meal-type products containing 3 g or less of fat per 100 g of product).

The agency also proposed in § 101.62(b)(6)(ii) to require that a disclosure statement of the amount of total fat in a serving of food appear in immediate proximity to the most prominent "percent fat free" claim, and that such disclosure statement be in type no less than one-half the size of the type of the "percent fat free" claim. In § 101.62(b)(6)(iii), FDA proposed that the type size of all the components of the "percent fat free" claim must be uniform.

Finally, FDA proposed in § 101.62(b)(iv) that a "100 percent fat free" claim must meet all of the criteria for "fat free" claims (i.e., foods containing less than 0.5 g of fat per serving and not containing any added ingredient that is a fat or oil). Furthermore, the agency advised that if the food is inherently free of fat, the label will disclose that fat is not usually present in the food (e.g., "a 100 percent fat free food").

The agency specifically requested comments as to whether the proposed requirements were sufficient to prevent "percent fat free" claims from being misleading, or whether such claims should be prohibited entirely.

100. Although the majority of comments supported the proposal to permit "percent fat free" claims on low fat foods, several comments opposed permitting the use of this claim. The primary reason cited in these comments was that this claim is misleading and confusing to consumers. One comment further stated that if FDA allowed "percent fat free" claims, it should only allow them on foods that meet the definition of "fat free." Another comment suggested that such claims be restricted to meat and poultry products, because they help to identify leanness.

The agency acknowledges that under current regulations, the use of a "percent fat free" claim has the potential to be misleading and confusing to consumers, especially when this claim appears on foods that derive a high percentage of their calories from fat. However, the agency concludes that with implementation of the provisions of this final rule regulating the appropriate use of a "percent fat free" claim (i.e., being restricted to use on products that meet "low fat" definitions), the claim will not be misleading or confusing. Furthermore, the comments that requested that the use of this term be prohibited did not provide evidence to persuade the agency that the requirements, as proposed, were insufficient to prevent misleading claims on food labels. In addition, FDA advises that the purpose of a "percent fat free" claim on nonmeat products does not relate to leanness but to information regarding the total amount of fat present in a serving of the food.

Further, the agency believes that to allow "percent fat free" claims only on "fat free" foods would be unduly restrictive. Such claims on foods that are "low" in fat, can, if properly made, be useful in assisting consumers to maintain healthy dietary practices. Consequently, the agency is denying these requests to prohibit or restrict the "percent fat free" claim.

101. One comment stated that "percent fat free" claims on bakery products may encourage consumers to purchase such products because they are low in fat, but the comment noted with concern that bakery products are high in calories, sugar, or sodium.

The agency recognizes that certain low fat foods may contain varying amounts of calories, sugar, or sodium. However, the agency does not expect a single claim (e.g., "97 percent fat free") to provide information regarding all of the nutrients contained in a product. Information on calories, sugar, and sodium will be provided in nutrition labeling, and therefore, available to the consumer at the time he or she makes a purchase decision. Moreover, if the nutrient levels in the food exceed levels at which a disclosure statement is required, a disclosure statement must appear in close proximity to the claim.

102. A comment from a foreign government opposed permitting "percent fat free" claims. The comment stated that its laws did not permit such terms to be used because they are potentially misleading. The comment suggested that FDA should not allow such claims on products.

As discussed in the previous comment, the agency recognizes that a "percent fat free" claim under regulations currently in effect can be misleading and confusing to the consumer. However, the provisions that the agency is establishing in new § 101.62(b)(6) regulating the use of a "percent fat free" claim address the aspects of such claims currently in use that have the potential to make them confusing or misleading. Thus, the agency concludes that in light of the action that it is taking, it is not necessary to ban these claims.

103. Other comments suggested that the "percent fat free" claim should be based on the amount of total calories contributed by the fat and not on the weight of the product, because basing the claim on the weight of the product has the potential to be misleading.

The agency disagrees with the comment. FDA believes that consumers are most familiar with claims expressed in terms of g per serving, and not claims based on the percentage of calories contributed by fat. FDA further believes, as stated in the fat/cholesterol proposal, that "percent fat free" claims imply that the food contains very small amounts of fat (i.e., "low" fat), and that the food is useful in structuring a diet that is low in fat. Basing the "percent fat free" claim on a designated percentage of total calories from fat would not limit the total amount of fat present in the food. Thus, a food high in calories may be able to make a "percent fat free" claim under a calorie criterion, because the percentage of total calories contributed by the fat falls within an established guideline. Yet, the amount of fat in such foods could exceed the amount that is defined as "low" fat. On such a food, the "percent fat free" claim would be misleading. Accordingly, the agency is not permitting "percent fat free" claims to be based on the percentage of calories contributed by fat.

104. Some comments requested that the agency require disclosure of the percent of calories from fat and the amount of available calories (i.e., total calories minus calories attributed to dietary fiber).

The comments requesting disclosure statements of percent calories from fat and available calories did not provide evidence on which the agency could make a finding that such disclosures were necessary to prevent a "percent fat free" claim from being misleading. Therefore, the agency finds no basis for requiring those disclosure statements. Furthermore, the agency believes that disclosure statements based on percent of calories would confuse consumers when all other disclosure statements are based on amount of g per serving. Therefore, the agency is denying the request for these disclosure statements.

105. The comments on the proposed requirement of a disclosure statement in immediate proximity to the "percent fat free" claim which specified the amount of fat in the product were equally divided in support of and against the provision. Some comments opposing the disclosure statement argued that the disclosure statement was unnecessary because the food must meet the definition of "low fat" before a "percent fat free" claim can be made. The comments also pointed out that a referral statement will direct the consumer to the nutrition label where fat is declared.

The agency recognizes that the "percent fat free" claim may not be made on the label or labeling of a product unless the food bearing the claim is "low in fat." This fact ensures that foods bearing a "percent fat free" claim will not contribute excessive amount of fat to the total diet. Thus, upon reconsideration, FDA does not find it necessary to require that foods bearing a "percent fat free" claim also disclose the amount of total fat per serving adjacent to the claim. Further, as one comment pointed out, the "percent fat free" claim will have to be accompanied by a statement referring consumers to the nutrition label, and that the total amount of fat in the product will be provided there. In addition, as discussed in response comment 214, FDA has concluded that it is not necessary to include absolute amounts in the principal display panel. Therefore, the agency is persuaded by the comments that these requirements obviate the need for a statement, adjacent to the claim, which discloses the amount of fat per serving in the product bearing such a "percent fat free" claim, and the agency is deleting this requirement in the final rule.

106. Two comments that supported the "no percent fat free" claim stated that the 3 g limitation was too restrictive and should be raised to 4 g. A third comment supporting the "percent fat free" claim stated that the only criterion should be 3 g or less per serving and that there should not be a second criterion of 3 g or less per 100 g.

As discussed in the fat/cholesterol proposal (56 FR 60478 at 60491), a "percent fat free" claim emphasizes how close the food is to being free of fat. The agency believes that this claim implies, and consumers expect, that products bearing "percent fat free" claims contain relatively small amounts of fat and consequently are useful in maintaining a diet low in fat. Thus, the agency finds that the appropriate approach to defining a "percent fat free" claim is that it be based on the definition of "low fat." Having said this, the agency points out that these comments raise objections to the definition for "low fat." The agency's decision on the final definition of "low fat" is discussed elsewhere in this document.

107. A few of the comments supporting the provision that "100 percent fat free" claims appear only on "fat free" foods, requested that "100 percent fat free" claims should also be allowed on foods to which fat has been added, as long as the food still complies with the "fat free" definition.

Although the agency has reconsidered its definition of "fat free" to allow foods with added fat that meet the definition of "fat free" to make a "fat free" claim, the agency has not been persuaded that a "100 percent fat free" claim should appear on foods with added fat. The agency believes that a "100 percent fat free" claim places more emphasis on the complete absence of fat in the food, and therefore the food should not have added fat. Thus, the agency is not permitting a food with added fat to make a "100 percent fat free" claim.

108. One comment objected to all "percent fat free" claims under the proposal. This comment stated that a "100 percent fat free" claim can be made on a food that contains 0.4 g of fat per serving and 3 g of fat per 100 g if the fat is not added, e.g., crackers with no added fat that contain 0.4 g per serving. However, if the crackers had the same amount of fat but as added fat, the claim would have to say "97 percent fat free." The comment asserted that such inconsistencies would be misleading and confusing to the consumer. Further, another comment objected to the provision that allows some foods to claim "100 percent fat free" when in fact they contain more than 0.5 g of fat per 100 g of the food and are, therefore, not 100 percent fat free. This comment stated that proposed § 101.62(b)(6)(iv) only requires that a food bearing this claim contain less than 0.5 g of fat per serving. Thus, a food with a serving size of 20 g, for example, could contain 2.45 g of fat per 100 g of the food.

The agency agrees with the latter comment. The agency did not intend to allow foods containing 0.5 g or more of fat per 100 g to bear the claim "100 percent fat free." Accordingly, the agency is revising the final rule in new § 101.62(b)(6)(iii) to require that a "100 percent fat free" claim can be made only on foods that meet the criteria for "fat free," that contain less than 0.5 g of fat per 100 g, and that contain no added fat. This revision also addresses the problem raised in the first comment. Furthermore, the agency advises that in declaring other "percent fat free" claims, the claim must accurately reflect the amount of fat present in 100 g of the food. For example, if a food contains 2.5 g of fat per 50 g then the claim should be "95 percent fat free."

109. A few comments suggested that the "percent fat free" claim be defined separately from, and not include, the "low fat" criteria because the "low fat" definition is unduly restrictive and does

not adequately differentiate the two claims. The comments further suggested that "percent fat free" claims for foods that are between 90 and 100 percent fat free be allowed. They contended that setting a threshold level of 97 percent fat free (3 g or less per 100 g) discourages consumers from eating products that are fairly low in fat but do not conform to the proposed definition for "low" and therefore gives the impression that FDA is making good food/bad food distinctions.

As stated in response to comment 106 of this document, a "percent fat free" claim is properly viewed as a "low fat" claim because it emphasizes how close the food is to being free of fat. Furthermore, basing the "percent fat free" claim on the criteria required for "low fat" products provides the consumer with a consistent method of comparison with respect to "low fat," "fat free," and "percent fat free" claims such that accurate comparisons can be made among different products. To establish separate criteria for a "percent fat free" claim could cause confusing and misleading information to be disseminated to the consumer and, thus, be contrary to the purpose of the nutrient content claims provisions of the act.

The agency also rejects the comments proposing that claims of up to "90 percent fat free" be allowed. The agency believes that such a definition would not be consistent with consumers' expectations of the fat content of foods bearing this claim because it would allow "percent fat free" claims on foods with significantly greater amounts of fat than "low fat" foods.

Furthermore, the agency is not convinced by the comments or other available information that if FDA does not permit a "90 percent fat free" claim, consumers would be discouraged from purchasing products that are "fairly" low in fat (less than 10 g per 100 g) but that do not meet the definition for "low fat." In the absence of a "percent fat free" claim, consumers will still be able to consult the nutrition label to determine the total amount of fat contained in a product and to make purchase decisions based on this information according to their individual dietary preferences.

Although the agency does not agree that a "percent fat free" claim should be allowed for foods containing up to 10 percent fat by weight, the agency has reconsidered the basis and application of the weight-based criterion for "low fat" and "percent fat free" claims such that the weight-based criterion only applies to foods with reference amounts 30 g or less or 2 tablespoons or less (see comment 45). Further, foods with reference amounts of 30 g or less or 2 tablespoons or less may bear such claims provided that they contain 3 g or less fat per reference amount and per 50 g. Therefore, foods with small reference amounts containing 6 g or less fat per 100 g will be able to bear a "percent fat free" claim. Consequently, claims of up to "94 percent fat free" will be allowed on these products that also meet the criteria for "low fat." In addition, foods with reference amounts greater than 30 g or greater than 2 tablespoons that meet the "low fat" definition may bear "percent fat free" claims. The agency believes that permitting such claims is consistent with dietary guidelines for reducing fat intake, because it would allow such claims on a wider variety of foods for which increased consumption is recommended in national dietary guidance. This issue is fully discussed in section III.A.1.b. of this document.

110. One comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per 100 g. Another comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per serving and per 100 g; no more than 30 percent of calories from fat; and no more that 10 percent of calories from saturated fat. The comment asserted that these three criteria would ensure that a "percent fat free" claim is not misleading, yet be less restrictive than the provisions proposed in the fat/cholesterol proposal.

Another comment proposed that the definition for "percent fat free" claims be based on either: (1) The food being "low fat," where low fat is 4 g or less per serving and being at least 90 percent fat free, or (2) the product being 90 percent fat free but providing no more than 4 g of fat per serving; the label disclose the number of g of fat per serving in conjunction with the "percent fat free" claim; and the product be at least 2 g of fat per serving less than the weighted average fat level of other similar products. The comment asserted that these criteria would provide an effective and less restrictive means of drawing consumers' attention to a reduced-fat content food, while allowing the consumer more reduced-fat products from which to choose.

The agency considered the alternative criteria for "percent fat free" claims as suggested in these comments. The suggested approaches establish differences between the "low fat" and "percent fat free" claims that the agency believes are inappropriate. As explained in comment 106 of this document, consumers expect a product with a "percent fat free" claim to be low in fat, and the comments did not present evidence to FDA to demonstrate to the contrary. Consequently, the most logical approach for defining a "percent fat free" claim is to choose criteria that make the claim consistent with the definition of "low fat" or "fat free." Thus, the agency rejects the alternative approaches recommended in the comments. Furthermore, the comments suggested alternatives that require comparison of amounts of fat among different products. This approach is more consistent with the criteria used for comparative claims such as "reduced" or "less" and is not appropriate for nutrient content claims such as "percent fat free." Further, in addition to not being consistent with the definitions for "low fat" or "fat free," the suggested alternatives are based on extremely complex definitions that could result in consumer confusion concerning the meanings of the terms "low fat," "fat free," and "percent fat free."

vii. Saturated fat free. 111. A number of comments strongly recommended that FDA define the term "saturated fat free" and terms that would be synonyms for "saturated fat free." These comments argued that a "free" claim is one of the most powerful claims, and that saturated fat is one of the more important nutrients from a public health perspective. They stated that this claim would be extremely useful because the foods that would qualify are the foods that consumers are being encouraged to eat more frequently. Furthermore, the availability of this claim would provide an incentive for the development of new foods that are "saturated fat free."

Some of the comments responded to FDA's reason for not defining this term. The agency argued that since less than 0.5 g per serving is "fat free," one-third of this amount, or 0.17 g per serving, would be the appropriate definition for "saturated fat free." The agency did not propose a definition because it concluded that saturated fat could not be accurately measured at this level. The comments did not dispute this point, but they argued it is appropriate to define "saturated fat free" as less than 0.5 g of saturated fat per serving based on the same criteria used for "fat free" claims, i.e., dietary insignificance and reliable detection.

One of these comments contended that a food that is "fat free" logically must be free of saturated fat because saturated fat is included in the definition of total fat. Other comments suggested that the definition be less than 0.25 g per serving on the basis of dietary insignificance. These comments did not discuss problems with

detection, except for one comment that stated that it should not be difficult to reliably detect saturated fat at 0.25 g per serving. This comment pointed out that in the proposed rule on mandatory nutrition labeling (56 FR 60366) less than 0.25 g of saturated fat per serving is the level that can be declared as "0." Another comment noted that consumers would likely be confused if foods declaring "0" g of saturated fat in the nutrition label bear the claim "low in saturated fat" instead of "saturated fat free."

The agency is persuaded by the comments that the term "saturated fat free" would be useful to individuals trying to reduce their intake of saturated fat. It is defining this term as less than 0.5 g of saturated fat per serving because the majority of the comments on this proposed rule and on the proposed rule on mandatory nutrition labeling (56 FR 60366) that addressed this issue stated that a lower value cannot be reliably detected. FDA has been convinced by these comments, which showed that less than 0.5 g of saturated fat is the reliable limit of detection of saturated fat in all types of foods, and thus analytically it equates to zero.

The agency notes that it is aware of the concerns that trans fatty acids, which are unsaturated fatty acids, may raise serum cholesterol and has requested data on this issue. A review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. However, because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a "saturated fat free" claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of trans fatty acids to bear a "saturated fat free" claim. Thus, the agency is including a limit on trans fatty acids of 1 percent of the total fat in the definition of "saturated fat free" because the analytical techniques for measuring trans fatty acids below that level are not reliable. Accordingly, the agency is providing in new § 101.62(c)(1)(i) that the term "saturated fat free" ("free of saturated fat," "no saturated fat," "without saturated fat," "zero saturated fat," "trivial source of saturated fat," "negligible source of saturated fat" or "dietarily insignificant source of saturated fat") may be used on the label of a food if the food contains less than 0.5 g of saturated fat per serving and 1 percent or less of total fat as trans fatty acids.

Consistent with the requirements for other "free" claims, the agency is requiring in new § 101.62(c)(1)(ii) that the listing of ingredients generally understood by consumers to contain saturated fat must be accompanied by a statement such as "adds a trivial amount of saturated fat." Also, the agency is requiring in new § 101.62(c)(1)(iii) that foods meeting the definition without special processing must be labeled in a manner that makes this clear.

To accommodate this insertion, proposed § 101.62(c)(1) through (c)(3) is being redesignated as § 101.62(c)(2) through (c)(4), respectively. It should be noted that proposed § 101.62(c) required that all foods bearing claims about saturated fat should disclose the amount of total fat and cholesterol in the food in immediate proximity to such claims. As discussed in response to comment 138 of this document, the provision on the disclosure of cholesterol with these claims is required by section 403(r)(2)(A)(iv) of the act. Because FDA is now defining the term "saturated fat free," the provision on the disclosure of total fat is revised to require the disclosure of total fat with a "saturated fat free" claim unless the food contains less than 0.5 g of total fat per reference amount (i.e., unless the food meets the definition of "fat free"), in which case the amount of total fat need not be disclosed. The agency concludes that disclosure of the amount of total fat is necessary when a "saturated fat free" claim is made for a food that is not "fat free" to prevent consumers who do not differentiate between a "saturated fat free" and "fat free" claim from being misled by a "saturated fat free" claim (see comment 139 of this document for related discussion).

112. One comment requested that FDA define the term "very low saturated fat" as less than 0.5 g per serving. This comment stated that "saturated fat free" should be defined as less than 0.25 g per serving. Other comments requested that FDA define "very low" claims for other nutrients.

The agency rejects this request because it concludes that "saturated fat free" should be defined as less than 0.5 g per serving, as explained in the previous comment. Defining the term "very low saturated fat" is unnecessary because the proposed value for "low saturated fat" is only double the value for "saturated fat free." Furthermore, the agency is not defining any new "very low" terms because it believes that consumers would be confused by these terms in addition to the "free" terms. The term "very low sodium" is being retained because it has been in use for a number of years and is defined as 35 mg or less of sodium per serving, which is 7 times the cutoff level for "sodium free" and one-quarter of the cutoff level for "low sodium." Accordingly, the agency is not defining "very low saturated fat."

viii. Cholesterol free. 113. Most of the comments on the definition of the term "cholesterol free" supported the definition in proposed § 101.62(d)(1) of less than 2 mg of cholesterol per serving. A few comments disagreed. Some of the latter comments stated that a "cholesterol free" claim is misleading if the food contains any cholesterol. One of these comments suggested that a "cholesterol free" claim be accompanied by the statement, "this product may contain up to 2 mg of cholesterol." Other comments stated that "cholesterol free" should be less than 5 mg per serving, so that nonfat dairy products can make this claim. One of these comments said that changing the requirement to 5 mg or less would be an incentive to food manufacturers to reformulate products so as to make this claim. Another comment said that FDA has failed to establish that 5 mg of cholesterol would not also be dietarily insignificant.

The agency is not persuaded that the proposed value of less than 2 mg of cholesterol per serving should be changed or needs to be defined on the label. The agency selected this value because it represents the typical limit of reliable detection for existing analytical methods. A value of zero is not an option because it is analytically impossible to measure. Furthermore, 2 mg per serving is low enough compared to the DRV for cholesterol, which is 300 mg, to be considered dietarily and physiologically insignificant. As discussed in the tentative final rule on cholesterol terms of July 19, 1990 (55 FR 29456 at 29460), FDA believes that a limitation of 5 mg for the term "cholesterol free" is misleading. A person who consumes foods labeled as "cholesterol free" would expect that they would not contribute significantly to the cholesterol levels of his or her diet. Yet the consumption of 5 to 10 foods per day containing up to 5 mg of cholesterol per serving could furnish 25 to 50 mg of dietary cholesterol. This amount of cholesterol cannot be considered to be insubstantial. Moreover, the analytical limits on detecting cholesterol support a lower limit than 5 mg. Accordingly, the

agency has not revised the definition of "cholesterol free."

114. A couple of comments said that consumers are confused when they see ingredients containing cholesterol in the ingredient statement of foods bearing "cholesterol free" claims.

The agency agrees that consumers may be confused by reading that eggs, for example, are listed as an ingredient of a food bearing a "no cholesterol" claim. The agency has reviewed these comments with the many comments on fat being added to foods labeled as "fat free." The agency has been persuaded by these comments that a clarification of this issue is needed to avoid consumer confusion. The agency believes that it is the listing of ingredients, such as eggs, that creates the confusion. Accordingly, the agency is revising § 101.62(d)(1)(i)(B) and (ii)(B) in the final rule to require that the listing of ingredients that are generally understood by consumers to contain cholesterol be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol." The agency points out that because of these inserted sections, proposed § 101.62(d)(1)(i)(B) and (d)(1)(i)(C) are redesignated as § 101.62(d)(1)(i)(C) and (d)(1)(i)(D), and proposed § 101.62(d)(1)(ii)(B) through (d)(1)(ii)(E) are redesignated as § 101.62(d)(1)(ii)(C) through (d)(1)(ii)(F).

115. A few comments requested that FDA ban all cholesterol content claims. The comments argued that dietary cholesterol has an insignificant impact on blood cholesterol levels compared to saturated fat, and that the response to dietary cholesterol varies from individual to individual.

The agency is denying this request. The Surgeon General's report (Ref. 4) and the NAS report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 12) considered the evidence on the effect of diet on an individual's health. One of the main conclusions from these reports is that consumption of diets high in fat, saturated fat, and cholesterol is associated with increased risk of developing certain chronic diseases. These reports recommended that Americans reduce their consumption of these substances in their diets. To help Americans achieve this goal, the 1990 amendments authorize FDA to define nutrient content claims, including those relating to cholesterol content. Accordingly, the agency is not revising the final rule to ban cholesterol claims.

116. The agency received a number of comments on the proposed saturated fat threshold (i.e., limit) that allows foods bearing "no cholesterol" claims as well as other cholesterol claims to contain only 2 g or less of saturated fat per serving. About 20 comments opposed this threshold. About half as many comments supported the proposed rule and stated that a threshold of 2 g or less of saturated fat per serving is appropriate. One comment stated that this threshold should have a second criterion of 15 percent or less of energy (calories) from saturated fat. Similarly, another comment favored a second criterion of 6 percent or less of saturated fat on a dry weight basis. The comments recommending a different threshold were almost evenly divided between a higher value and a lower value. One comment requested that the threshold apply only to "cholesterol free" and "low cholesterol" claims, not to comparative claims. Other comments stated that foods bearing cholesterol claims should contain no saturated fat.

Many of the comments opposing the threshold on saturated fat with cholesterol claims were from manufacturers of dairy products that have up to 95 percent of their cholesterol removed. These products contain more than 2 g of saturated fat per serving. The comments stated that cholesterol claims should be allowed on these products regardless of their saturated fat content. They contended that the proposed saturated fat threshold is inappropriate and unduly restrictive because the relationship of cholesterol and saturated fat has not been satisfactorily defined. A few comments against the threshold favored disclosure of saturated fat. One comment said that disclosure of saturated fat, rather than a threshold, would be more consistent with the 1990 amendments (section 403(r)(2)(A)(iii)(II) of the act). They stated that a saturated fat threshold based on section 403(r)(2)(A)(vi) of the act fails to take into account the fact that certain foods containing more than 2 g of saturated fat may contain "substantially less" cholesterol than foods for which they might substitute.

Some of the comments for a higher threshold recommended a value of 3 g or less of saturated fat per serving. The comments said that this threshold would allow nuts and peanut butter to make a "no cholesterol" claim. A few comments stated that the threshold should be 4 g or less to be consistent with the level of saturated fat above which risk is likely to increase and disclosure is required. One comment stated that consumers believe that cholesterol is found in all fats and oils. They argued that claims are needed to help consumers select foods that do not contain cholesterol, rather than foods that do contain cholesterol (e.g., margarine for butter).

Most of the comments for a lower threshold recommended 1 g or less of saturated fat per serving and 15 percent or less of calories from saturated fat, to be consistent with the definition of "low in saturated fat." One comment suggested that the first criterion be 1.5 g or less of saturated fat per serving, and another comment suggested that the second should be no more that 7 calories from saturated fat per 100 calories.

These comments were concerned that the threshold proposed would encourage a proliferation of inappropriate cholesterol claims. Also, they were concerned that consumer education efforts would be hampered by a saturated fat limit of 1 g for "low in saturated fat" claims, of 2 g for cholesterol claims, and of 4 g for disclosure of saturated fat (e.g., a product bearing a sodium claim that contains more than 4 g of saturated fat per serving must disclose: "See [appropriate panel] for information on saturated fat and other nutrients"). The comments encouraged FDA to strive for consistency along with strictness and simplicity.

The agency is not persuaded that the saturated fat threshold should be eliminated or changed. FDA finds that there is general scientific agreement on the relationship between saturated fat and cholesterol and serum cholesterol levels. In the general principles proposal (56 FR 60421 at 60426), the agency noted that under section 403(r)(2)(A)(vi) of the act, it can by regulation prohibit a nutrient content claim if the claim is misleading in light of the level of another nutrient in the food. Further, FDA stated that it has tentatively made such a finding with regard to cholesterol claims and the presence of saturated fat, as fully discussed in the fat/cholesterol proposal (56 FR 60478 at 60495). FDA pointed out that NAS's "Diet and Health" report (Ref. 12) stated that "saturated fatty acid intake is the major dietary determinant of the serum total cholesterol and low-density lipoprotein (LDL) cholesterol levels in populations and thereby of coronary heart disease risk in populations" (56 FR 60482). Furthermore, an FDA survey has found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart

disease (Ref. 16). Consequently, FDA continues to believe that to ensure that cholesterol claims do not mislead consumers it is necessary to permit their use only when the foods also contain levels of saturated fat that are below a specified threshold level. Accordingly, the agency is denying the requests to eliminate the threshold. This decision applies to "cholesterol free," "low cholesterol," and comparative cholesterol claims.

The agency does not agree that disclosure of the amount of saturated fat in proximity to a cholesterol claim is sufficient to prevent consumers from being misled. As stated above, consumers expect foods with cholesterol claims to affect blood cholesterol levels, and saturated fat is the major dietary determinant of blood cholesterol levels. These expectations are not met if disclosure of saturated fat is permitted because the saturated fat is still present. Therefore, the agency is also denying the request to allow disclosure of saturated fat instead of a threshold.

Additionally, the agency does not agree that the saturated fat threshold should be a higher value or a lower value. The rationale for the threshold level of 2 g or less of saturated fat per serving is explained in the July 19, 1990, tentative final rule (55 FR 29456 at 29458). In summary, the value is consistent with the recommendations of recent dietary guidelines (Refs. 7, 12, and 17) that saturated fat intake should be less than 10 percent of calories. The agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the guidelines with respect to saturated fat. For this reason, the agency concludes that levels of 2 g or less are not misleading and finds no basis for lowering the threshold below 2 g.

A review of the composition of food shows that a reasonable number of foods qualify for cholesterol claims under the criteria that FDA is establishing. For example, a number of oils including soybean, corn, safflower, and olive oil, qualify for a "no cholesterol" claim (Ref. 6). Accordingly, the agency is denying the requests to change the threshold.

Finally, the agency is not persuaded that it is necessary for the threshold to have a second criterion. The agency proposed a second criterion of 6 percent or less saturated fat on a dry weight basis in the July 19, 1990, tentative final rule (55 FR 29456). In response to comments stating that the second criterion was unnecessary and would unfairly penalize foods that have a high moisture content, the agency proposed to eliminate this provision. The agency still agrees that this provision is unnecessary and is not persuaded by the comments herein to reverse this action.

117. At least one comment suggested that a food bearing a "cholesterol free" claim should have a 3 g limit on fat content. Another comment believed that such a food should be "fat free."

The agency disagrees with these comments because it has concluded that disclosure of fat on a food bearing a "cholesterol free" claim is preferable to a fat limit as fully discussed in response to comment 143 of this document. The agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels.

118. A few comments stated that a "cholesterol free" claim is misleading on a product that contains trans fatty acids. These comments stated that consumers select foods that contain no cholesterol to lower their blood cholesterol levels and argued that trans fatty acids increase these levels.

The agency understands the concerns about trans fatty acids expressed in these comments and has requested data on this issue. However, as discussed in comment 111 of this document, a review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. For this reason the agency believes that a "no cholesterol" claim on a food containing trans fatty acids is not misleading. Accordingly, the agency is making no change in the final rule in response to these comments. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

2. Low

In the general principles and fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "low" for total fat, saturated fat, cholesterol, sodium, and calories. The agency stated that it did not believe that the term "low" should necessarily mean that a nutrient is present in a food in an inconsequential amount, as with "free," but rather that the selection of a food bearing the term should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients.

FDA proposed the terms "little" or "few," "small amounts of," and "low source of" as synonyms for the term "low" and specifically requested comments on how consumers commonly understand the meaning of all these terms. The agency also asked whether the terms are in fact synonymous.

FDA also proposed that "low" claims used on foods that inherently contain low levels of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. General comments. 119. A few comments addressed the concept of using 2 percent of the DRV per serving as the starting point in defining "low" claims. These comments questioned FDA's statement that 2 percent or more of the DRV is a "measurable amount." They said that amounts under this level could be measured accurately as evidenced by the fact that less than 0.5 g of fat per serving, or less than 1 percent of the proposed DRV, is the cutoff proposed for the "fat free" claim.

The agency agrees with this comment that amounts of fat less than 2 percent of the DRV for this nutrient can be measured accurately. The agency believes that, in general, less than 0.5 g of fat per serving represents the cutoff below which fat cannot be measured accurately in all food matrices and thus was the level chosen to define "fat free" (56 FR 60484, November 27, 1991). The agency acknowledges that its discussion of a "measurable amount" being 2 percent or more of the DRV of a nutrient in a serving of a food is not clear (56 FR 60439). This terminology was taken from § 101.3(e), issued in 1977, which describes how foods are to be named, and under what circumstances the word "imitation" must precede the name of a food that has a decreased level of an essential nutrient. FDA determined that nutrients present at a level of 2 percent or more of the U.S. RDA were present in a "measurable amount" and thus were of sufficient importance to be considered in deciding whether a substitute product should be labeled as an "imitation."

In the proposed rule, the agency selected less than 2 percent as the starting point in defining "low" claims based on the precedent established in § 101.3(e) that a decrease of a nutrient in a food by this amount was not sufficiently important to the diet to justify concern. Thus, the agency

tentatively concluded that this level was appropriate to use in defining "low." In this context, the agency did not mean to imply by the words "measurable amount" that lower amounts could not be measured. Given this explanation, the agency concludes that no changes are necessary in response to these comments.

120. At least one comment requested that the definitions for the nutrient content claims "free" and "low" not overlap. For example, "low cholesterol" should be defined as 2 to 20 mg of cholesterol rather than less than 20 mg of cholesterol per serving.

The agency agrees that a "low" claim on a product that could make a "free" claim could be confusing. However, FDA concludes that it is not necessary to make these definitions mutually exclusive because it is unlikely that a "low" claim would be used on a food that is eligible to bear a "free" claim. Accordingly, the agency is denying this request. However, the agency advises manufacturers to use the most appropriate claim to avoid confusion.

121. A few comments requested that FDA define "low sugar." One comment requested that FDA define this term as 3 g or less of sugar per serving or less than or equal to 10 percent sugar for the cereal category. This comment stated that because there is such a large number of products from which to select, it is important that cereals that are low in sugar be able to communicate this fact to consumers. Of the 180 products that label sugar content, about 20 percent contain 3 g or less of sugar per serving. Also the comment stated that 3 g of sugar provide 12 calories, which is 10 percent of the calories contributed by a typical 1-ounce serving of cereal. This comment also requested that "very low sugar" be defined as one-half of the quantity for "low sugar" or 1 g or less of sugar per serving. Another comment recommended a definition of 5 g or less of sugar per serving. This comment stated that presently 20 percent of adult caloric intake is attributed to sugar. Using an arbitrary 25 percent decrease in this level, a reference diet of 2000 calories, and 20 servings per day, the comment computed a value of 5 g for the cutoff. Using the same rationale, this comment requested that "very low sugar" be defined as 3 g or less of sugar per serving.

The agency does not believe that these comments provide an acceptable basis for defining "low sugar." The fact that 20 percent of cereals may contain 3 g or less of sugar per serving is not a sufficient reason to define "low sugar" in this manner, even for cereal. Likewise, a value based on a 25 percent decrease from current intake is not a sufficient basis to define this term. To be consistent with the approach the agency has taken for other "low" definitions, a definition for a "low" level of sugar would have to relate to the total amount of the nutrient recommended for daily consumption, as discussed in the general principles proposal (56 FR 60439). However, because the available consensus documents do not provide quantitative recommendations for daily intake of sugars, FDA is not proposing a reference value for this nutrient. The agency concludes that without a reference value for sugar intake, the term "low sugar" cannot be defined. For the same reason, the agency is also not defining the term "very low sugar." Accordingly, the agency is not accepting the recommendations of this comment. The agency points out, however, that much of the information that these comments seek to convey can be communicated by use of a "reduced sugar" or "less sugar" claim made in accordance with new § 101.62(c)(4).

b. Synonyms for low. Several comments discussed synonyms for the descriptive terms "low" and "very low" that FDA defined in the general principles and fat/cholesterol proposals. The agency notes that it defined "very low" only in the context of sodium claims (i.e., "very low sodium").

122. One comment offered the term "lowest" as a synonym for "low" and suggested that it be applicable to all nutrients for which FDA is defining "low" nutrient content claims.

FDA disagrees with this comment because "lowest" is a comparative term that describes the position of a product with regard to one or more of its attributes relative to that of other products within a particular category. Therefore, FDA believes that "lowest" is not an appropriate synonym for "low," and the agency is not adopting this suggested term.

123. Two comments suggested that terms like "short" or "small" be permitted as synonyms for "low."

These comments did not provide supporting information to persuade the agency that consumers commonly understand the terms "short" or "small" to have the same meaning as "low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule. The agency has, however, provided for the use of "a small amount of" as a synonym for "low."

124. One comment offered the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" as synonyms for "very low."

The agency notes that it has defined the term "very low" only for of sodium content claims and has not provided for any synonyms for this term. The comment did not provide supporting information to persuade the agency that consumers commonly understand the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" to have the same meaning as "very low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "very low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule.

c. Specific definitions. i. Low and very low sodium.

125. Some comments disagreed with the agency's proposal to retain 140 mg as the level for "low sodium, contending that the basis of the definition for this term should be consistent with that for other nutrients, which would result in "low sodium" being defined as 96 mg or less per serving, i.e., 4 percent of the DRV. One comment specifically opposed lowering the criterion to 96 mg per serving, noting that it is important to retain consistency with existing definitions. Others argued that the sodium/salt sensitive portion of the population is small in number, so that there would be little public health benefit in reducing the "low sodium" definition. Other comments generally contended that consumers are familiar with 140 mg through its widespread use in describing "low sodium" foods over the last 8 years, and that there have been no apparent problems. One comment proposed that "low sodium" claims should be allowed on foods containing 10 percent of the DRV, per serving or per 100 g. It provided no basis for this suggestion which would result in increasing the cutoff level for "low sodium" foods from 140 mg to 240 mg.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "low sodium." As discussed in the general principles proposal (56 FR 60421 at 60441) and noted by some of the

comments, the descriptive terms for sodium have been in use for approximately 8 years, and the agency believes that consumers are familiar with them. In general, comments received in response to the 1989 ANPRM and at the public hearings that followed, did not indicate a need for change, and most of the comments to this rulemaking supported the existing criteria, even though it was not derived in the same manner (i.e., which would have yielded a value of 96 mg per serving) as other "low" claims.

The agency also disagrees with comments suggesting a definition for "low sodium" of 240 mg per serving. If the definition were established at this level, a person could easily exceed the DRV for sodium (e.g., if more than 10 foods are consumed per day which are "low sodium"). This result would be inconsistent with dietary recommendations and with the approach that FDA is taking in defining other terms. As discussed in the general principles proposal (56 FR 60421 at 60439), the agency believes 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. Therefore, the agency is retaining its criteria for "low sodium" claims.

126. Many comments agreed with the proposed definition for "very low sodium," stating that it is useful and has come to be understood by consumers. However, one comment stated that the term is not necessary.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "very low sodium." "Very low sodium foods" will be useful to individuals in the population wishing to reduce their total sodium intake to a more moderate level and will be especially useful to individuals on medically restricted diets (see 56 FR 60441). In general, comments received in response to the 1989 ANPRM and at the public hearings did not indicate a need for change, and most of the comments to this rulemaking supported keeping the existing criteria. Therefore, the agency is retaining 35 mg as the eligibility level for "very low sodium" claims.

ii. Low calorie. 127. Many comments agreed with the agency's definition of "low calorie." Some comments, however, disagreed. One comment suggested that "low calorie" be defined at 4 percent of the DRV or RDI, rather than the 2 percent. One comment suggested that the maximum calorie level was too low, and that only a few products would qualify to make a "low calorie" claim.

The agency agrees with the majority of the comments that 40 calories or less is the appropriate per serving criterion for the "low calorie" definition. FDA is not persuaded by the comments or by its own review of the calorie content of foods (Ref. 18) that increasing the per serving allowance in the definition of "low calorie" is prudent if the term is to be useful to consumers attempting to control their intake of calories.

As explained in the general principles proposed rule (56 FR 60439), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. While a DRV for calories has not been established, FDA used a reference caloric intake of 2,350 calories for reviewing the definition of "low calorie" and for establishing DRV's for other nutrients. As discussed in the RDI/DRV final rule published elsewhere is this issue of the **Federal Register**, FDA has changed the reference caloric intake to 2,000 calories. Using the general approach described above, 2 percent of 2,000 calories computes to 40 calories. Accordingly, the agency is not changing the per reference amount criterion for the definition of "low calorie."

128. One comment suggested that the definition of "low calorie" should be based on foods that can be eaten freely without adding significantly to the caloric content of the total diet.

FDA disagrees with this comment. The term "calorie free" already describes foods that can be eaten freely without adding significantly to the caloric content of the total diet. Accordingly, the agency is not defining "low calorie" in this manner.

iii. Low fat. 129. Only a few comments supported proposed § 101.62(b)(2) that defines "low fat" as 3 g or less per serving and per 100 g of the food. Most of the comments on this issue objected to the second criterion of 3 g or less per 100 g. Some of these comments suggested alternatives to the second criterion.

The second criterion for the term "low fat," as well as the second criterion for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the first criterion of 3 g or less per serving.

The majority of the comments recommended that "low fat" remain at 3 g or less per serving. About 20 comments requested that the cutoff be 4 g or less per serving. These comments argued that defining "low fat" in this manner could still lead to a significant reduction of fat in the total diet as well as allow more flexibility for product development. A few comments requested that the cutoff be at more than 4 g per serving.

Some of the comments that requested that the cutoff be 4 g or less presented the following rationale: A diet of 2,350 calories per day with 30 percent of calories from fat allows a maximum of 78 g of fat per day. The typical adult consumes 20 servings of food per day. These comments estimated that 13 of these servings contain fat. Dividing 78 g by 13 gives an average of 6 g of fat. Based on this reasoning, 4 g of fat would be below the average of 6 g (a 1/3 reduction) and could be considered to be "low fat."

These comments pointed out that if each of 13 servings of foods contained 4 g of fat, the total amount of fat would be only 52 g, well short of 78 g. Another comment based its calculations on 10 servings of food containing fat. It observed that if 5 of 10 fat-containing foods had 4 g, they would provide 20 g of fat in the diet. Thus, the other 5 servings could contain 11 g of fat each for a total of 75 g, which was the proposed DRV for fat. Other comments stated that 4 g or less of fat per serving is appropriate because even if all 20 servings of food a day contained 4 g of fat (i.e., less than 5 percent of the DRV), the daily total would slightly exceed the DRV.

The agency agrees with the majority of the comments that 3 g or less of fat is the appropriate per serving criterion for the "low fat" definition. FDA is not persuaded by the comments or by its own review of the fat content of foods (Ref. 19) that increasing the per serving allowance in the definition of "low fat" is necessary or prudent if the term is to be useful to consumers attempting to control their intake of fat.

As explained in the fat and cholesterol proposed rule (56 FR 60486), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for such a nutrient's uneven distribution in the food supply. This adjustment recognizes the practice of dietary planning in which a person consumes, in a day, a reasonable number of servings of foods labeled as "low," balanced with a number of servings of foods that do not contain the nutrient in question and a number of servings of foods that contain the nutrient at levels

above the "low" level and is still able to stay comfortably within the guidelines of the various dietary recommendations (Refs. 7, 12, and 17)

With respect to fat, current dietary guidelines recommend that a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,000 calories per day would allow for consumption of a maximum of 67 g of fat per day. FDA is adopting this value rounded to 65 g as the DRV for fat. Two percent of the DRV is 1.3 g, which rounded to the nearest one-half g would be 1.5 g.

The agency is not using 1.5 g as the cutoff of a "low fat" claim, however, because fat is not ubiquitous in the food supply. Because fat is not ubiquitous but is found in more than a few food categories, FDA concludes that an appropriate upper limit for a "low fat" claim should be set at two times 2 percent of the DRV or 3 g per serving. The agency remains convinced that this amount is a reasonable definition for "low fat" because an average level of 3 g in 16 to 20 servings of food per day (balancing the number of foods that do not contain fat with those that contain higher levels of fat to yield an average of 3 g of fat per serving) would supply 48 to 60 g of fat daily, within the DRV of 65 g of total fat. An average level of 4 g in 16 to 20 servings would supply 64 to 80 g of total fat, exceeding the DRV. Similarly, an average of 5 g would supply 80 to 100 g of fat. For this reason the agency concludes that 4 g or more of fat per serving is not an appropriate definition for "low fat." Accordingly, the agency is not making the suggested change.

130. Some of the comments that requested that FDA change the definition of "low fat" (proposed § 101.62(b)(2)) to 4 g or less of fat per serving also requested that FDA define "very low fat." They stated that 2 g or less of fat per serving could be considered "very low fat" if 4 g or less of fat were the definition of "low fat." One comment offered the rationale that on a per serving basis, "very low fat" should be 0.5 g to 2 percent or less of the DRV (based on 75 g of fat) for fat, and "low fat" should be 5 percent or less of the DRV.

The agency is rejecting this recommendation because it is based upon an increase in the proposed definition of "low fat," which the agency is not making as explained in the previous comment. Also, as discussed in response to comment 124 of this document, additional "very low" terms will be confusing to consumers. Accordingly, the agency is not defining "very low fat."

131. At least one comment recommended that "low fat" foods be defined only as those foods containing no more than 3 g of fat per 100 g. The reason given for this recommendation is that it would simplify the comparison of foods.

As explained in response to a similar suggestion for "fat free" claims (see comment 98 of this document), FDA does not believe that this approach alone is appropriate for the definition of nutrient content claims because it does not adequately account for the way foods are consumed.

132. A few comments objected to the agency's approach of defining "low fat" in terms of g of fat per serving (proposed § 101.62(b)(2)(i)). One comment recommended that a "low fat" food be defined as a food having no more than 30 percent of calories derived from fat. Other comments recommended limits of 25 percent and 20 percent of calories derived from fat. Similarly, another comment stated that a "very low fat" food should have no more than 10 percent of calories derived from fat.

The agency disagrees with this suggestion for several reasons. Dietary recommendations to obtain no more than 30 percent of calories from fat are aimed at the total diet, not at individual foods. The agency believes that expressing claims in terms of g per serving as the basis for all "low" nutrient content claims is preferable because this amount is absolute. The percent of calories from fat varies disproportionately with the total number of calories in a food. If the number of calories is low, the percent of calories from fat can be relatively high. For example, the percent of calories from fat for radishes is over 25 percent. Thus, they would not be considered a "low fat" food using one of the approaches suggested. In fact, radishes contain only about 0.3 g of fat per serving and qualify as a "fat free" food using FDA's approach. Consequently, FDA concludes that the requested approach can be extremely misleading especially when applied to certain categories of foods that are consistent with recommended diets (e.g., fresh fruits and vegetables).

Furthermore, FDA recognizes that consumers are most familiar with nutrient content claims being expressed in terms of g per serving. Comments that the agency has received in response to the 1989 ANPRM and in the public hearings that followed also supported continued use of serving sizes in the definition of nutrient content claims, as did the IOM report (Ref. 14). Finally, one of the goals of nutrient content claims is to help consumers construct a diet that is consistent with dietary guidelines. Claims based on absolute per serving amounts are much easier to use in this way than claims based on percentages computed for the individual food. Accordingly, the agency is not defining "low fat" in terms of percent of calories from fat.

133. A number of comments suggested that FDA should vary the quantitative definition of "low fat" according to food category and designate as "low" those foods that are relatively low compared to other foods in the same food category. In support of this approach, the comments argued that a single criterion may cause consumers to avoid food categories in which no foods qualify for a claim, making the task of educating consumers about appropriate choices within those categories more difficult.

The agency considered this approach and is rejecting it for the reasons discussed in the general principles proposal (56 FR 60421 at 60439). In summary, the agency believes that relative claims can be used to highlight certain foods in the same food category. The use of different criteria for "low fat" foods in different food categories would make it difficult for consumers to compare products across food categories and to substitute one food for another in their diets. Furthermore, this approach would make it possible for some foods that did not qualify to use the nutrient content claim to contain less fat than foods in other categories that did qualify. FDA has received many comments asking for consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report (Ref. 14) recommended such consistency. None of the comments provided any basis for why these factors should not be controlling. Accordingly, the agency will not vary the quantitative definition of "low fat" from food category to food category.

134. At least one comment suggested that foods be described as "low fat" if they contain one-third less fat than the "regular" food.

FDA disagrees with this terminology because it believes it is not appropriate. However, FDA agrees that foods with a one-third reduction in fat content compared to an appropriate reference food should be able to make a claim and is providing in new § 101.62(b)(4) that such foods may be described as "reduced fat" or "less fat." Consequently, the agency concludes that no change is warranted in response to this comment.

135. One comment suggested that a food that is "low fat" should also be

"low cholesterol," and that the descriptor should be "low fat/low cholesterol." Using the same rationale, the comment suggested that the claim "fat free/cholesterol free" be used in place of "fat free" and "cholesterol free." Another comment expressed concern about "fat free" being used to describe foods that contain high levels of cholesterol.

The agency believes that this approach is overly restrictive and is not in accord with section 403(r)(2)(B)(ii) of the act, which provides that cholesterol should be identified on the PDP (i.e., "See ———— panel for information on cholesterol and other nutrients") only at levels associated with increased risk taking into account the significance of the food in the total diet. The agency has determined that these levels for cholesterol are those exceeding 20 percent of the DRV or 60 mg of cholesterol per reference amount, per labeled serving size, or, for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g of food. Section 403(r)(2)(A) of the act, which makes special provisions for cholesterol, saturated fat, and fiber claims, makes no such provision for fat claims. Accordingly, the agency is making no change in response to these comments. The agency notes that it is unaware of any "fat free" foods that contain 60 mg cholesterol.

iv Low saturated fat. 136. The agency received several comments on proposed § 101.62(c)(1) which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids. Most of the comments supported the criterion of 1 g or less per serving. Other comments requested that the cutoff be a higher value. One comment stated that this claim should be defined only in terms of percent of calories from saturated fat but did not suggest a percentage. Another comment stated that it would be more appropriate to permit this claim on foods that are high in total fat and relatively low in saturated fat but did not make a specific recommendation.

The second criterion for the term "low in saturated fat" is discussed in comment 137 of this document. In this section, the agency is addressing the comments on the first criterion of 1 g or less of saturated fat per serving.

The comments recommending a cutoff of 2 g per serving stated that this value would be consistent with Canada's definition of "low in saturated fat" and with the proposed saturated fat threshold on cholesterol claims. They pointed out that FDA's rationale for the 2 g threshold is that it is consistent with current dietary recommendations that 10 percent of calories come from saturated fat. One comment complained that a cutoff of 1 g would result in canola oil being the only oil able to bear this claim. The comment said that this oil is very minor in both production and consumption in the United States. It alleged that FDA has failed to recognize the strong body of scientific evidence that consumption of polyunsaturated fat lowers blood cholesterol. The comment contended that in terms of its effect on blood cholesterol, the effect of the low saturated fat content of canola oil is negated by its polyunsaturated fat content. The comment said that it has been shown conclusively in humans that both corn oil and soybean oil are better than canola oil in lowering serum cholesterol. The comment argued that the proposed definition "is clearly discriminatory, arbitrary, and ill-serves the U.S. industry and the consumer."

Another comment, which supported a definition of 2 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat, presented data that it claimed showed that saturated fat intake both for the total population and the 90th percentile is basically identical whether the first criterion is 1 or 2 g per serving. It concluded that a cutoff of 1 g would unreasonably restrict consumer choices of foods with no dietary impact on saturated fat.

The agency has reconsidered this issue and agrees with the majority of the comments that 1 g or less is the appropriate per serving criterion for the "low in saturated fat" claim, which is the proposed value. FDA is not persuaded by the arguments or by its own review of the saturated fat content of foods (Ref. 20) that increasing the per serving allowance in the definition is necessary or prudent if the term is to be useful to consumers attempting to control their intake of saturated fat. FDA acknowledges that only a limited number of fats and oils will be able to make this claim but points out that in addition to canola oil, high oleic safflower oil, almond oil, apricot kernel oil, and hazelnut oil qualify. Also, mayonnaise type salad dressing and various types of low calorie salad dressings can make this claim. With respect to the statement that corn oil and soybean oil are better than canola oil in lowering serum cholesterol, the agency notes that this statement was not supported by data in the comment.

As explained in the fat/cholesterol proposed rule (56 FR 60486) and in the section on "low fat" in this final rule, FDA is defining "low fat" as 2 percent of the DRV for fat times two to adjust for the fat distribution in the food supply, or 3 g of fat per serving. Using the same approach for saturated fat and the recommendation of current dietary guidelines (Refs. 7, 12, and 17) that the consumption of saturated fat be less than 10 percent of calories, the agency concludes that "low in saturated fat" should be defined as 1 g or less per serving.

This conclusion reflects the fact that total fat and saturated fat have similar distributions in the food supply. An FDA analysis has determined that both total fat and saturated fat are present in over half of 18 USDA-defined food categories (Ref. 21). For the purpose of that analysis, a nutrient was considered to be "present" in a food category if over one-half of the foods in the category contained 2 percent or more of the proposed DRV. Further, the agency remains convinced that this amount is a reasonable definition for "low in saturated fat" because an average level of 1 g in 16 to 20 servings of food per day would supply 16 to 20 g of saturated fat daily, within the DRV for saturated fat of 20 g (§ 101.9(c)(9)(i)). An average level of 1.5 g in 16 to 20 servings per day would supply 24 to 30 g of saturated fat, exceeding the DRV. Similarly, an average level of 2 g would supply 32 to 40 g of saturated fat. For this reason, the agency concludes that 1.5 g or more of saturated fat per serving is not an appropriate definition for "low in saturated fat." Accordingly, the agency is denying the requests that the cutoff for the per serving criterion be increased or eliminated.

137. Some comments recommended that the second criterion in proposed § 101.62(c)(1), which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids, be eliminated, and a few comments suggested that it be changed to a lower value.

The comments that recommended that the second criterion should be eliminated said that this criterion prevents claims on some of the foods recommended by NCEP for lowering saturated fat intake. Also, one comment pointed out that when fat is reduced in a food that is relatively low in saturated fat, the percent of calories from saturated fat is increased (i.e., a food able to make this claim could be disqualified by fat removal). Other comments stated that the second criterion is not needed because manufacturers will no longer be able to manipulate serving size. Furthermore, one comment contended that there is no evidence that foods that are nutrient dense are consumed in excess. A few comments said that "percent of calories

from saturated fat" should apply to the total diet, not to individual foods, and that 15 percent is inconsistent with the guidelines. Values of 10 percent and 7 percent were recommended.

The agency is not persuaded by the comments that it should eliminate the second criterion or lower this value. The agency continues to believe that a second criterion is needed to prevent misleading "low" claims on nutrient-dense foods with small serving sizes. The second criterion in the agency's definition for "low in saturated fat" is for this purpose. A general discussion of second criteria for "low" claims may be found in section III.A.1.b. of this document.

The agency agrees with the comment that "percent of calories from saturated fat" generally should apply to the total diet, not to individual foods. For this reason, the agency did not accept the recommendation that a "low fat" food should be defined as having no more than 30 percent of calories derived from fat as discussed in response to comment 132 of this document. The agency also pointed out in comment 132 of this document that for a given level of fat, the "percent of calories from fat" varies with the total number of calories in a food, that is, this approach focuses on the relative amount of the nutrient present in the food rather than the absolute amount. If the number of calories is low, the percent of calories from fat is relatively high. The percent of calories from saturated fat can increase either by increasing the amount of saturated fat or by decreasing the amount of total calories. As one comment observed, removal of fat could make the percent of calories from saturated fat increase, conceivably disqualifying a food from making a "low in saturated fat" claim. However, as stated above, this second criterion is necessary to prevent misleading "low in saturated fat" claims. As explained in the fat and cholesterol proposed rule (56 FR 60478 at 60492), the agency selected a second criterion of no more than 15 percent of calories from saturated fat because it tentatively determined that the approach used in selecting the second criterion for the other "low" claims yielded a criterion that was too restrictive (i.e., less than 1 g of saturated fat per 100 g of food). Consequently, FDA sought a different approach and considered the criteria of other nations. FDA found merit in Canada's approach of no more that 15 percent of calories coming from saturated fat, although the agency does not agree with Canada's first criterion of 2 g or less of saturated fat per serving. While dietary recommendations are for less than 10 percent of calories in the diet being provided by saturated fat, the fact that saturated fat is not ubiquitous in the food supply would allow higher amounts in those foods that contain saturated fats to balance off those that are lower, resulting in a total daily diet that meets dietary recommendations.

An examination of food composition data (Ref. 20) reveals that a regulation that allows foods containing 1 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat to make a "low in saturated fat" claim results in a reasonable number of foods being able to make this claim. These foods include most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; a few nondairy cream substitutes and dessert toppings; egg substitutes; mayonnaise type salad dressing, low calorie salad dressings, canola oil, and high oleic safflower oil; fish and shellfish; many cereals, breads, and soups; and some cookies and candies. However, evaporated milk, non-dairy desert toppings, and margarine spreads will not be able to make a "low in saturated fat" claim because the percent of calories from saturated fat in these foods exceeds 15 percent. "Low in saturated fat" claims on these foods would be misleading because they do not contain especially low levels of saturated fat.

The agency acknowledges that this definition prevents this claim from appearing on some of the foods that NCEP recommends be used as substitutes for other foods in achieving a lower intake of saturated fat. For example, the NCEP recommends using skim or 1 percent fat milk as a substitute for whole milk, and 1 percent fat milk will not be able to make a "low in saturated fat" claim. The agency agrees with NCEP's recommendations but does not believe that all such substitute foods, including 1 percent fat milk, are necessarily "low in saturated fat." The NCEP, in many cases, recommends selections that are "lower" in fat than the foods for which they substitue in the diet. The agency continues to believe that this claim should enable consumers to easily identify the foods that contain especially low levels of saturated fat, and that the proposed definition achieves this purpose. Accordingly, the agency is denying the request that the second criterion of no more than 15 percent of calories from saturated fat be eliminated or changed in value.

138. At least one comment requested that FDA eliminate the requirement in proposed § 101.62(c) that the amount of cholesterol be disclosed in proximity to the claim "low in saturated fat." The comment stated that disclosure of cholesterol is unwarranted because dietary cholesterol has no effect on serum cholesterol levels. Other comments supported the proposed rule with respect to disclosure of cholesterol. At least one comment stated that the cholesterol disclosure is too lenient. This comment stated that a "low in saturated fat" claim should only be allowed on foods that never contain cholesterol.

The agency points out that the provision on the disclosure of cholesterol with a "low in saturated fat" claim, as well as the other saturated fatty acid claims, is required by section 403(r)(2)(A)(iv) of the act. Accordingly, the agency is making no change in response to these comments. The effect of dietary cholesterol on serum cholesterol levels is discussed in response to comment 115 of this document requesting that all cholesterol claims be banned.

139. A few comments objected to the requirement in proposed § 101.62(c) that the amount of fat in a food be disclosed in proximity to the claim "low in saturated fat." One comment said that this provision goes beyond the demands of the 1990 amendments and is unwarranted. Another comment requested an exemption from fat disclosure for margarine. The comment said that it is unfair because disclosure is not required for butter. One comment stated that fat disclosure is only necessary for products that contain excessive fat. The comment recommended that fat disclosure be required only if the fat level exceeds 11.5 g per serving and noted that such a requirement would be consistent with the level at which fat is disclosed with cholesterol claims. Comments said that at the very least, fat disclosure should not be required at levels of 3 g or less per serving (i.e., a "low fat" food would not have to have a fat disclosure). Another comment recommended that if the fat level of a food exceeds 11.5 g per serving, the label should state, "high in fat." It said that stating the amount of fat is not meaningful to most consumers. Other comments supported the proposed rule with respect to disclosure of fat.

The agency agrees that this provision is not required in the 1990 amendments and is persuaded that fat disclosure should not be required at levels of 3 g or less per serving. The agency concludes that such disclosure is unnecessary because 3 g or less is the per serving criterion for the term "low fat." A consumer who does not differentiate between a "low in saturated fat" and "low fat" claim

would not be misled by a "low in saturated fat" claim as long as the fat level of the food is 3 g or less per serving. For uses of "low in saturated fat" on foods with more than 3 g of fat, disclosure of fat content is required to avoid misleading the consumer. For this reason, the agency is denying the requests that disclosure of fat content be required only when the fat content exceeds 11.5 g per serving. The fat content is a material fact at levels above 3g when a "low in saturated fat" claim is made.

Also, the agency is denying the request that margarine be exempt from fat disclosure. The disclosure of total fat on foods (except foods that are "low fat") that bear a "low in saturated fat" claim is necessary to ensure that consumers who do not differentiate between a "low fat" and a "low in saturated fat" claim are not misled by the latter claim. The agency notes that butter is not required to disclose fat because it does not bear a "low in saturated fat" claim.

Finally, the agency is not requiring that the label of a food with a "low in saturated fat" claim state that it is "high in fat" if it contains more than 11.5 g per serving. FDA has not defined "high in fat." In addition, 11.5 g was the proposed disclosure level. As explained in comment 13, FDA has raised the disclosure level to 13.0 g of fat. However, to require a "high in fat" statement on foods that bear a claim and contain more than that level of fat would be inconsistent with the disclosure concept in section 403(r)(2)(B) of the act.

140. At least one comment stated that the "low in saturated fat" claim is misleading on a food that contains hydrogenated oil (i.e., contains trans fatty acids).

As discussed in comment 111 and 118 of this document, the evidence suggesting that trans fatty acids raise serum cholesterol remains inconclusive. For this reason, the agency finds that it cannot conclude that a "low in saturated fat" claim on a food containing trans fatty acids is misleading. Accordingly, the agency is making no change in the final rule in response to this comment. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

141. A few comments requested that "——— percent unsaturated fat" be allowed as a synonym for a claim about saturated fat. One of the comments stated that without the ability to make this claim, there is an economic incentive for manufacturers to substitute soybean oil for canola and safflower oil. They said the data do not support FDA's concern that positive claims about high fat will increase consumption.

The agency is not allowing the term "unsaturated fatty acids" to appear in the nutrition label because of uncertainty about its definition, specifically, the inclusion of trans isomers of monounsaturated fat, as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, the agency concludes that it would be inappropriate to define the term "——— percent unsaturated fat," and the agency is denying this request.

v. Low cholesterol. 142. Only a few comments supported proposed § 101.62(d)(2) that defines "low cholesterol" as less than 20 mg per serving and per 100 g of the food. Most of the comments on this issue objected to the criterion based on weight, and some of these comments suggested alternatives to this criterion.

The weight-based criterion for the term "low cholesterol," as well as for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the criterion of less than 20 mg of cholesterol per serving.

The majority of the comments recommended that "low cholesterol" remain at 20 mg or less per serving. A few comments requested that the cutoff be a lower value, and a few other comments wanted a higher value. The comments favoring a cutoff of 15 mg pointed out that many foods consumed throughout the day have ingredients that contain cholesterol (e.g., bread). They stated that the recommended intake of less than 300 mg of cholesterol per day could easily be exceeded if these foods are eaten in sufficient quantity. One of the comments favoring a cutoff of 30 mg also believed that "cholesterol free" should be less than 5 mg per serving. The comment contended that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" because the cutoff for "low fat" is six times the cutoff for "fat free."

The agency agrees with the majority of the comments that 20 mg or less cholesterol is the appropriate per serving criterion for the "low cholesterol" definition. As explained in the fat/cholesterol proposed rule (56 FR 60478 at 60486), FDA considered that a "low" claim for a nutrient that is ubiquitous in the food supply should be an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for the nutrient's uneven distribution in the food supply. If the nutrient is found at measurable levels in foods from only a few food categories, the agency proposed to define "low" as three times 2 percent of the DRV. Cholesterol, which is found only in foods of animal origin, is in this group of foods. The DRV for cholesterol is 300 mg, 2 percent of which is 6 mg. Therefore, the value for "low cholesterol" computes to 18 mg, which rounded to the nearest 5 mg increment, is 20 mg per serving.

Consequently, the agency is denying the request that the cutoff for "low cholesterol" be less than 30 mg because it concludes that this value is too high to be useful to consumers attempting to control their intake of cholesterol. Moreover, the agency disagrees with the rationale presented for 30 g that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" based on a value of 5 mg, because the cutoff for "low fat" is six times the cutoff for "fat free." The agency emphasizes that the "low" values are derived from the DRV's, not from the limit of detection. Also, the agency is denying the request that the cutoff for "low cholesterol" should be less than 15 mg on the basis that is too restrictive. Cholesterol is not so widespread in the food supply that such low levels are necessary to help consumers to structure their diets to be consistent with dietary guidelines for cholesterol. A "low cholesterol" claim based on 20 mg will be useful to consumers in structuring a total diet that is consistent with dietary guidelines.

Accordingly, the agency is not revising the final rule to change the amount allowed per serving for a "low cholesterol" claim.

143. The agency received relatively few comments on the requirement for disclosure of total fat with cholesterol claims. Some of the comments supported the provision of the proposed rule that the amount of fat must be declared next to a cholesterol claim if the fat content exceeds 11.5 g per serving or per 100 g of food. Other comments favored disclosure at other levels of fat, including all levels of fat, while some comments opposed disclosure of any amount of fat. One comment said that disclosure of the amount of fat would not be useful to the average consumer and suggested the statement, "this product is not low in total fat."

A few comments stated that the term "low cholesterol" on the label of a food containing high levels of fat is misleading, even if the amount of fat is disclosed. These comments recommended that cholesterol claims have a fat threshold above which claims are disallowed. One comment requested that a "low cholesterol" claim, as well as a "cholesterol free" claim, not be allowed on foods containing more than 3 g of fat and 0.15 g of fat per g of dry matter. This comment argued that a limit on total fat is needed to prevent manufacturers from meeting the saturated fat threshold by replacing saturated fat with trans fatty acids. As discussed in response to comment 117 of this document, another comment proposed a 3 g limit on fat specifically for "cholesterol free" claims but did not refer to "low cholesterol" claims. One other comment requested that a "low cholesterol" claim not be allowed on food containing more than 5 g of fat and more than 20 percent total fat on a dry weight basis.

The agency has reviewed this issue and continues to believe that fat disclosure is preferable to a fat limit above which the claim "low cholesterol," as well as other cholesterol claims, cannot be made. The agency has the authority under the act to establish a fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." The agency has used this authority to prohibit cholesterol claims on foods containing more than 2 g of saturated fat per serving, which is discussed in response to comment 116 of this document. However, the agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels. Thus, consumer expectations regarding blood cholesterol levels are met as long as the food contains the requisite amount of cholesterol and 2 g or less of saturated fat per serving.

The agency proposed that amounts of fat exceeding 11.5 g per serving or per 100 g of food have to be disclosed. The 11.5 g amount represents 15 percent of the DRV for fat. Disclosure of the amount of fat, rather than the statement, "this product is not low in total fat," is in accordance with section 403(r)(2)(A)(iii) of the act. This section states that the amount of total fat shall be disclosed in immediate proximity to a cholesterol claim if a food, taking into account its significance in the total diet, contains fat in an amount that increases the risk for persons in the general population of developing a diet-related disease or health condition.

In response to comments requesting that FDA modify the disclosure level in § 101.13(h) to 20 percent of the DRV, the agency is changing the final rule to provide that disclosure levels for fat are those exceeding 13 g of fat per reference amount, per labeled serving size, or, for foods with a reference amount of 30 g or less or 2 tablespoons or less, per 50 g of food. The rationale for this change is presented in the final rule on health claims, published elsewhere in this issue of the **Federal Register**.

144. About 15 comments opposed the provision in proposed § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) that the amount of cholesterol in certain foods bearing "cholesterol free" or "low cholesterol" claims must be "substantially less" than the food for which it substitutes (i.e., it must meet the requirements for a comparative claim using the term "less" in proposed § 101.62(d)(5)(i)(A)). The foods included were those that contain more than 11.5 g of fat per serving or per 100 g of food and that contain, only as a result of special processing, an amount of cholesterol per serving that meets the relevant criterion for a "free" or "low" claim. The proposed requirements for comparative claims that apply are that the food contain at least 25 percent less cholesterol, with a minimum reduction of more than 20 mg cholesterol per serving, than the reference food.

The majority of the comments opposed the minimum reduction of cholesterol of more than 20 mg. One comment contended that the requirement for a minimum reduction goes beyond the requirements of section 403(r)(2)(A)(iii)(I) of the act that the level of cholesterol should be substantially less than the level usually found in the food or in a food that substitutes for the food. Many of these comments opposed this minimum because it would disallow a cholesterol claim on products such as 2 percent milk that has up to 95 percent of its cholesterol removed. These comments also opposed the proposed saturated fat threshold because the dairy products that have undergone cholesterol removal contain more than 2 g of saturated fat per serving. These comments requested that a cholesterol claim be allowed on the label of a food, regardless of the food's fat or saturated fat content, provided that the food has at least 33 percent of the indigenous cholesterol removed, and that the content of total fat is disclosed.

At least two comments supported the proposed minimum but opposed the disclosure statement (i.e., disclosure of the percent that the cholesterol was reduced, the identity of the reference food, and quantitative information comparing the level of cholesterol in the product per serving with that of the reference food). At least one comment opposed the required minimum, the 25 percent reduction, and the disclosure statement. This comment stated that the claims "cholesterol free" and "low cholesterol" should refer to an absolute level of cholesterol rather than to a relative level.

The agency is persuaded by these comments that the minimum reduction of cholesterol of more than 20 mg is unduly restrictive because it discriminates against products containing relatively small amounts of cholesterol. Accordingly, the agency is eliminating this requirement in the final rule for the "cholesterol free" and "low cholesterol" claims as well as for comparative claims (as discussed in response to comment 158 of this document). However, the agency continues to believe that "substantially less" cholesterol should be interpreted as 25 percent less cholesterol than the reference food. Twenty-five percent represents the extent of reduction necessary to make a "less" or "reduced" claim. Consequently, the agency is denying the request that the labeled food contain 33 percent less cholesterol, or that no reduction in cholesterol be required.

Furthermore, under section 403(r)(2)(A)(iii)(II) of the act, the disclosure statement must appear in immediate proximity to the claim, as proposed. FDA is providing, however, in § 101.62(d)(1)(ii)(F)(2) and (d)(2)(iii)(E)(2) in this final rule that the quantitative information comparing the level of cholesterol in the product with that of the reference food may appear on the information panel in conjunction with nutrition labeling. The agency is making this change in § 101.13(j)(2)(iv) to prevent label clutter on the PDP, as discussed in response to comment 214 of this document. The request that a cholesterol claim be allowed regardless of saturated fat content is addressed elsewhere in this document (see comment 116 of this document), as is the need for fat disclosure with cholesterol claims (see comment 143 of this document).

vi. Lean. 145. FDA received several comments that supported use of the terms "lean" and "extra lean" with FDA-regulated meat products or meal-

type products in accordance with definitions of these terms as proposed by the Food Safety and Inspection Service (FSIS). Meal-type and main dish products are defined and fully discussed elsewhere in this final rule.

One comment requested that FDA allow use of the terms "lean" and "extra lean" on the labels of fishery products in a manner similar to that proposed by FSIS. The comment noted that the composition of some fishery products would prevent them from bearing the nutrient content claim "low fat" on their labels in accordance with the definition of this term in FDA's fat/cholesterol proposal. The comment also pointed out that FDA's general principles and fat/cholesterol proposals did not provide for use of the term "lean" or "extra lean" on the labels of fish products. However, if these foods were considered under FSIS' proposed regulation, a substantial number of them would qualify for use of the term "lean" or "extra lean" on their labels.

Another comment stated that FDA should permit product lines that contain both USDA- and FDA-regulated meal-type products to bear descriptive terms such as "lean" and "extra lean" that can be applied to the entire product line for labeling and advertising purposes. The comment further stated that, if FDA does not allow the terms "lean" and "extra lean" on food products regulated by the agency, then these terms will most likely not be used on any meal-type products. The comment also stated that the USDA proposed criterion for saturated fat should be eliminated because it is too restrictive.

These comments raise an issue that FDA finds has merit. By way of background, on November 27, 1991, FSIS published a proposed rule (56 FR 60302) on nutrition labeling of meat and poultry products. In that proposal, FSIS presented definitions of the descriptive terms "lean" and "extra lean" that would only be applicable to the meat and poultry products that FSIS regulates under the authority of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.). FSIS proposed that the term "lean" could be used to describe a meat or poultry product that contained less than 10.5 g fat, less than 3.5 g saturated fat, and less than 94.5 mg cholesterol per 100 g. The term "extra lean" could be used to describe a meat or poultry product that contained less than 4.9 g fat, less than 1.8 g saturated fat, and less than 94.5 mg cholesterol per 100 g. FSIS also proposed to permit these terms to be used to describe multi-ingredient meal-type products.

Data supplied by the American Heart Association (AHA), in response to the April 2, 1991, FSIS ANPRM (56 FR 13564) on nutrition labeling of meat and poultry products, provided the basis for the criteria that FSIS used in its proposed definitions of these terms. These data consisted of levels for total fat, saturated fat, and cholesterol of selected fresh and processed "meat" items (various types of beef, veal, pork, lamb, poultry, and fish) on a "cooked weight" basis. Using recommended food consumption patterns and dietary guidance recommendations as bases, AHA selected threshold values for fat, saturated fat, and cholesterol levels of these muscle foods on a 1 oz and 3 oz "cooked weight" basis. Threshold values for "lean" represent approximately 7 percent fat in raw meat and 10 percent fat by weight in cooked meat. Threshold values for "extra lean" represent approximately 5 percent fat by weight.

The levels in FSIS' proposed definitions were derived by converting AHA's threshold values from a 1 oz to 100 g basis. Upon making this calculation, FSIS found that the values obtained approximated the agency's criterion for use of the terms "lean" and "extra lean" on the labels of meat and poultry products as discussed in a November 18, 1987, FSIS policy memorandum 7OB(Ref. 22).

Based on comments received in response to its nutrition labeling proposal (56 FR 60302), FSIS, in a final rule published elsewhere in this issue of the **Federal Register**, has changed the rounding rule that it originally used. In addition, FSIS has developed modified criteria for levels of total fat, saturated fat, and cholesterol such that the ratio of saturated fat to total fat would be 40 percent for both nutrient content claims. FSIS considers the ratio of 40 percent to be reasonable because it is representative of the ratio of saturated fat to total fat inherent in ruminant muscle. Although AHA's suggested criteria were based upon fresh and processed cooked meat (cut or ground), in its final rule, FSIS is adopting criteria on an "as packaged" basis to achieve consistency with that agency's past labeling policy.

Under the FSIS final rule, to bear the term "lean," a meat or poultry product must contain less than 10 g fat, less than 4 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g. To bear the term "extra lean," the product must contain less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g for individual foods. The criteria in the definitions of these terms for meal-type products under the FSIS final rule are presented elsewhere in this final rule.

The comments supporting use of th terms "lean" and "extra lean" on the labels of meat products and meal-type products have persuaded FDA to include provisions in this final rule consistent with those of FSIS to provide for use of the terms "lean" and "extra lean" to describe certain comparable foods regulated by FDA under the act. In the proposal, FDA solicited comments on whether additional defined terms were needed (56 FR 60421, 60431), and these comments demonstrated that the agency needed to add terms useful for these types of foods. FDA has statutory authority to enforce the act's provisions that prohibit misbranding of all foods except for those products exempted under the act (section 902 of the act (21 U.S.C. 392)). Thus, FDA is responsible for regulation of the labeling of certain types of meat products (e.g., seafood, bison, rabbit, game meats) not regulated by USDA under the Federal Meat Inspection Act (21 U.S.C. 601–623 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451–469) or in situations in which these products are not subject to USDA regulation. In addition, FDA is responsible for regulation of meal-type products not regulated by USDA under either of the aforementioned acts.

The agency recognizes that seafood and seafood products play a comparable role in the diet to that of meat and poultry products and, like meat and poultry products, contribute to the total dietary intake of fat, saturated fat, and cholesterol. In addition, FDA-regulated meal-type products are consumed in the same manner as USDA-regulated meal-type products covered by the FSIS rule. FDA concludes that providing for use of the descriptive terms "lean" and "extra lean" as nutrient content claims on the labels of seafood (including finfish and shellfish) and meal-type products that it regulates would be of value to consumers in maintaining healthy dietary practices. The terms "lean" and "extra lean" will describe foods of these types with relatively lower levels of fat, saturated fat, and cholesterol. In addition, the agency recognizes that the same conclusion applies to other meat products regulated by FDA (e.g., bison, rabbit, game meats).

Analyses of FDA's Food Composition Data Base (Ref. 23), which is based on USDA's Agriculture Handbook Number 8 on food composition, show that many fish/shellfish products (on a raw basis with a reference amount of 110 g) would qualify to bear "lean" or "extra lean" claims under FSIS' definitions of these

terms that FDA is adopting. Haddock, swordfish, and clams, for example, could be appropriately labeled as "extra lean," while Spanish mackerel and Bluefin tuna would be eligible for use of the term "lean" on their labels. On the other hand, neither term could be used on such seafood items as shrimp, Chinook salmon, or any other seafood item with a composition that exceeds the limits on the levels of total fat, saturated fat, or cholesterol established for use of the term "lean." Similarly, for game meats and related FDA-regulated meat products (on a raw basis with a reference amount of 110 g), based on data from USDA's Agriculture Handbook Number 8 on food composition (Ref. 24), domesticated rabbit could be differentiated from deer (venison) because domesticated rabbit would qualify for "lean" and deer for "extra lean."

FDA's action in promulgating equivalent definitions of these terms will enable consumers to compare the nutritional values of meat products and meal-type products that may serve as substitutes for one another in a balanced diet. Therefore, FDA is including in this final rule § 101.62(e) that permits use of the terms "lean" and "extra lean" on individual foods and on meal and main dish products. Use of these descriptive terms for FDA-regulated meal and main dish products is addressed elsewhere in this final rule. Because the agency is including this definition in the final rule, it is redesignating proposed § 101.62(e), a provision that addresses misbranding, as § 101.62(f) in the final rule.

FDA recognizes that the definitions of "lean" and "extra lean" for meat items allow this claim to be used when cholesterol levels exceed FDA's disclosure levels for this nutrient in the food (i.e., 60 mg). The agency considered whether to prohibit these claims on FDA-regulated meat products that contain greater than 60 mg cholesterol. However, the agency concluded that it would be of benefit to consumers to permit the claim on meat products that have a cholesterol content exceeding the disclosure level because the claims identify foods relative to other foods in this broad food class that contain lower amounts of fat and saturated fat. Thus, use of these claims would assist consumers in selecting such foods in constructing a total diet. Furthermore, when the cholesterol level in the food exceeds FDA's disclosure level, § 101.13(h) requires a disclosure statement referring the consumer to the nutrition information panel for additional information about cholesterol content.

3. "High" and "source"

Section 3(b)(1)(A)(iii)(VI) of the 1990 amendments requires that the agency define the term "high." Section 403(r)(2)(A)(v) of the act states that foods bearing a "high" claim for fiber either must be "low" in fat, or their labeling must disclose the level of total fat in the food in immediate proximity to the claim with appropriate prominence. In the general principles proposal (56 FR 60443), the agency proposed definitions for "high" and for "source," terms that may be used to emphasize the presence of a nutrient.

The agency proposed in § 101.54(a) to exclude total carbohydrate and unsaturated fatty acids from coverage under the proposed definition for "high" and "source." The agency explained that a nutrient content claim for these nutrients would be misleading.

The agency proposed in § 101.54(b)(1) that the terms "high," "rich in," or "major source of" may be used to describe the level of a nutrient in a food (except meal-type products) when a serving of the food contains 20 percent or more of the proposed RDI or the proposed DRV for that nutrient. The agency also proposed in § 101.54(c)(1) that the terms "source," "good source of," or "important source of" may be used to describe a food when a serving of the food contains 10 to 19 percent of the proposed RDI or the proposed DRV.

The agency also proposed in § 101.54(d) that 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 proposed § 101.62(b)(2), then the label must disclose the level of total fat per labeled serving in immediate proximity to the claim and preceding the referral statement required in § 101.13.

The agency requested comments concerning its approach of limiting the number of descriptors that emphasize the presence of a nutrient to two levels. The agency explained that it took this approach to assist consumer understanding of, and confidence in, nutrient content claims. The agency also requested comments on whether an additional term describing an upper level amount of a nutrient (such as "very high") is necessary and appropriate. The agency also requested comments on the use of synonyms for terms like "high" and "source" and on consumer understanding of the terms proposed as synonyms for "high" and "source."

a. Synonyms

146. A few comments agreed that "rich in" and "major source of" are appropriate synonyms for "high." However, many comments disagreed with the proposed synonyms. Many of the latter comments stated that the agency should not allow use of any synonyms because the use of synonyms will be very confusing to consumers and could easily mislead them. A few comments requested the additional synonym "excellent source of" for "high."

Other comments agreed that "good source of" and "important source of" are appropriate synonyms for "source." However, many comments disagreed with the proposed synonyms. A few comments requested the use of additional synonyms for "source" such as: "meaningful source," "significant source," "provides," and "fortified with." Some stated that the term "provides" informs consumers that the food supplies the nutrient in question and has been in common use on food labels for years further assuring consumer familiarity with it. Some stated that the term "fortified with" has also been used on food labels for years, and is easily understood by consumers.

The agency notes that section 3(b)(1)(A)(ix) of the 1990 amendments provides that, in defining terms used for nutrient content claims, the agency may include similar terms that are commonly understood to have the same meaning as defined terms. Thus, the 1990 amendments clearly give the agency the authority to allow for synonyms. Moreover, section 403(r)(4)(A)(ii) of the act authorizes any person to petition the Secretary (and FDA, by delegation) for permission to use terms consistent with those defined by the agency under section 403(r)(2)(A)(i). Therefore, it is clear that the act contemplates that synonyms can be used. Further, the agency still believes, as stated in the general principles proposal (56 FR 60421 at 60444), that certain synonyms should be allowed in order to provide some flexibility in the use of defined terms.

The agency has, however, reconsidered the proposed synonyms for "high" and has revised some of them in this final rule to include terms that it believes would be more readily understood by consumers, and that convey the qualitative aspects of "good source" and "high." FDA recognizes that the synonyms it is providing for involve judgment on its part, and that individuals may have different views on appropriate synonyms. Nonetheless, FDA believes that a limited number of

synonyms will provide flexibility for food manufacturers in making claims and has endeavored to exercise reasonable judgment in providing for some synonyms while avoiding granting so many synonyms as to promote consumer confusion about their meaning.

Thus, in § 101.54(b), FDA is retaining "rich in" and adding "excellent source" as synonyms for "high." The agency is also providing for the use of "contains" and "provides" as synonyms for "good source" in § 101.54(c). FDA has deleted the proposed synonyms "major source of" for "high," and "important source of," for "good source." FDA notes that the terms it has added to the final rule, "excellent source," "contains," and "provides" are terms that have been used in the past and thus consumers will be familiar with them.

b. Definitions

147. Several comments agreed with the agency's proposed definition of "high" and the rationale upon which it was based, while other comments disagreed with the proposed definition. A few of the comments argued that 20 percent of the RDI or DRV is too high and would lead to little consumer benefit because few foods would be eligible to bear a "high" claim. One comment suggested lowering the eligibility level to 15 percent of the RDI or DRV so that more products would meet the definition without unnecessary supplementation.

The agency recognizes that many foods will not be able to meet the definition for "high." However, the agency is not persuaded by comments suggesting that it lower the eligibility level in the definition of "high" for this reason. The agency tentatively concluded in the proposal, and continues to believe, that a criterion of 20 percent or more of the RDI or DRV provides an appropriate basis for upper-level nutrient content claims.

Furthermore, the agency does not agree with comments that few foods would be eligible to bear "high" claims. In arriving at a definition for "high," FDA used its 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 per serving (Ref. 35). For the majority of the 17 nutrients considered, at least 10 percent of the foods in the data base contained 20 percent or more of the proposed RDI or DRV. 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 were a substantial number of foods in at least one food category that would qualify for "high" claims if the proposed definition were used.

Thus, the agency concludes that the 20 percent eligibility level will permit a sufficient number of food items to bear a "high" claim to allow consumers to use the claim in selecting a varied diet, and that this level provides an appropriate basis for upper-level nutrient content claims and can readily be used by consumers to implement current dietary guidelines. Therefore, FDA is retaining the 20 percent eligibility level in the definition of "high."

148. Several comments suggested lowering the eligibility level of "high" and "source" for dietary fiber claims. They argued that the proposed levels are too restrictive given that fiber is not ubiquitous in foods, and that it would preclude some good sources of dietary fiber, such as fruits, vegetables and whole grain breads, from bearing a "high fiber" claim. Suggested levels were as follows: "high" as 3 g and "source" as 1 g per serving; "high" as more than 4 g and "source" as 2 to 4 g per serving; and "high" as 4 to 8 g and "very high" as greater than 8 g per serving.

The agency has reviewed the comments and is not persuaded to lower the eligibility levels for "high" or "source" claims for dietary fiber. The agency agrees that fiber is not ubiquitous in foods. However, FDA notes that there are some fruits and vegetables that do qualify for "high," and considerably more that qualify for "source," claims for fiber under the proposed definitions. Based upon nutrient values for the 20 most commonly consumed raw fruits and raw vegetables (56 FR 60880, November 27, 1991, and corrected at 57 FR 8174, March 6, 1992), at least 25 percent of the products listed would be able to meet the proposed definition for "source." Furthermore, the agency believes that it is important to maintain consistency in defining terms for all nutrients and food components. Therefore, FDA is making no change in response to these comments.

149. A few comments requested that FDA define "high" and "source" for soluble and insoluble fiber. The comments stated that the Expert Panel on Dietary Fiber for the Federation of American Societies of Experimental Biology (FASEB) estimates that the dietary fiber in the current diet is comprised of approximately 70 to 75 percent insoluble fiber and 25 to 30 percent soluble fiber, and that some individuals are seeking products with higher levels of the specific fiber components.

The agency has established a DRV for dietary fiber but not one for insoluble or soluble fiber because no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been established. Therefore, the agency has no basis on which to define "high" for insoluble and soluble fiber and has not made the suggested change.

150. One comment suggested that "high" and "source" claims for protein should be based on protein quality as well as level because such claims may be misleading if a food contains a lower quality protein. The comment suggested as a second criterion that a "high" in protein claim be allowed only for foods with a protein digestibility-corrected amino acid score (PDCAAS) greater than or equal to 40, and that for a "source" of protein claim, the food must have a PDCAAS of greater than or equal to 20.

The agency notes that § 101.9(c)(7)(i), proposed as § 101.9(c)(8)(i), provides that the percent DRV for protein must represent the corrected amount of protein based on its PDCAAS. Thus, the agency has already factored in the PDCAAS (see the discussion of protein quality in the Mandatory Nutrition Labeling proposal). Therefore, the agency believes that adding a second criterion based on the PDCAAS for "high" and "good source" in protein claims is not necessary. To determine whether a product qualifies for a claim as "high" in, or as "good source" of, protein, manufacturers must use the percent DRV for protein in a food that represents the corrected amount of protein based on its PDCAAS.

151. Some of the comments recommended defining the term "very high" to provide for use of this claim when a food contains 30 percent or more of the RDI or DRV per serving, so that consumers can distinguish between foods with "high" levels of nutrients and those with significantly more. Some comments recommended that the agency permit the term "principal source" as a synonym for "very high." However, a few comments agreed with the agency's position that the term "very high" should not be defined because allowing such a term could discourage consumption of a wide variety of foods in favor of fewer highly fortified foods and supplements. Other comments

proposed a three- or four- level system for claims that emphasize the presence of a nutrient. One suggested a three level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 49 percent; and "excellent source of" as 50 percent or more. A suggested four-level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 34 percent; "very good source of" as 35 to 49 percent; and "excellent source of" as 50 percent or more.

The agency has reviewed these comments and is not persuaded that it should define terms that correspond to levels of a nutrient that normally do not occur naturally in foods, e.g., "very high." In the general principles proposal (56 FR 60421 at 60443), the agency stated that defining a term such as "very high" could discourage adherence to current dietary guidelines such as those stated in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7), which 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. The comments provided no information to cause the agency to change its position.

152. A majority of comments agreed with the agency's proposed definition for "source," while a few comments disagreed. Generally, the latter comments contended that the agency should not define "source" because consumers cannot reasonably be expected to distinguish between foods that are "high" in a nutrient as opposed to foods that are simply a "source" of a nutrient.

The agency agrees that consumers may not be able to understand the distinction between the meanings of "high" and "source." For example, the term "high" has a quantitative connotation, while the term "source" merely connotes that a nutrient is present but does not signify the quantity present. Therefore, the term "source" alone does not enable the consumer to conclude that the level of nutrient present is less than "high." However, the agency believes that the term "good source" conveys the appropriate information for a midlevel content claim, i.e., that a dietarily significant level of the nutrient is present, but that the level present is not exceptional with respect to levels naturally found in foods. Therefore, the agency is revising in § 101.54 the primary term for midrange nutrient content claims from "source" to "good source."

Thus, FDA concludes that adopting a two-level approach to claims that emphasize the presence of a nutrient based upon "good source" (as a replacement for "source") and "high" as the representative terms will provide meaningful information to consumers consistent with the intent of these proposed definitions.

FDA is, however, making a change in § 101.54. In proposed § 101.54(a)(3), FDA referred to § 101.36, in which the agency proposed to set forth the requirements for nutrition labeling of dietary supplements. In October of 1992, the Dietary Supplement Act of 1992 was enacted, which imposes a moratorium on implementation of the 1990 amendments. In response to this moratorium, FDA is not adopting § 101.36 at this time. Therefore, FDA has deleted the reference to § 101.36 from § 101.54(a)(3). FDA intends to revisit this issue in accordance with the provisions of the Dietary Supplement Act of 1992.

153. One comment stated that for fresh fruits and vegetables, the eligibility level for "source" should be 5 percent of the RDI for a nutrient because several nutrients occur naturally in fruits and vegetables at levels below 10 percent of the RDI.

The agency is not persuaded that the criteria for a mid-range nutrient content claim should include a lower eligibility level for fresh fruits and vegetables. As stated in the general principles proposal (56 FR 60421 at 60444), the agency has long held that a food is not a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving. The agency is unaware of any evidence suggesting that this policy should be changed, and none was presented in any comments to the proposal. Therefore, the agency is not including a lower eligibility level in the definition of "source" for fresh fruits and vegetables.

154. Some comments disagreed with the agency's exclusion of total carbohydrates from coverage under the proposed definitions for "high" and "source." The comments stated that "high" and "source" should be defined for complex carbohydrates because health authorities recommend that consumers increase the amount of complex carbohydrates in their diets.

The agency does not agree that it should define "high" and "good source" for complex carbohydrates. The agency has concluded that it is unable to define "complex carbohydrates," as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, there is no basis for nutrient content claims about this nutrient.

155. One comment suggested establishing definitions for "source" for polyunsaturated fatty acids and monounsaturated fatty acids because health authorities recommend increasing the intake of unsaturated fat while decreasing the intake of saturated fat.

Because the agency has determined that a DRV for unsaturated fat (including polyunsaturated and monounsaturated fatty acids) is potentially misleading, as explained in the RDI's and DRV's final rule, published elsewhere in this issue of the **Federal Register**, the agency concludes that there is no basis for defining "high" and "good source" for unsaturated fat.

156. A few comments opposed proposed § 101.54(d) that requires that unless a food meets the definition for "low fat" (3 g or less fat per serving and per 100 g), a "high fiber," "source of fiber," or "more fiber" claim must be accompanied by a declaration of the amount of total fat per serving in immediate proximity to the claim and preceding the referral statement. These comments stated that this provision targets only fat as an unhealthy nutrient, and therefore it is discriminatory and anti-competitive.

The focus on fat in conjunction with fiber claims derives from the statute itself. As stated above, section 403(r)(2)(A)(v) of the act provides that a claim may not state that a food is high in fiber unless the food is low in total fat, or the label discloses the level of total fat in the food. Thus, § 101.54(d) is required by the statute, and the agency is retaining this requirement in the final rule. Moreover, it is consistent with the statute's focus on fat in conjunction with fiber claims to require a similar fat disclosure when a "good source" or "more" claim for fiber is made.

c. relative claims

Sections 3(b)(1)(A)(iii)(III), (b)(1)(A)(iii)(IV), and (b)(1)(A)(iii)(V) of the 1990 amendments require that the agency define the terms "light" or "lite" (referred to collectively in this document as "light"), "reduced," and "less," unless the agency finds that the use of any of these terms would be misleading under section 403(a) of the act. These terms are used for comparing the amount of nutrient in one food with the amount of the same nutrient in another food or class of foods. The comparisons are called "relative claims." In the general principles proposal, the agency proposed definitions for "light," "reduced," and "less," as well as the terms "fewer" and "more." In addition, the agency proposed in § 101.13(j), requirements

specifying: (1) The reference foods that may be used as a basis for comparing the level of nutrients in one food with the level of those nutrients in another food for the various types of relative claims; (2) the information about the foods being compared that must accompany the claim; and (3) the minimum absolute amount of a nutrient by which the food must differ from the reference food in order to make a relative claim.

The definitions for relative claims proposed in the general principles proposal placed "less" (or "fewer"), "reduced," and "light" on a continuum using two criteria, both of which a food would have to meet to bear a specific relative claim. First, the proposal would have required that a food be reduced in the particular nutrient by a specific minimum percentage, depending on the claim. Secondly, it would have required that the level of a nutrient in the food be reduced by a minimum absolute amount (e.g., 3 g fat). The agency believed that such a regulatory scheme would limit consumer confusion with respect to the meaning of these terms.

To provide a basis by which comparisons between two foods could be made using relative terms, the agency proposed three types of reference foods (56 FR 60421 at 60445). These reference foods were: (1) A composite value of all foods of the same type, referred to as an industry-wide norm (proposed § 101 13(j)(1)(i)), which could be used as a basis of comparison for all relative claims; (2) a manufacturer's regular product (§ 101 13(j)(1)(ii)) which could be used for "reduced," "less," and "more" claims; and (3) a food or class of foods whose composition is reported in a current valid data base (proposed § 101 13(j)(1)(iii)) for use with "less" and "more" claims.

However, the agency acknowledged that it is possible that because of the natural vagaries of the language (56 FR 60421 at 60458), the terms "reduced" and "less" (or "fewer") may have no innately understood differences. Consequently, the agency acknowledged that any proposed regulatory distinction between the two terms may still be misleading. Therefore, the agency discussed the possibility, as an alternative approach, of providing the same definition for "reduced" and "less" and requiring information describing exactly how the foods differ to accompany the claim. Under this scheme, the percent that the nutrient in the labeled food differed from the reference food, a comparison of the actual amounts of nutrient in the labeled food and the reference food, and the identity of the reference food would have been conspicuously disclosed on the PDP of the label. The agency did not, however, discuss what reference foods would be appropriate as the basis for these claims if they were given the same definition. In the proposal, FDA discussed the possibility of publishing a supplemental notice on this alternative. Although a document was drafted and made available at a hearing that the agency held in January of 1992, it was never published in the **Federal Register** and thus must be considered a draft. However, the agency has fully considered comments it received on the alternative approach in arriving at this final rule.

1 "Reduced" and "less" (or "fewer")

a General provisions

Relative claims have traditionally been defined by the agency using a minimum percentage reduction. Under existing regulations, to make a "reduced sodium" claim or a "reduced calorie" claim, for example, the food must be reduced by 75 percent in sodium (§ 101.13(a)(4)) or 33 1/3 percent in calories (§ 105.66(d)). Moreover, in earlier documents on cholesterol claims, the agency proposed to require that cholesterol be decreased by 75 percent for a food to make a reduced claim (51 FR 42584, November 25, 1986; 55 FR 29456, July 19, 1990). The minimum percentage reduction has been used by the agency to ensure that the level of the nutrient that is the subject of a claim in a food that bears a claim has been decreased by a significant amount compared to the reference food.

In the general principles proposal FDA proposed that for a food to bear the term "reduced," it must contain at least one-third fewer calories or 50 percent less fat, saturated fat, cholesterol, or sodium than the reference food. To bear the term "less" (or "fewer") the agency proposed that a food must contain at least 25 percent less of the nutrient than the reference food.

However, the agency was concerned about misleading relative claims that highlight a decrease in the amount of a nutrient on products that normally contain only a small amount of that nutrient. For example, if such claims were allowed on the basis of a percentage reduction only, a food containing 50 calories per serving could be reformulated to contain 33 calories (a one-third reduction) and thereby qualify to make a "fewer" claim. The agency was concerned that such claims would be misleading because the difference in the amount of the nutrient would be insignificant with respect to the total daily diet.

To ensure that claims for products having relatively small amounts of nutrient not bear a claim unless the difference in the amount of nutrient was significant relative to the total daily diet, the agency proposed that a product also be reduced by an absolute minimum amount in order to bear a claim. The agency proposed to require that the minimum reduction necessary for the food to bear a relative claim be equal to the value of "low" for that nutrient, i.e., a reduction of at least 40 calories, 140 mg of sodium, 3 g fat, 1 g saturated fat, or 20 mg cholesterol. Consequently, the agency proposed that the definitions for "reduced" and "less" claims be based on both a minimum percentage difference and a minimum absolute difference in the amount of the nutrient.

In the general principles proposal (56 FR 60421 at 60458), as discussed above, FDA also requested comment on an alternative approach under which "reduced" and "less" (or "fewer") would have the same definition, and there would be a numeric disclosure of the actual amount and the percentage that nutrient in the labeled food differed from the reference food Under this approach, there would not be a single, across-the-board minimum percent reduction required to support the claim, but any claimed reduction or difference in the level of a nutrient would have to be large enough to be nutritionally significant.

157. Many comments said that there was an insufficient distinction between the terms "less" and "reduced" to warrant separate definitions for these terms, and that use of the two terms was confusing. They suggested that "reduced" not be defined. Other comments suggested that "less" (or "fewer") was the redundant term and should not be defined. However, many more comments stated that "reduced" and "less" should have the same definition. These comments said that the distinction made by FDA is artificial and confusing, and that consumers do not understand there to be any real distinction between the two terms. Many comments said that declaration of the extent of the reduction is more meaningful than the descriptive term used because it provides more information about the nutrient content of the product. Some stated that separate definitions would make it more difficult for manufacturers to meet consumer demand for modified products that comply with defined terms.

The agency has reviewed these comments and is persuaded that the terms "less" and "reduced" may not

have two distinct nutrition meanings to the ordinary consumer, and that, therefore, it could be confusing if the terms were to have two distinct nutrition definitions. The agency considered eliminating one or the other of these terms but chose not to do so. Both of these terms are listed in section 3(b)(1)(A)(iii) of the 1990 amendments. While FDA could have decided not to define one of the terms listed in that section if it found that the use of the term would be misleading, the agency has no information on which to base such a conclusion for either "less" or "reduced."

The current use of both "reduced" and "less" suggests that both terms have a place in the market. The terms are commonly understood to have different meanings. "Reduced" applies to a characteristic of an entity that has been altered with the resulting entity differing from the original by only that alteration, while "less" encompasses "reduced" and can also apply to a difference in a characteristic between two distinct entities (Ref. 25). Accordingly, as discussed in detail below, the agency is revising new §§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4), by providing the same definition for the terms "less" (or "fewer" in the case of calories) and "reduced," (See comments 158 through 160 of this document). It is also deleting the separate definition for "less" (or "fewer") proposed in §§ 101.60(b)(5), 101.61(b)(7), 101.62(b)(5), (c)(4), and (d)(5). Instead of distinct definitions for each of the two terms, the agency will rely on the information that accompanies the claim to inform consumers of the levels of reduction of a nutrient achieved by the labeled food. However, as is discussed in greater detail in comment 204 of this document, the agency believes that because of their different commonly understood meanings, the two terms may not always be used interchangeably.

158. There was only limited support for the definitions proposed for "reduced" and "less," which would have required a minimum percentage reduction and a minimum absolute reduction for a product to bear such a claim.

Generally, the comments expressed concern that the two part definition, particularly because of the minimum absolute reduction, was too strict. Many comments opposing the minimum absolute reduction requirement requested that it be deleted in the final rule. These comments said that such a requirement discriminated against products with small serving sizes. They cited situations in which the modified product might contain substantially less of a nutrient, on a percentage basis, compared to the reference food, but where the labeled food did not contain an amount of the nutrient sufficient for the food to be reduced by the minimum absolute amount. (One comment gave as an example, a serving of sour cream that contains 60 calories. A one-third reduction is 20 calories, which is only one-half of the 40 calories proposed as the minimum calorie reduction necessary in order to make a claim.) The comments stated that although differences in the absolute amount of a nutrient in such products might be small, the nutritional benefits derived from several servings of similarly modified foods over a day could have a significant impact on the level of the particular nutrient in the total diet.

Comments suggested a wide variety of alternative definitions, including various minimum percentage reductions, some with minimum absolute reductions and others without. Several comments that supported a definition based solely on a minimum percentage reduction stated that such a criterion is necessary to ensure that claims are made only for nutrient reductions that are nutritionally significant, especially for those foods containing large amounts of a nutrient. They gave as examples salty soups having 1,000 mg of sodium and candy bars with 300 calories.

Only a few comments preferred a minimum absolute reduction over a percentage reduction as a sole criterion. However, most of those comments voiced little reason for their preference. Of those commenting, a very few stated that without the proposed minimum reduction requirements, claims might be permitted on products where only very small reductions were made. They said that if the products were already very low in, or free of, the nutrient, such claims would be misleading.

A few comments suggested that a minimum absolute reduction other than the proposed values based on the definition for "low" should be used to control claims made for very small nutrient reductions, e.g., 20 or 30 calories, instead of the proposed 40 calories; 1.5 or 2 g fat instead of 3 g fat; 0.5 g saturated fat instead of 1 g; 35 or 100 mg sodium instead of 140 mg; and 10 or 15 mg cholesterol instead of 20 mg.

Some comments suggested that there should be no single, across-the-board minimum percentage difference or minimum absolute reduction, but that there should be a general requirement that the nutrient reduction be large enough to be nutritionally significant. Others suggested that "reduced" or "less" claims be permitted for any decrease in the level of a nutrient in a food so long as small improvements in a product were not exaggerated, and the absolute difference was disclosed. One comment suggested that any definition would serve as a floor representing the minimum amount of reductions that manufacturers would make, and that because of competitive forces, actual reductions would increase.

The agency proposed that both a minimum percentage reduction of a nutrient in a food and a minimum absolute reduction were necessary in order to ensure that meaningful reductions in the amount of nutrient in a food would occur, and thereby increase the likelihood that selection of nutritionally reduced foods would have a positive effect on an individual's overall dietary intake of the nutrient. The agency believed that a minimum absolute reduction was necessary to ensure that relative claims were significant and would not be made on products that, although they had a large percentage reduction, had only insignificant changes in the amount of nutrient. Such reductions could occur if relative claims were based only on a minimum percentage reduction in products that normally contain only a small amount of the nutrient. On the other hand, the agency was also concerned that products containing large amounts of a nutrient not have insignificant reductions compared to the amount of nutrient in the food and its overall contribution of the nutrient to the total diet.

The comments have convinced the agency that a definition using both criteria is too restrictive and will prohibit claims on a number of products that are useful in constructing diets consistent with dietary guidelines. However, the agency is not convinced, nor have the comments supported with data or other information, that having no minimum criteria will provide sufficient assurance that reductions in the level of a nutrient will be sufficient to prohibit misleading claims by assuring that only foods with nutritionally significant reductions may bear a "reduced" or "less" claim. Without such criteria, it would be difficult to ensure that nutrient reductions in a product were large enough to be significant in the case of products with a small amount of a nutrient or sufficient relative to the food's contribution of the nutrient to the total diet for products with a large amount of a nutrient.

In addition, the agency does not agree with the suggestion that additional labeling can be used to counteract a misleading claim that is used to represent a truly insignificant reduction in the level of a nutrient. Stating the absolute amount of difference, as recommended by the comment, would suggest that the product had undergone nutritionally significant reductions when it had not.

Therefore, FDA concludes that it is necessary to establish specific requirements to define when the difference in the level of a nutrient is large enough that claims about the difference are not misleading, and the terms "less" and "reduced" may be used.

The agency believes that of the options suggested in the comments, either a percentage reduction or a minimum absolute reduction offers the greatest assurance that the reductions achieved will be nutritionally significant.

The agency has evaluated both types of criteria. If an absolute minimum reduction were used as the sole criterion, there would always be a nutritionally significant change in the amount of the nutrient for all foods bearing the terms "reduced" or "less." However, the agency also considered the argument that was strongly made in the comments that a minimum absolute reduction for relative claims may unfairly discriminate against products with small serving sizes. Furthermore, the agency is persuaded by the comments that smaller reductions, in nutrient-dense foods traditionally used in small amounts for example, 20 calories in sour cream rather than 40 calories, may be beneficial to consumers and will not be misleading if changes in absolute amounts are declared. Although the agency remains convinced that only claims about significant changes in a product should be authorized, it acknowledges that for products with small servings, nutrient reductions that do not meet the proposed absolute minimum reduction requirements can be significant in the context of a daily diet.

Many foods with small serving sizes, crackers for example, may be consumed several times throughout the day. Thus, the agency agrees that the small absolute reductions that occur with consumption of each serving of such foods may have a significant cumulative effect on the amount of a nutrient consumed over the course of a day. The agency understands that label claims that highlight such changes could assist consumers in making useful changes in their diet.

However, if only a minimum absolute reduction is required in order for a product to bear a "reduced" or "less" claim, products with larger serving sizes that contain large amounts of a nutrient could still contain a large amount of the nutrient after reduction.

On the other hand, with a minimum percentage reduction requirement, more products containing small amounts of a nutrient would qualify to make "reduced" or "less" claims based on smaller absolute reductions in the amount of a nutrient than would be permitted under the requirements of the proposal. Such a criterion would also require larger, more nutritionally significant changes on products containing large amounts of the nutrient.

The agency has carefully weighed the concerns expressed by the comments. The agency believes that the terms "less" and "reduced" should be used only when a nutritionally significant reduction in the level of the nutrient has been reached so as not to mislead consumers into believing that a product would provide nutritionally significant reduction in the level of a nutrient when it would not.

The agency has determined that it is most appropriate to require a minimum percentage reduction rather than a minimum absolute reduction in order for a product to bear a "reduced" or "less" claim for the following reasons. First, the use of a minimum percentage reduction instead of a minimum absolute reduction is compellingly supported by comments and generally consistent with the agency's proposed approach. Secondly, it will allow more foods with smaller reductions in a nutrient to make a "reduced" or "less" claim. By eliminating the minimum absolute amount that a nutrient must be reduced for a product to bear a claim, the agency believes that manufacturers may have an additional incentive to produce modified products that are helpful in maintaining healthy dietary practices. Although these changes are smaller per product, they will cumulatively contribute overall to reduction in the amount of certain nutrients in the diet. Thirdly, this approach will assure nutritionally significant changes in products containing large amounts of a nutrient.

Therefore, FDA concludes that it is appropriate to require a minimum percentage reduction in the level of a nutrient in order for a food to bear a relative claim. Accordingly, the agency is deleting from new § 101.13(j)(3) and from the regulations on claims for specific nutrients (§§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)), the requirement for an absolute reduction in the level of a nutrient in order for the food to bear a claim.

159. Several comments suggested that to prevent relatively small quantitative reductions from being touted as large percentage reductions, as an alternative to a minimum absolute reduction, "reduced" and "less" claims not be permitted on products if the reference food qualifies for a "low" claim.

The agency is concerned that for products in which the level of a particular nutrient is very low, requiring only minimum percentage reductions would mean that very small, nutritionally insignificant changes could be made in the amount of the nutrient, and the product would still qualify to make a "reduced" or "less" claim. It agrees that the suggested approach would provide assurance that the changes made to qualify for a "reduced" or "less" claim are not so small as to not be nutritionally significant. The agency notes that the value for "low" is the level at or above which the amount of a nutrient becomes significant relative to the total diet. A difference between two foods in a nutrient that is present in both foods at a level that is less than that of nutritional significance is not a significant difference. Such differences cannot be considered meaningful relative to the overall diet because even the level of the nutrient in the reference food is so low that the impact of its consumption on total dietary intake of the nutrient is minimal.

Thus, the agency agrees with the comments that contended that it would be misleading for products to make a relative claim if the nutrient is present at a "low" level in the reference food. Consequently, the agency is prohibiting "reduced" and "less" claims that are based on a difference from a reference food that meets the requirement for a "low" claim with respect to the nutrient in question. The agency is revising new § 101.13(j)(3) to include this requirement.

The agency believes that the overall approach described above will provide the best balance between encouraging manufacturers to produce foods with significant nutrient reductions by authorizing them to tell the public about the products' attributes and protecting consumers from being misled by claims directing them to foods that are not meaningfully improved in nutrient content.

160. Many comments discussed the percentage that a food should be reduced to bear a "reduced" or "less" claim. They suggested a wide range of percentage reductions, from a 50

percent reduction for "reduced" or "less" for all nutrients (including calories) to a 10 percent reduction for all nutrients. Some comments stated that FDA has historically used a 10 percent reduction as the minimum amount required for nutritional significance, and, therefore, it was an appropriate basis for a "reduced" claim. Other comments said that small incremental nutrient changes such as 10 percent are beneficial to consumers and represent modifications that are achievable. The comments argued that banning label information about incremental changes is likely to hurt consumers and discourage innovation.

Many other comments stated that a 25 percent reduction was an appropriate minimum reduction requirement. These comments said that using this level would allow "reduced" and "less" to have the same definition as originally proposed for "less." In addition, they said that a 25 percent reduction is a nutritionally significant reduction.

One such comment said that there is a sound scientific foundation upon which to require a minimum percentage reduction of 25 percent. The comment included comparisons of target daily intakes to current intakes and concluded that a 25 percent reduction is fully consistent with the reduction in intake needed to achieve current national dietary goals for fat, saturated fat, and cholesterol. The comment also concluded that although these calculations suggested that a 40 percent overall reduction in sodium was necessary to reach dietary goals, a 25 percent reduction was more practicable. This comment said that its conclusion was based on experience in marketing foods with reductions in sodium. It said that it had found that smaller incremental reductions were necessary to avoid consumer rejection of altered foods. The comment said that taste preferences will change as consumers adapt to lower salt levels, and that a 25 percent incremental reduction at this time would be a practical approach to the 40 percent reduction that is ultimately desired.

Another comment stated that a 25 percent threshold for claims was appropriate because it is supported by a variety of international governments and organizations, including Codex Alimentarius.

A few comments said that a one-third minimum reduction in the level of a nutrient was an appropriate criterion for a food to bear a "reduced" or "less" claim. They stated that a one-third reduction was a significant reduction, and that it is consistent with the percentage reduction required for "reduced calorie" claims (§ 105.66). Other comments suggested that foods should be permitted to bear a "reduced" or "less" claim only if there was a 50 percent or greater reduction in a nutrient (including calories) than the reference food. They said that requiring this percentage reduction was important for consistency across the nutrients. Other comments said that a minimum percentage reduction of 50 percent was necessary to ensure that the reduction is truly nutritionally significant compared to the original food and is useful to consumers in following dietary guidelines. A very few comments suggested that the definition for "reduced sodium" and "reduced cholesterol" should be returned to the 75 percent reductions previously established or proposed.

The agency does not agree that it has established a precedent for using 10 percent as a criterion for a minimum percent reduction in the level of a nutrient. Current agency regulations (§ 101.9(c)(7)(v)) provide that a food is not a significant source of a nutrient unless the nutrient is present at a level that is 10 percent of the U.S. RDA, and that no claim may be made that a food is nutritionally superior to another unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving than the other food. For "reduced" and "less" claims, on the other hand, the percentage is used as the basis for a direct comparison between the amount of the nutrient in each of the foods. Therefore, the agency concludes that this comment did not provide sufficient justification to permit "reduced" or "less" claims on products having only a 10 percent reduction.

In addition, in the final rule on sodium labeling (49 FR 15510 at 15521, April 18 1984), the agency stated that a 10 percent reduction criterion for comparative claims was too low because of product variability. The agency said that because of expected statistical distribution of a nutrient (in that case sodium) in the food, there is a measurable probability that the sodium content of a sample of a product for which a lowered sodium content claim was made would actually exceed the sodium content of a sample of the unaltered product. Because it had been suggested that such product variations may not be as common now as they were in 1984 because of manufacturers' ability to more precisely control the amount of nutrient in a product, the agency solicited comments on this suggestion. However, comments provided no data to substantiate that improvements in food technology or other factors make it practicable for manufacturers to reliably achieve a 10 percent reduction. Thus, in the absence of data to support a different finding, the agency concludes that, because of product variability, a 25 percent reduction is the lowest level of reduction that can be supported.

The agency's decision to require a 25 percent reduction as the basis for a "reduced" or "less" claim is also based on the recognition, as outlined in the general principles proposal (56 FR 60421 at 60451), that this level will provide an incentive for manufacturers to reduce the level of the relevant nutrients in their food and at the same time has the potential to produce meaningful changes in overall nutrient intake for consumers. The comments provided significant support of these conclusions.

While the agency agrees that large reductions (such as 33, 50 or 75 percent) in the levels of certain nutrients present in a food may increase the likelihood that these foods will decrease the nutrient intakes of individuals who select these foods, FDA cannot agree that these percentage reductions are the most appropriate criteria on which to base "reduced" and "less." The comments supporting levels higher than a 25 percent reduction did not provide evidence that a 25 percent reduction would not be adequate, nor did they specifically demonstrate why a higher level than 25 percent is needed.

FDA recognizes that it has previously provided guidelines and definitions for nutrient reductions in foods, and that these specified reductions were greater than 25 percent. However, the agency now believes that with the advent of mandatory nutrition labeling and an ever increasing interest in healthy eating, more manufacturers will attempt reductions in the levels of nutrients like fat, saturated fat, cholesterol, and sodium in their foods. With the definition set at the reasonably achievable level of a 25 percent reduction, more foods are likely to be available, and consumers will be able to select from more and different foods in order to meet dietary guidelines. Furthermore, as suggested by one comment, market competition will undoubtedly spur some manufacturers to exceed this minimal reduction, thereby resulting in foods with even greater levels of reduction.

Therefore, the agency has concluded that an appropriate minimum percentage reduction for the terms "reduced" and "less" is 25 percent. Accordingly, the agency has revised new §§ 101.60(b)(4)(i), 101.61(b)(6)(i), 101.62(b)(4)(i), (c)(4)(i), (d)(4)(i)(A), and (d)(4)(ii)(A) to reflect this change.

161. One comment stated that the percentage reductions expressed on the label should not exceed the actual amount of the reduction of the nutrient in the product. Thus, the comment argued that manufacturers should be prohibited from "rounding up" the amount of the reduction to make it appear greater than it actually is.

The agency advises that for a product to bear a claim, the level of the nutrient must be reduced by at least a certain value. Thus, the amount of the reduction must be equal to or greater than the specified amount. There is no provision for rounding up the difference in nutrient content.

It is not clear to FDA whether the "rounding up" referred to in this comment is the rounding off provided in the regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. If the comment was concerned about such rounding, the agency advises that declaration of nutrients in, for example, 5 calorie increments or 0.5 g fat increments, which is permitted in nutrition labeling under § 101.9(c), is not permitted in determining the difference in nutrient levels between two foods. However, as discussed in the preamble of the proposal on mandatory nutrition labeling (55 FR 29487, July 19, 1990), the rounded differences are nutritionally insignificant. The agency would not consider a claim to be misleading if the declaration of the difference in absolute amount of nutrient between the foods were rounded off in conformance with rounding provisions for nutrition labeling in § 101.9.

162. A few comments requested that the regulation provide for use of "modified" as a synonym for "reduced" or "less."

The agency does not consider the word "modified" by itself to be a nutrient content claim. While it implies the product has been changed, "modified" does not necessarily imply that the change is in the content of a nutrient. As discussed elsewhere in this document, the word "modified" is permitted for use as part of the statement of identity on foods that qualify for "reduced" or "less" claims. However, "modified" is intended to be used in the presence of these claims, not in lieu of them. The term advises consumers that the product has been changed, and the nutrient content claim describes the change. Accordingly, FDA is not amending the regulation as requested.

163. One comment requested that the agency provide for the term "lower" as a synonym for "less." The comment stated that the term was currently in use on a comparative basis.

The agency agrees that "lower" should be permitted as a synonym for "less." Although the comment provided no further verification of the meaning of the term, the "American Heritage Dictionary," 1976 edition, (Ref. 25) defines the term to mean "below a similar or comparable thing." Such a definition is consistent with the principles for "less" claims which are used to compare two similar or comparable foods. Accordingly, the agency is including in §§ 101.60(b)(4) and (c) (4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)"lower" as a synonym for "less" (or "fewer").

164. One comment suggested that "less" rather than only the term "fewer" should be allowed for calorie claims.

As was stated in the general principles proposal (56 FR 60451), the agency defined "fewer calories" instead of "less calories" because the term "fewer" is grammatically correct. The agency does not believe that it is appropriate to amend the regulation to specify use of an improper term. However, FDA does not ordinarily consider a product to be misbranded because it bears a label statement that is grammatically incorrect. Accordingly, because the criteria for "less" and "fewer" claims are the same, the agency will not consider "less calories" to be misleading.

b. "Reduced" and "less" claims for sugar

In the general principles proposal, FDA proposed a definition for "less sugars" that included a minimum percentage difference of 25 percent but did not include a minimum absolute amount criterion. The agency did so because the minimum absolute amount criterion for other nutrients was the amount proposed to be defined as "low." The proposed criteria for "low" claims were based on DRV's for the nutrients, and because there was no DRV for sugars, there was no "low sugars" definition. The agency solicited comments for an appropriate requirement that could be used as the second criterion for this claim and signaled its intentions to establish a second criterion if one were not forthcoming.

165. Only a few comments addressed the term. Some supported defining the claim "less sugars," while a few others suggested that the term "less sugars" is not useful to consumers, is misleading, and should not be used. However, those objecting did not provide information as to why this was so.

As discussed in comment 80 of this document, the agency has determined that the term "sugars free" may be confusing to consumers and therefore is providing for use of the term "sugar free." The agency believes that "less sugars" would also be confusing. Therefore, for consistency the agency has determined that "less sugar" is the more appropriate term to describe reductions in the sugars content. Further, because the comments provided no arguments why the term should be eliminated, and because the term would provide certain useful information to consumers in comparing the sugars content of one food to another, the agency is not persuaded that the definition for "less sugar" should be eliminated. Accordingly, the agency has retained this definition.

In addition, FDA has included use of the term "reduced" in the provision for "less sugar" (§ 101.60(c)(4)). Although the agency had not proposed criteria for "reduced sugar" claims, now that the term "reduced" and "less" have the same criteria, it would be inconsistent not to also permit use of "reduced sugar" claims.

166. Only one comment suggested a second criterion for the definition of "less sugar." It recommended that the claim be permitted only if the labeled food contained at least 2 g less sugar than the reference food.

The comment did not provide rationale or other information to substantiate the recommendation. Consequently, FDA still does not have a basis for a minimum absolute reduction to be used in lieu of a definition for "low sugar." However, as discussed above in response to comment 158 of this document, FDA is no longer using the minimum absolute reduction as a criterion for "reduced" and "less" claims.

In view of this fact, the agency is persuaded that the need for a second criterion for sugar is similarly diminished. The agency has established in new § 101.13(j)(3) (see comment 159 of this document) a requirement that a relative claim may not be made if the amount of nutrient in the reference food is less than the value for "low." Although for consistency, a similar requirement for sugars might be useful, the agency does not believe that there is a compelling reason to definitively establish the criterion, especially given the fact that the basis for such a criterion, a DRV for sugar, does not exist. The agency will evaluate on a case-by-case basis whether claims on food that emphasize a very small reduction in the amount of sugar are misleading.

2. "Light"

a. General

In the general principles proposal (56 FR 60421 at 60449), FDA said that although the term "light" or "lite" is primarily a relative claim that compares one food to another food, it is often used to directly describe the food itself in the way that an absolute claim such as "low calorie" is used. The agency proposed several circumstances in which the term "light" could be used.

167. Several comments were concerned about the way that the term "light" is used in the marketplace. A few comments asserted that the term "light" is purely marketing puffery. Other comments said that "light" has no scientifically acceptable meaning but instead has a multitude of meanings and as such will do more to mislead consumers than assist them in making better food choices. Another comment said that because of the various consumer interpretations of the meaning of the term "light," there needs to be further research on its meaning before the term can be defined. A few comments stated that because "light" has no meaning, it should not be defined.

Section 3(b)(1)(A)(iii)(III) of the 1990 amendments requires FDA to define "light" or "lite" unless it finds that the term is misleading. While the agency agrees that some current uses of the term are misleading, it has not made a finding that the term is inherently misleading, or that it cannot be used in a nonmisleading manner. The agency concludes that it has sufficient information, including consumer surveys cited in the general principles proposal (Refs. 26 and 27) and other information submitted in comments with which to establish an appropriate definition for the term. By defining "light" and the conditions for its use in a meaningful way, the agency intends to help alleviate the confusion caused by the many uses of the term and to ensure that products that bear the term are useful in maintaining healthy dietary practices.

168. A few comments stated that "light" is not an expressed claim, but rather that it is an implied claim. The comments pointed to the House report on the 1990 amendments (H. Rept. 101-538, 101st Cong., 2d sess. 19 (June 13, 1990)) which said that an implied claim is a statement that "implies that the product is low in some nutrient (typically calories or fat) but does not say so expressly" and cited "lite" as an example of such a claim. One comment went on to say that as an implied claim, "light" should be permitted with any nutrient content claim, provided that the food qualifies for the claim.

The agency acknowledges that the House report stated that "lite" was an example of an implied claim. However, the agency believes that this term is used as an expressed claim because, as discussed in the general principles proposal (56 FR 60421 at 60449), it has a history of use both as a relative claim and as an absolute claim. "Light" has been used as a direct statement of the level of both calories and fat in food (see § 101.13(b)(1)). In the proposal, FDA stated that in spite of the reference to "light" in the legislative history, it intended to treat this term as an expressed claim (56 FR 60421 at 60449 through 60450). The comments that addressed this issue did not provide any justification for not following the course that the agency proposed. Therefore, FDA is defining "light" as an expressed claim in this final rule.

b. Definition of "light" based on fat and calories

In the general principles proposal (56 FR 60421 at 60449) the agency acknowledged that "light" has been used for a number of years to connote a wide variety of meanings such as low or reduced calories; reduced fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. The agency cited studies that showed a stable perception by the majority of consumers that "light" means that the caloric level has been altered. However, it noted that "light" has also been used to directly describe the food itself in much the same way as the term "low" has been used. Because the agency believed that the definition of the term "light" should be based primarily on consumers' perception that "light" means "reduced in calories," the agency proposed that a food be permitted to bear the term "light" without further qualification if the food had been specifically formulated or processed to reduce its calories by at least one-third compared to a reference food specified in § 101.13(j)(1)(i), with a minimum reduction of more than 40 calories per reference amount and per labeled serving size.

The agency also noted that it had recently 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. The agency also noted that other normally high-fat products are using "light" to describe fat and calorie reductions. In view of these facts, and because the agency believed that products with large amounts of fat should not be labeled as "light" unless a substantial amount of the fat in the food was also reduced, the agency proposed that if the food derives 50 percent or more of its calories from fat, its fat content must also be reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes. The proposal also would have required a minimum reduction of more than 3 g of fat per reference amount and per labeled serving size in order to bear the term "light."

169. A number of comments supported the agency's view that the percentage of a food's calories that are derived from fat should be considered in determining whether the food contains a substantial amount of fat and should, therefore, be required to be reduced in fat for the product to bear the term "light." Several comments supported the agency's proposal that 50 percent or more of a food's calories from fat was an appropriate level at which fat reduction should be required. Another comment suggested that if 40 percent or more of a food's calories are normally derived from fat, a fat reduction should be required, but it offered no substantiation for the suggestion. One comment suggested that a food contains relatively high levels of fat if 30 percent or more of the food's calories are derived from fat. It noted that the 30 percent threshold relates to the dietary guideline that no more than 30 percent of the calories in the total diet should be derived from fat. The comment suggested that a food that normally contains more than 30 percent of calories from fat would be inconsistent with this guideline and therefore should be required to be reduced in fat in order to bear the term "light."

The agency has considered these comments and is not persuaded by the comments that it is necessary to change its determination that foods that normally derive more than 50 percent of their calories from fat should be reduced in fat to make a "light" claim. The agency acknowledges that the dietary guidelines recommend that Americans eat a diet that consists of 30 percent or fewer calories from fat. However, because fat is found in only about one-half of the food supply, it is not necessary that each food contain only 30 percent of its calories from fat for the total diet to meet this goal. Rather, because a diet would normally consist of a combination of foods containing various levels of fat, those foods that derive somewhat more than 30 percent of their calories from fat would be balanced by foods that contain less than 30 percent of their calories from fat. A diet consisting of both types of foods

would be consistent with dietary guidelines. Consequently, it would not be necessary for all foods that derive over 30 percent of their calories from fat to be reduced in fat to meet dietary guidelines. There were no comments that suggested the percentage of calories from fat should be raised to a higher percentage. Therefore, the agency is retaining the provision as proposed, that products that normally contain over 50 percent of their calories from fat contain a substantial amount of fat and should, therefore, have the amount of fat they contain reduced to qualify for a "light" claim.

170. While a number of comments agreed with the agency's assessment that "light" is primarily associated with reduced calorie content, a greater number of comments maintained that consumers primarily perceive "light" to mean lower in fat. One comment cited a 1989 Gallup Organization consumer poll stating that 8 out of 10 consumers select "light" products in order to reduce fat consumption. Others cited a survey reported in an article entitled "Americans to Make LIGHTER Choices in the 90's" that appeared in "Calorie Control Commentary," vol. 12, No. 1 (Spring 1990), stating that 83 percent of consumers select products labeled as "light" in the belief that such products are low in fat. One comment included a study that found that 46 percent of consumers think that products labeled as "light" should have "almost no fat" or "no fat at all." Another comment stated that "light" has been used for decades to refer to fat reductions without evidence of consumer misunderstanding. The comment included a survey of 1,000 trademarks using the word "light" and noted that 35 percent of those trademarks were associated exclusively or primarily with reduced fat content in products. Many comments favored allowing "light" claims for foods on the basis of fat reduction alone.

The agency has carefully reviewed these comments and, on the basis of the evidence presented in them, has been convinced that in addition to "reduced in calories," the term "light" is also commonly understood to mean "reduced in fat." Consumers apparently view reductions in fat as a major reason for purchasing "light" products. Therefore, FDA does not consider that the term "light" is appropriately used only on products in which there has been a reduction in calories. The term also is appropriate on products in which there has been a reduction in fat.

171. Many comments contended that the proposed definition for "light" is too restrictive, especially for foods that normally contain large amounts of fat. The comments maintained that certain products, such as butters, ice creams, chocolate-coated ice cream novelties, cheeses, cakes, brownies, muffins, frostings, peanut spreads, savory snacks (pretzels and chips), popcorn, and coffee creamers could not be altered to qualify for a "light" claim under the proposed definition. A number of these comments pointed out that many fat substitutes contain a substantial amount of calories, and that even though it is often possible to reduce the fat content in products by 50 percent, it is not always possible to also reduce the calorie content by one-third unless all or most of the fat is removed.

The comments stated that in the case of ice cream novelties, for example, because some of the preferred fat replacers, such as carbohydrate or protein solids, contain a substantial amount of calories, it is difficult to remove enough of the calories normally contained in the product to achieve a one-third calorie reduction solely by replacing the fat. To accomplish this calorie reduction, the comment said, would require that virtually all of the fat be removed and replaced with an ingredient such as polydextrose which has a lower calorie content than other fat replacers. However, in achieving this caloric reduction, the comments maintained, consumer acceptance is "lost along the way."

The comments asserted that similar problems occur with cheeses and other products. The comments contended that manufacturers' present inability to make products that can substitute for products normally high in fat, that are acceptable to most consumers, and that can meet the "light" definition will significantly reduce labeling and marketing incentives for such products. Several comments maintained that, as a result, many reduced fat alternatives will be removed from the market, and that development of more "light" products will be retarded. Several comments asserted that having fewer options will cause difficulty for consumers who wish to reduce their fat intake to 30 percent or less of their calories from fat, as recommended by dietary guidelines. They stated that, consequently, the criteria for use of the term "light" should not incorporate both a 50 percent fat reduction and a one-third calorie reduction for products with a substantial amount of calories from fat.

The agency has reviewed these comments and is persuaded that because of the difficulty in achieving "light" products that are reduced both in calories and in fat, the agency will not require that both nutrients be reduced for a food to bear the term. FDA believes that while the criteria for making a "light" claim must result in labeling that consumers can understand and rely on, the criteria should also be reasonably achievable to encourage manufacturers to produce altered products that will assist consumers in maintaining healthy dietary practices. The agency recognizes that it is difficult to achieve reductions of both calories and fat in a number of products containing more than 50 percent of calories from fat, particularly dairy products such as cheeses, ice creams, and frozen confections. In addition, consumers will not purchase, and therefore will not benefit from, altered products that do not meet their acceptance requirements.

In the general principles proposal, FDA stated that a majority of consumers associate "light" with a reduction in calories, even though there are other meanings for the term. However, as discussed in comment 170 of this document, the comments provided information that establishes that consumers strongly associate the term "light" with reduced fat levels. Thus, as discussed in more detail below, FDA no longer believes that a reduction in calories in the food is essential or is always expected by consumers who choose a food because it bears the term "light." Accordingly, the agency has deleted from § 101.56(b) the requirement that products that contain more than 50 percent of calories from fat be reduced both in calories and in fat to bear the term "light."

172. In the general principles proposal, FDA requested comment on whether it was necessary to prohibit a "light" claim on a product containing more than half its calories from fat that is reduced by one-third in calories but that has not also been reduced in fat by the required minimum. The agency asked for comment on whether the claim was misleading and should be prohibited, or whether a statement informing the consumer that the product was not reduced in fat would make the label not misleading. In response, the comments did not support the use of a label statement in alerting consumers that a particular product that was labeled as "light" was high in fat. In addition, although comments did not directly suggest that "light" be permitted on foods that derive one-half of their calories from fat that had been reduced by one-third in calories but not by one-half in fat, many comments did suggest that in such foods, fat reduction is necessary.

The Surgeon General's report (Ref. 4) and the NAS's report "Diet and Health:

Implications for Reducing Chronic Disease Risk" (Ref. 12), in considering the effect of diet on an individual's health, concluded that consumption of a diet high in fat, saturated fat, and cholesterol is associated with increased risk of development of certain chronic diseases. These reports and "Nutrition and Your Health: Dietary Guidelines for Americans" (Dietary Guidelines) (Ref. 7) recommend that Americans reduce their consumption of these substances in their diets. Given the significance of dietary intake of fat and saturated fatty acids, FDA believes that it is important to assist consumers in modifying their diets to reduce their intake of these food components and thereby to maintain healthy dietary practices. By ensuring that foods that normally contain large amounts of fat are substantially reduced in fat in order to bear the term "light," FDA believes that it will assist consumers in constructing diets that are consistent with dietary guidelines by providing substitute foods in which there is a large reduction in fats that will assist them in reducing the fat content of their diets. Therefore, FDA concludes that it would not be appropriate to permit the term "light" to appear on a food that normally derives one-half of its calories from fat that has not been reduced in fat content by the required minimum amount. Accordingly, because the term "light" implies that the food is useful in achieving a diet that conforms to dietary guidelines, foods with relatively high levels of fat (i.e., more than 50 percent of calories form fat) must be substantially reduced in fat if they would be useful in such diets. If the fat level in such foods is not reduced, the use of the term "light" in their labeling would be misleading.

To summarize, FDA concludes that consumers understand the term "light" to connote a reduction in fat as well as a reduction in calories, depending on the food involved. Accordingly, the agency has determined that it is appropriate for a food to bear the term when it has been sufficiently reduced in fat or, where appropriate, calories. (The amount of fat or calories necessary to constitute such a reduction is discussed below.) The agency is therefore providing in § 101.56 that the term "light" may be used when the labeled food differs from the reference food by a minimum percentage reduction in either fat or calories (comments 170 and 171 of this document). However, FDA also concludes that for foods that derive more than 50 percent of their calories from fat, the minimum percentage reduction in fat is necessary for the term "light" to not be misleading (comment 172 of this document). The agency, therefore, is providing in § 101.56(b)(1) a requirement for a minimum percentage fat reduction for such foods.

173. Of those commenting on the subject, a large number of comments stated that because it is a relative claim, "light" should be defined in the same manner as the other relative claims, "reduced" and "less." Many comments said that if "reduced," "less," and "light" all had the same definition, consumer confusion about the meaning of these relative terms would be diminished, especially if the exact nature of the modification was specified adjacent to the claim, as would be required by the accompanying information provisions. One comment said that allowing this more liberal definition for "light," but providing information on the exact nature of the reduction, was consistent with the policy of allowing other "light" claims provided the subject physical or organoleptic properties were specified. A few comments said that if FDA set reasonable parameters for use of the terms "light," "reduced," and "less," consumers would receive truthful, easy to understand information, and food manufacturers would be encouraged to produce foods with significant nutritional reductions because they would be able to tell consumers about their product's attributes.

Another comment said that defining "reduced," "less," and "light" at a lower standard than originally proposed for "light" would minimize the number of brand names prohibited on the grounds that the food did not meet the definitional requirements. One comment said that the same definitions for the term "reduced," "less," and "light" would significantly lower the cost to the manufacturer, and eventually to the consumer, by significantly reducing the costs associated with compliance. Other comments said that any definition would serve as a floor, and that competition and innovations in the market place would push actual reductions higher.

The agency has considered the arguments that because "light" is a relative claim, it should be defined in the same manner that the other relative claims "reduced" and "less" are defined. However, the agency is not persuaded by the comments that such a definition is appropriate. "Light" is a term that has special usefulness as a marketing tool for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in the level of fat or calories. Although the agency recognizes that specifying the exact nature of the modification would help mitigate confusion caused by similar definitions for all relative claims, the agency is not convinced that defining "light" in the same manner that other relative claims are defined would be consistent with the special position of the term "light" in the marketplace and with the strong impression that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines as the available data and comments show.

The agency remains concerned about striking the proper balance between allowing manufacturers flexibility in the use of the term "light" and providing a definition that will ensure that products are improved significantly in the nutritional attributes addressed by the term. Striking the proper balance will provide consumers with meaningful product information and meaningful product choices. To define the term "light" with the same definition as for the terms "reduced" and "less" would sufficiently dilute the term so as to diminish its usefulness. Moreover, the agency is convinced that reserving the term "light" for those products that are more significantly improved will provide a greater incentive for manufacturers to continue to improve their products by providing a unique marketing vehicle by which such nutritionally significant changes can be highlighted for the consumer (See comment 174 of this document).

The agency recognizes the effect that any definition may have on brand names. However, FDA does not believe that it should permit or encourage "light" claims without further qualification on products that do not represent a major modification in fat or calorie consumption, as appropriate. Furthermore, the agency does not believe that the costs associated with compliance relative to distinctions between the two definitions for "light" and "reduced" and "less" are sufficient to warrant modification of this decision, and the comment did not provide cost information to substantiate its assertion. Accordingly, the agency is not providing the same definitions for "reduced," "less," and "light."

174. Comments expressed a variety of opinions as to the minimum percentage of fat by which a food should be reduced to qualify to bear the term "light." A number of comments objected to the 50 percent fat reduction requirement. They asserted that in certain product categories, it is not technically feasible to develop products that are reduced in fat by 50 percent or more and that are acceptable to the

consumer. The comments stated that consumers want products lower in fat but with organoleptic properties similar to the reference foods. Other comments noted a variety of manufacturing problems, such as undesirable changes in the texture, flavor, cooking applications, and storage requirements of a food, that are encountered with a 50 percent reduction in fat in a product. In addition, the comments maintained that replacement of the sensory properties of fat is difficult in low moisture content bakery products. The comments also asserted that a 50 percent or greater fat reduction in cheeses results in products with low consumer acceptance, higher moisture content, increased potential for bitter flavor development, poorer physical properties, such as rubbery texture, and microbial instability during curing and storage.

The comments also stated that a 50 percent or greater fat reduction in savory snacks, such as pretzels and chips, will have significant concomitant reductions in flavor and texture acceptability. Some comments contended that because of these problems, there is a greater likelihood that industry will develop and market fat modified foods with a one-third fat reduction than foods with a 50 percent reduction. The comments maintained that without these reduced fat products, consumers will be less able to achieve a diet composed of a variety of different foods (including products normally high in fat such as many dairy products) that is consistent with dietary guidelines.

Some comments suggested that the fat content need only be reduced by 25 percent in order to bear the term "light." The comments maintained that such a reduction would ensure truthful and nonmisleading "light" claims. One comment maintained that a 25 percent reduction was appropriate especially since the product was also required to have a minimum absolute reduction in fat of 3 g, which is significant.

A number of comments favored using "light" claims on foods whose fat content is reduced by one-third or more. Some comments suggested that a one-third reduction in fat was significant and would be desirable because it is consistent with a one-third reduction in calories. They maintained that it was easy for consumers to understand the meaning of the term "light" if a food must be reduced by a single percentage of either fat or calories in order to bear the term. One comment suggested that a one third or greater fat reduction would make a valuable contribution towards helping consumers to reduce fat intake.

Other comments stated that products should be reduced in fat by a minimum of 50 percent in order to bear a "light" claim. One comment, which acknowledged that the term "reduced" may have insufficient marketing appeal to encourage industry to create new, healthier products, proposed that "light" replace "reduced" altogether and suggested that the nutrient that is the subject of the "light" claim, for example fat, be reduced by 50 percent or more. Some comments stated that such a revised definition of "light" is desirable because the term "light" is a powerful marketing tool, and by reserving the use of "light" for truly significant reductions, FDA will create an incentive for food companies to develop new products that are nutritionally superior. One comment maintained that a 50 percent reduction in fat is sufficiently substantial to benefit consumers and feasible for industry to achieve. One of these comments suggested that 50 percent or "half as much" is an easy level for consumers to remember. Finally, one comment stated that a consumer study, conducted under their sponsorship by the University of Michigan, suggested that 78 percent of the respondents viewed "light" products to have at least a 50 percent reduction in fat.

The agency has carefully considered all of the comments. Although the agency recognizes the difficulties involved in reducing fat by 50 percent, it is not convinced that they are so great as to prevent manufacturers from producing and marketing a significant number of products with a large enough fat reduction to bear the term "light." The agency notes that the technology problems associated with fat reductions in baked goods would not be pertinent to such products' ability to bear a "light" claim because these products generally do not contain 50 percent of their calories from fat, and the 50 percent fat reduction is, therefore, not required. The same is true for certain savory snacks such as pretzels. A fat reduction is required only for products that derive more than 50 percent of their calories from fat.

The agency is not persuaded by the comments that a 25 or 33 1/3 percent reduction in the amount of fat is sufficient for a food to bear a "light" claim. The comments establish that "light" is a special term with particular marketing appeal, and as such it should have a higher standard than that used for "reduced" and "less" claims which may be used on the label of foods having a 25 percent reduction in fat. The agency believes that the definition for light should take into account consumers' perception of the term as it relates to reductions in fat. One example provided in the comments demonstrates that 78 percent of those surveyed believe that when "light" is associated with fat reduction, it means at least a 50 percent reduction in fat.

As discussed above, the agency believes that a standard for "light" should be higher than that for "reduced" and "less" claims because it would encourage innovation, leading to a greater variety of products with substantial reductions in fat, and thereby help consumers to make significant reductions in the amount of fat in the total diet. Although the agency recognizes that some products would achieve reductions greater than 25 percent if that level were the minimum fat reduction required for products to bear the term "light," additional product innovation will be encouraged because of the desirability of the term, and a wider variety of products with greater fat reductions will, in time, be developed in response to the definition that FDA is adopting. Encouraging the development and marketing of innovative fat reduced foods will provide consumers with a greater variety of foods from which to choose in building a total diet.

In addition, the agency is aware of a variety of currently marketed products, such as cheeses and cheese products, that do have reductions in fat in excess of 33 1/3 and 50 percent, including products that are fat free. With the variety of such products currently on the market, the agency is not persuaded that it is not possible to make and market consumer-acceptable products that are reduced in fat by more than 33 1/3 percent. Furthermore, manufacturers wishing to make and market similar products with fat reductions between 25 and 50 percent will still be able to inform to consumers, through use of the terms "reduced" and "less," that the product did contain a certain percentage less fat than their regular product or other similar products. Although the agency is aware from comments that such terms are less marketable than the term "light," these terms are a method of effectively communicating product changes to consumers.

In summary, FDA concludes that the 50 percent minimum fat reduction is an appropriate criterion for use of the term "light." Accordingly, the agency is retaining this provision in the final regulation.

175. One comment suggested that the term "light" should be permitted on foods whose fat content is 10 percent or less. It noted that this would conform to

the policy of FSIS for the term "light" and would be consistent with FSIS' definition for "lean."

The agency does not agree. Both agencies are developing regulations on use of "light" and "lean." In its Nutrition Labeling of Meat and Poultry Products proposal (56 FR 60302), FSIS adopted FDA's proposed criteria for "light" in place of the 10 percent or less fat content criterion used previously. Because FSIS is no longer using this criterion, the comment that FDA could harmonize the two agencies' policies by adopting the 10 percent or less criterion is not correct. Furthermore, FDA is adopting in this final regulation, FSIS' definition for "lean." Thus, these regulations will provide distinct definitions for both terms. The comment did not present any other rationale to justify its request.

176. Several comments recommended that a food be required to meet the definition of "low fat" to qualify for use of the term "light." One comment referred to a consumer survey that, it claimed, found that many consumers expect "light" foods to have "almost no fat" or "no fat at all." The comment also stated that if foods cannot meet these strict criteria now, "light" should be used only on the few foods that do qualify until food technology developments can achieve the appropriate changes. The comment argued that such an approach would encourage development of products with greater nutrient reductions.

The agency does not agree that a food should have to be "low fat" to bear the term "light." The agency acknowledges that many consumers expect "light" foods to not contribute significant amounts of fat. However, FDA does not agree that the submitted survey substantiates that consumers generally expect "light" foods to have "almost no fat" or "no fat at all." FDA's interpretation of the survey is that some consumers expect a "light" product to have "somewhat less fat" or "one-half the fat." The agency believes that requiring a 50-percent minimum reduction for foods that derive more than 50 percent of calories from fat will ensure that foods bearing "light" claims will not mislead consumers. In addition, FDA is requiring declaration of the percentage of fat reduction on all foods that bear "light" claims, not just those for which the reference foods derive 50 percent of calories from fat (§ 101.56(b)). This declaration will inform the consumer of the meaning of the term for each food that bears it.

The agency also does not agree that overly strict definitions for claims will encourage manufacturers to produce foods with greater improvements in nutrient content. As stated in the general principles proposal with respect to "reduced sodium" claims (56 FR 60421 at 60448), the current requirement for 75 percent sodium reduction is too strict. Consequently, very few foods bear the claim. The agency believes that consumers are more likely to make better food choices if a greater variety of improved foods is available, and if information on the improvement is available. Consequently, FDA is not adopting the suggestion in the comments to require that foods meet the definition of "low fat" to qualify to bear the term "light."

177. A few comments stated that the term "light" should be permitted to be used on products that are "low" in a nutrient. They stated that in the legislative history of the 1990 amendments, Congress said that it considered the term "light" to imply that a product is "low" or "reduced" in fat or calories. Another comment suggested that there are a large number of product labels that have enjoyed longstanding marketing under an interpretation of § 105.66 that "light" means either "low calories" or "reduced in calories," and that the agency should continue to allow the descriptor "light" to mean "low" or "reduced" in any nutrient.

The agency has reviewed these comments and is not convinced that the term "light" should be permitted to be used on products that are "low" in a nutrient. In proposing definitions for terms, FDA tentatively determined that it should provide unique definitions for each of the individual terms that the statute required FDA to define. However, the definitions, while distinct, provide for a range of terms to describe significant levels or differences in levels of nutrients. FDA has been persuaded by the comments that it is appropriate that the terms "reduced" and "less" have the same quantitative definition. However, the agency is not convinced by the comments that it would be appropriate for a product that is "low" in a nutrient to bear a "light" claim based only on the "low" level of that nutrient in the product. On the contrary, as discussed below in comment 179 of this document, a "light" claim is prohibited on foods for which the reference food is "low" in the nutrient. The agency has concluded that "light" implies a difference in nutrient content between two foods. Thus, in general, a reduction in a nutrient that is already "low" is insignificant, and a claim about that difference is misleading. The agency believes that the term "low" should be used to describe the level of the nutrient in such a food.

178. Most comments addressing the issue agreed with FDA's inclusion of calorie reduction as a component of the definition of "light." Most also agreed with the proposed requirement that a food's caloric content be reduced by one-third or more to qualify for use of the term. The comments said that such a reduction was significant and sufficient to justify a "light" claim. However, some comments proposed that the caloric content of a food be reduced by 50 percent or more in order for the food to be labeled as "light." One comment suggested that a 50 percent reduction in calories would be consistent with the level of fat reduction required for "light" claims and would reduce the number of insignificant claims.

The agency is not persuaded by the comments that a calorie reduction criterion for "light" claims other than the proposed one-third reduction is appropriate. The comments did not provide information to substantiate why a 50 percent calorie reduction was more appropriate. The agency discussed the one-third reduction requirement in the general principles proposal in reference to "reduced calories." It noted that because of the ubiquity of calories across all food categories, the reduction in calories in each food necessary to achieve an overall reduction of public health significance could be less than the 50 percent reduction necessary for other nutrients, including fat. Thus, given the difference in the occurrence of the nutrients in the food supply, a 50 percent reduction in fat and a one-third reduction in calories do perform a consistent function in the total diet. Moreover, permitting calorie claims at one-third reduction will allow a greater variety of nutritious foods to bear claims useful in reducing or maintaining calorie intake or body weight.

In addition, FDA has used the one-third reduction in calories as the basis for "reduced calorie" claims in § 105.66 since 1980. In that time, the agency has not found a problem with insignificant reduction in calories in foods bearing such claims. Accordingly, the agency is not revising in § 101.56(b) the percentage of calories that a food must be reduced in order to bear a "light" claim.

179. Many comments disagreed with the proposed requirement for a minimum absolute reduction of 3 g of fat or 40 calories for a food to bear a "light" claim. One comment asserted that the proposed minimum 40 calorie and 3 g criteria would eliminate "light" claims on sour cream, because those

criteria cannot be met while still retaining organoleptically acceptable products. Some comments proposed a minimum absolute reduction of 2 g of fat per serving.

FDA proposed the minimum absolute reduction requirement for "light" claims for the same reason that it proposed a minimum absolute reduction for "reduced" and "less" claims: to prevent claims for trivial reductions in nutrient content. In addition, the objections raised in comments about required minimum absolute reductions for "light" claims have the same basis as those for "reduced" and "less" claims. As was discussed in comment 158 of this document, the agency has become convinced that such a requirement discriminates against those products with small serving sizes, which could not bear "reduced" or "less" claims because they contain an insufficient amount of the nutrient to make the reduction necessary to justify a claim. The agency also was persuaded by the comments that the consumption of several servings of such products (bread for example) over the course of a day would result in significant reductions in the amount of a nutrient when considered cumulatively. Consistent with its position on "reduced" and "less" claims, FDA is persuaded that the minimum absolute reduction in the amount of a nutrient that a product must be reduced in order to bear a "light" claim, namely 40 calories or 3 g of fat, should be deleted. Accordingly, the agency is deleting this requirement from new § 101.56(b).

In addition, consistent with the requirements for "reduced" and "less" claims, the agency considers "light" claims to be misleading on products that base their reduction on reference foods that are already "low" in the target nutrient. As discussed in comment 159 of this document, the agency considers such a reduction to be trivial. Accordingly, the agency has prohibited such a reference food for products bearing a "light" claim in new § 101.56(b)(4).

180. The general principles proposal (56 FR 60421 at 60446) provided that like "reduced" and "less" claims, a "light" claim must be accompanied by a declaration of the percent of nutrient reduction, the identity of the reference food, and the absolute amount of calories and, where appropriate, fat in both the labeled food and the reference food. However, a number of comments suggested that for a "light" claim meaning "reduced calorie" or "reduced fat," a disclosure statement, qualifying statement, or other similar statement, such as the definition of the term, should appear on the label in close proximity to the "light" claim. One comment suggested that such a disclosure statement should incorporate the words "low" or "free" when they are appropriate, and that the disclosure should include a prominent comparison of both calories and fat in the food bearing the "light" claim and in the reference food. Some comments proposed that where a "light" claim is made based on fat content alone, a defining statement such as "light in fat" or "light in fat only," should appear on the label, and where a "light" claim is based on calories, a statement such as "light in calories" or "light in calories only" should appear. Several comments suggested that if a "light" product is not designated as "light" on the basis of reduced fat, it should bear a qualifying statement such as "This product is not lower in fat," and that if the product is not designated as "light" on the basis of reduced calorie content, it should bear a qualifying statement such as "This product is not lower in calories." The comments suggested that this clarification is necessary because many people are uncertain as to whether the "light" claim refers to reductions in fat or calories. Another comment proposed that where a "light" claim is made on the basis of fat content, there should be a prominent calorie disclosure which would list the percent reduction of calories compared to the reference food.

The agency advises that although the general principles proposal required accompanying information for the nutrient that has been reduced (i.e., the percent and the amount, compared to the reference food that the calories and, where appropriate, fat have been reduced), the agency did not propose to require this information for the nutrient that had not been reduced. While FDA has determined that declarations of absolute amounts of fat and calories may appropriately be made on the information panel instead of the PDP (see comment 214 of this document), the agency agrees with the comments that the term "light" may be misunderstood unless it is properly clarified. The agency concludes that because it is permitting the unqualified use of "light" when either a minimum percentage reduction in fat or a minimum percentage reduction in calories is met, but not necessarily both, the specific nature of the reduction for each nutrient must be declared. This declaration is necessary to prevent the term "light" from misleading the consumer into believing that the food has been significantly reduced in both calories and fat when it has not. This modification is in accord with suggestions in comments and is consistent with provisions of sections 403(a) and 201(n) of the act (a label is misleading if it fails to bear a material fact). Accordingly, the agency is modifying new § 101.56(b)(3) to require that the percentage that the fat is reduced, and the percentage that calories are reduced, be declared in immediate proximity to a "light" claim in conformance with the requirements of new § 101.13(j)(2), regardless of which nutrient is reduced by at least the minimum amount required in the definition.

However, the agency has determined that if a labeled product has a sufficiently small amount of fat or calories, so that it complies with the definition of "low" for the nutrient (whether normally or by modification), it would not be misleading if the percentage that the nutrient has been reduced is not specified on the label (see § 101.56(b)(3)(iii)). The absence of such information would not be misleading because the product is "low" in the nutrient and thus would be consistent with any expectations that the consumer might have that the product will be useful in achieving a diet consistent with dietary guidelines.

i. Other nutrients

The agency did not propose a definition for "light sodium" (56 FR 60421 at 60451). It stated that use of the term "light" to reflect a sodium reduction in a food would be misleading on products that were not also reduced in calories and, where appropriate, fat because consumers expected these nutrient reductions in association with the term "light." However, the agency tentatively concluded that the term "light" when used on a salt substitute would not be misleading in view of the long marketing history of these products, and because a salt substitute has virtually no calories and would, therefore, not be expected to be reduced in calories or fat. The agency, therefore, proposed that the term "light" could be used on a salt substitute if the product contained 50 percent less sodium than ordinary table salt.

181. Many comments agreed with the proposal that "light" should be defined for use on salt substitutes. They stated that "light" was an appropriate term on such products because they had essentially no calories. However, some comments stated that "light" would be confusing on a salt substitute because consumers associated the term "light" with reduced calories. Others said th "light" should not be permitted on a salt substitute as an unqualified term if the

product cannot meet the definition for "low sodium." A few comments stated that if "light" is defined for salt substitutes, the amount of sodium in the product should be declared. They said that information on the amount of sodium in a salt substitute is very important for persons who must restrict their salt intake.

The agency concludes that, as proposed, "light" is appropriate for use on salt substitutes. Salt substitutes bearing the term have had a long history of use without apparent consumer confusion. As one comment pointed out, the possibility of confusion is minimized because these products have no calories as well as no fat. Also, the agency is not persuaded that such products should be prohibited to bear a "light" claim if they are not "low sodium," i.e., 140 mg per serving, because such a rule would prohibit "light" claims on most, if not all, sodium reduced salt substitutes. Such a product would have to be reduced in sodium by approximately 85 percent to qualify for the claim.

Further, the agency advises that it recognizes that salt substitutes bearing the term "light" are used primarily by persons who are trying to limit their sodium intake, and that the amount of sodium in such a product is important information. The amount of the nutrient, in this case sodium, that is in the labeled product compared to the reference product (table salt) is required to be stated on the information panel. This statement should provide adequate information for consumers about the amount of sodium in the product. Accordingly, FDA is not changing the proposed provisions for "light" claims on salt substitutes.

182. Several comments suggested that the term "light" without qualification should be permitted for use on foods reduced in sodium. The comments suggested definitions of "nutritionally significant reduction in the amount of sodium" and minimum percentage reductions of 25, 33 1/3, or 50 percent. The comments cited a report of a study by the Calorie Control Council, "Americans Find 'Light' to Their Liking" (Ref. 27), in support of their suggestion that the term "light" should be authorized for use on products that are reduced in sodium. According to the comments, the study demonstrates that 71 percent of those surveyed knew that "light" is used to refer to a variety of product qualities such as lower in calories, fat, cholesterol, or sodium or lighter in texture, color, taste, or weight. The comments stated that their experience suggested that consumers perceive "light" to mean reduced in "more than one macronutrient," and that the term was widely used in the market place. One comment said that "light" should be defined for sodium, so that if a company could not comply with the "light" fat or "light" calories requirements, they would not be prohibited from using the term "light."

Other comments disagreed, saying that "light" claims for sodium should not be defined because consumers associate "light" with calorie content. They suggested that any product bearing the term "light" will be perceived as containing fewer calories and not less sodium. One comment cited a recent Canadian study (Tandemar Research, Inc., Consumer Use and Understanding of Nutrition Information of Food Package Labels (Jan. 1992)), in which only 3 percent of those surveyed volunteered that "light" meant "less salt," as support for its claim that "light" should not be defined to describe a reduction in sodium. Another comment related experience in marketing a product that was reduced in sodium as part of a line of "light" products, saying that there had been a number of complaints from consumers who were confused because they expected the product to be reduced in fat, not in sodium, and consequently the company had dropped the product from the "light" product line.

Another group of comments suggested that "light" should be defined for soy sauce and other low calorie foods that are used primarily as salt substitutes. They said that like salt substitutes, these products also contained virtually no calories. They added that even if a "light" claim on one of these products was misinterpreted to mean "reduced in calories or fat," no harm would come to the consumer because these products had an insignificant amount of fat and calories. Therefore, such a product would not be misleading. Yet another comment suggested that foods that are used in place of salt, but that are not calorie free, should be required to meet a calorie/fat based definition for "light."

The agency has carefully considered all of these comments concerning use of the term "light" without qualification to reflect reductions in sodium. As discussed above, the agency remains concerned that the use of the term "light" without qualification on products that are reduced in sodium but not reduced in fat or calories would be misleading to consumers because of consumers' expectations that a product labeled as "light" has been reduced in fat or calories. The agency has already considered the study by the Calorie Control Council (Ref. 27) and acknowledges that "light" has been used to connote a wide variety of meanings, such as reduced sodium and lighter in texture, color, or weight. However, the same study suggests that controlling calories (85 percent of respondents) and fat (83 percent) were two of the major reasons for use of "light" products. In addition, the report of the Calorie Control Council summary used by FDA stated that 69 percent of those surveyed cited "lower in calories" as the first response when asked the meaning of the term "light." Clearly, although consumers do consider that "light" can mean "light" in sodium, they are primarily concerned with fat and calorie reductions in "light" products. Therefore, the agency remains convinced that "light" claims without qualification on products would be misleading if the product did not have significant reductions in fat or calories. Accordingly, the agency is not providing a definitions for "light" for use on all products having only reductions in sodium.

However, on careful consideration of the comments, the agency is persuaded that, like "light" claims on salt substitutes, "light" claims without qualification on sodium reduced products containing only a few calories and little fat (i.e., a "low calorie," "low fat" food) are not misleading to consumers and can assist consumers in maintaining healthy dietary practices. The food meets the expectations of the consumer that the product is useful in achieving a diet consistent with dietary guidelines for calories and fat, albeit because the food was normally low in fat and calories rather than low in fat and calories by modification. Consequently, the agency has determined that if the sodium content of a "low calorie," "low fat" food has been reduced by 50 percent, it may appropriately bear an unqualified "light" claim. This determination is consistent with the suggestions in the comments and the definition proposed for "light" on a salt substitute. Further while other percentage reductions were suggested, no justification for any of those other reductions was provided in the comments. Accordingly, the agency is providing for this use of "light" as a 50 percent reduced sodium claim in § 101.56(c).

183. A few comments suggested that "light" sodium claims would not be misleading if a disclosure statement such as "this product is not lower in fat or calories" or other qualifying information about the nature of the modification was specified adjacent to the term. One comment cited the findings from the Calorie Control Council's study that 67 percent of those

responding believe that "light" is appropriate to differentiate product qualities so long as the term is clearly explained.

The agency has carefully considered these comments. Given the significant traditional association between the term "light" and sodium content, and the dietary guidelines that suggest a reduction in sodium intake (Ref. 7), FDA has concluded that while an unqualified "light" claim for sodium would generally be misleading, it is appropriate to provide for such a claim with respect to sodium content for use on foods that contain more than 40 calories and 3 g of fat per reference amount if the claim is appropriately qualified. The agency has determined that such a claim can be used to highlight a large, that is, a 50 percent or more, reduction in the sodium content of such food. Such a requisite reduction is consistent with the definition of "light" for fat and for sodium on foods that contain less than 40 calories and 3 g of fat per reference amount.

Therefore, to ensure that this additional "light" claim for sodium does not mislead or confuse consumers, FDA has concluded that it is necessary to tightly limit the circumstances in which it may be used. Thus, FDA is requiring in § 101.56(c)(2)(i) that this use of the term "light" must be qualified to distinguish it from the unqualified use of the term that describes reductions in fat or calories. The qualified term that FDA is defining is "light in sodium." Second, to convey to consumers that "light in sodium" is a single term, and to ensure that a misleading impression is not created by manipulations in type size, FDA is requiring in § 101.56(c)(2)(i) that the entire term be presented in uniform type size, style, color, and prominence. Consequently, if a manufacturer wishes to use the term "light" in a brand name to describe a reduction in sodium, the qualifying phrase "in sodium" or the statement "light in sodium" must appear in immediate proximity to the term "light," in uniform type size, style, color, and prominence.

Therefore, in § 101.56(c)(2), FDA is providing for a qualified "light in sodium" claim when there has been at least a 50-percent reduction in sodium content of a food as compared to an appropriate reference food (see § 101.13(j)(1)). In addition, for reasons that are similar to the discussion in comment 179 with respect to light claims for foods that are low in fat or calories, the agency believes that a "light in sodium" claim on a food whose reference food is already "low in sodium" would be misleading. Therefore, in § 101.56(c)(2)(iii) the agency is prohibiting such a claim except for meals and meal-type products (see comment 272).

184. A few comments suggested that "lightly salted" should be permitted, particularly for use on nuts. The comments suggested that the definition should be either one-third less added sodium or 140 mg of sodium per serving ("low sodium"). The comments said that because of a long history of use, consumers were familiar with the term "lightly salted." The comments also stated that "lightly salted" was an easy way for consumers to identify products with less added salt. One comment requested an exemption for "lightly salted nuts," saying that it would be similar to the "sugar free" exemption proposed for chewing gum.

The agency agrees with the comments that "lightly salted" is a claim long used, for example, on nuts, to mean that less salt has been added to the labeled product than to the regular product. In this sense, it is used as a relative claim. As such, "lightly salted" may be an appropriate term to reflect such a salt reduction. However, to be consistent with the other uses of the term "light," the agency has determined that the product must have at least 50 percent less added sodium than the regular brand. In addition, as discussed in comment 75 of this document, the agency has determined that a claim of "no added salt" would be misleading on products that are not sodium free, unless the label has a statement "Not a sodium free food" or "Not for control of sodium in the diet." Consistent with that determination, a comparable disclaimer, i.e., "Not a low sodium food," must be placed on the information panel of "lightly salted" products that are not "low" in sodium. This disclaimer will assist the consumer who may wish to control his or her sodium intake by consuming the labeled product rather than the regular version of the product from being misled into thinking that the labeled product is "low" in sodium when it is not. In addition, because this is a relative claim, the appropriate accompanying information, as specified in § 101.13(j)(2) is required. Accordingly, the agency has provided for "lightly salted" in § 101.56(g).

185. A few comments suggested that "light cholesterol" should be defined. The comments suggested definitions ranging from the criteria for "low cholesterol" to 50 percent less cholesterol. They said that to ensure such a claim was not misleading, the statement, "this product is not lower in fat or calories" could be added to the claim. However, the comments provided no justification as to why the agency should promulgate such a definition other than the finding from the Calorie Control Council Study cited previously that "light" has been used to refer to products lower in cholesterol.

The agency is not convinced by the comments that a "light" claim is appropriate on products that are reduced only in cholesterol. As discussed above in comments 170 and 182 of this document, consumers most associate "light" with reductions in fat, calories, and in certain respects, sodium. There is not the same strong association between "light"and cholesterol content. Although the report on the Calorie Control Council study mentions cholesterol as one of many qualities with which the term "light" has been associated, the report does not provide a basis to distinguish cholesterol from these other qualities as it does with fat, calories, and sodium. Thus, the agency does not consider the mention of cholesterol in the Calorie Control Council report to provide adequate justification for a "light cholesterol" claim. It does not establish a particular association between "light" and cholesterol reduction. Consequently, the agency is not providing a definition for "light" for use on products that are reduced only in cholesterol.

186. A few comments also suggested that "light saturated fat" should be defined. The definitions suggested for this term ranged from "a nutritionally significant reduction in the amount of saturated fat" to 50 percent less saturated fat. There was no justification other than the report of the Calorie Control Council's study.

As with cholesterol, the agency is not convinced that a "light" claim is appropriate on products that are reduced only in saturated fat. In the report of the Calorie Control Council Study used by FDA (Ref. 27), saturated fat is not specifically mentioned as a quality associated with use of the term "light." Consequently, the agency has no basis to determine that consumers perceive "light" to mean reduced in saturated fat. Lacking any other justification, the agency is not persuaded that use of "light" is appropriate on products that are reduced in saturated fat.

187. A few comments suggested that "light sugar" claims should be permitted. One comment stated that a "light sugar" claim should be defined to mean that the food had 25 percent less sugar and at least 5 g less sugar than the appropriate reference food. Other comments stated that "light sugar"

should be defined to mean 50 percent less added sugar. However, none of the comments provided a rationale for why "light sugar" should be defined.

The agency has reviewed these comments and is not convinced that there is sufficient reason to provide a definition for this term. The agency has determined that definitions of "light" for nutrients other than calories, fat, and, on certain products, sodium would be misleading. In addition, although the agency has not defined "less added sugar," the term "less sugar" could be used to communicate changes in the amount of sugar in the food of the sort that could be communicated if the agency adopted the suggested definition for "light sugar." However, lacking an adequate justification for the term "light sugar," the agency is not convinced that such a definition should be established. Accordingly, the agency is not providing for a definition for this term.

ii. Other uses of the term "light"

In the general principles proposal (56 FR 60421 at 60451) the agency proposed that the unqualified use of the term "light" not be permitted on the label or in labeling of a food unless the term was used to describe a reduction in calories and, where appropriate, a reduction in fat (discussed above) or on a salt substitute that contained at least 50 percent less sodium than salt. However, the agency proposed that the term "light" could also be used to describe physical or organoleptic characteristics of a food so long as that attribute adequately qualified the term "light," e.g., "light in color" or "light and fluffy," and was in the same type size, style, color, and prominence as the word "light" and in immediate proximity thereto. The agency also proposed that if the term "light" had been associated through common use with a particular food, such as "light brown sugar," to the extent that the term "light" had become part of the statement of identity, such use of the term would not be considered a nutrient content claim.

188. A majority of those commenting on the subject had no objections to products bearing the term "light" to refer to other physical or organoleptic properties of a product, so long as that property was specified. They said that in these circumstances, consumers are aware of the meaning of the term "light." However, a few comments objected to allowing such "light" claims. One stated that use of the word "light" to describe color, texture, or taste may mislead some consumers and undermine credibility of the term.

The agency acknowledges that the term "light" has at times been used in describing the physical characteristics about a product without appropriate qualifying information. An example of such a claim is "light" used to describe an oil that is "light" in color but is not altered in nutrient quality. This use is clearly misleading. However, the agency is not convinced by the comments that a claim using the word "light" to describe a physical or organoleptic property, if it adequately characterized the nature of the claim, such as "light in color" or "light and fluffy," would be misleading because the word "light" would be defined as part of the claim. In new § 101.56(e)(2), FDA is requiring that product attribute in question (e.g., the color or the fluffiness of the product) be placed in immediate proximity with the term "light." Accordingly, the agency concludes that its regulations provide adequate assurance that this type of claim will not be abused, and therefore, it is adopting the provisions (new § 101.56(e)) that provide for such claims as proposed.

189. Several comments agreed with the proposal that the physical or organoleptic properties of the food that are described in such claims should be identified immediately adjacent to, and in the same type size, style, and color as, the word "light." One comment said that without this requirement, the claim would be misleading, and the same uses of "light" that exist in today's marketplace will be perpetuated, undermining the basic purpose of the 1990 amendments. However, other comments objected to this type size requirement, saying that the attribute information should not be required to be the size of the claim. Suggestions were that the attribute should be in type one-half the size of the word "light," one-half the size of the brand name, one-half the size of the name of the food, or as prominent as the statement of identity. Another comment said that there should be no type size or placement requirements for the defining attribute. Another comment said that the graphics requirement for this information was so unreasonable and burdensome as to constitute a virtual prohibition for use of the term.

The agency has considered these comments and is persuaded that the type size requirements proposed for the information that defines a "light" claim about a physical or organoleptic property of a product would be burdensome, and that this information need not be as large as the claim to effectively clarify the physical or organoleptic properties of the labeled product. However, because of the special nature of the term "light," and the great potential for its misuse, the agency believes that it is essential that this defining information be declared adjacent to the term, and that the word "light" not have undue prominence relative to this information. The agency believes that to severely diminish the size of the defining information, or to remove it spatially from the claim, would affect the ability of the information to clarify what might otherwise be a misleading claim. FDA concludes that by permitting such information to be as small as half the size of the term "light," it will eliminate the burdensomeness of the proposal and yet still insure that the information was sufficiently prominent so as to mitigate any misimpressions caused by the use of this term. Accordingly, the agency is revising § 101.56(e)(2) to permit the defining information to be one-half the type size of the word "light."

190. Of those commenting, a majority agreed that if the term "light" had, through common use, come to be part of the statement of identity (e.g., "light brown sugar"), the term "light" need not be further defined or qualified. However, a few comments disagreed. They said that all such physical or organoleptic uses of the term should be specifically clarified no matter what the history of use of the term was. Another comment stated that this provision should be narrowed in scope so that this unqualified usage of the word "light" would be limited to situations in which the term reflected physical or organoleptic properties of the food, such as color or weight and not nutritional qualities.

The agency advises that the provision in proposed § 101.56(f) was intended to apply only to use of "light" to describe physical and organoleptic properties of the food. It was not intended to permit uses of "light" that are contrary to other parts of the regulation. Accordingly, FDA has modified new § 101.56(f) to clarify the permitted use of the term. Where the word "light" has come to be part of the statement of identity through longstanding use of the term, it is generally used to characterize a product not in comparison to a regular product, but to a contrasting version of the product e.g., "light brown sugar" versus "dark brown sugar." Without use of the term "light" to distinguish the food from its counterpart, there would be confusion as to the specific identity of the product. Therefore, the agency concludes that for such products, the word "light" is fundamental to an understanding of the product's identity. Consequently, in such circumstances, FDA is allowing, under § 101.56(f), the

use of the term "light" without qualification other than the other components of the identity statement.

191. Another comment suggested that because of a 60-year history of use, the term "light," without qualification, should be allowed on a particular brand of fruit cake to differentiate it from the "dark" version of the same brand of fruit cake.

The agency agrees that it would be appropriate in this long standing situation, for the manufacturer to use the word "light" without qualification to differentiate a version of a particular brand of fruit cake that is "light" in color from a version of the same brand of fruit cake that is "dark" in color. However, FDA advises that for this use the term "light" must appear in the statement of identity, e.g., "light fruit cake." In addition, FDA would expect the dark version of the product to be labeled "dark fruit cake," so that the terms "light" and "dark" have the same conspicuousness on the label. The agency believes that such a use is not misleading to consumers because it is clear from the relative use of the terms "light" and "dark" that the word "light" in this instance refers to the color and not to any other properties of the fruit cake.

192. One comment requested that the agency clarify and codify the method for a manufacturer to demonstrate that its use of the term "light" on a product is permissible because the term has come, through long use, to be part of the statement of identity.

The agency believes that the situations in which such a demonstration would be appropriate are sufficiently few that specific provisions are not necessary to implement this procedure. When the use of the term is broadly applicable to a class of products, a petition would be appropriate. There is provision in part 10 (21 CFR part 10) for this type of request. However, the agency does not believe that it is generally necessary to submit a formal petition to address this matter. Except for those regarding brand names, petitions are broadly applicable to a class of products and do not address a single manufacturer's product. If a manufacturer wishes to have advice on whether a product's use of the term "light" in its statement of identity is appropriate, the manufacturer may submit to the agency evidence to substantiate the longstanding, nonmisleading use of the term for this purpose. The agency will review each situation on a case-by-case basis and notify the manufacturer whether the label declaration is appropriate.

193. Another comment asked for advice on whether its brand name "Sunny Delight" was subject to the requirements for "light" nutrient content claims.

The agency advises that the term "Sunny Delight" would not, by itself, constitute a nutrient content claim. The ordinary meaning of the word "delight," as long as it is presented as a single word without any use of printing, hyphenation, or spelling that unduly emphasizes "light," does not state or imply the level of a nutrient. However, FDA also advises that it will evaluate label statements using forms of the word "light" to determine if they are used in a context in which they make claims that a nutrient has been reduced in the food.

iii. Additional terms

194. One comment stated that additional terms such as "extra light" or "ultra light" should be defined. They said that the state of California allows these definitions to describe reductions in milk fat and urged the agency to define "light" with enough flexibility to allow this labeling to continue. The comment said that "extra light" should be defined as a two-thirds fat reduction, and that "ultra light" should have no fat (a 100 percent fat reduction) compared to whole milk.

The comments have not provided sufficient justification for the terms "extra light" or "ultra light." Therefore, the agency is not providing definitions for those terms at this time. The agency is not persuaded that the consumer would understand the differences among "light," "extra light," and "ultra light," especially since definitions for such terms would be available for use on a wide variety of food. In addition, the comment did not present justification for establishing an additional definition for use on foods that appear to qualify for "low fat" and "fat free." The agency advises that, under new § 101.69, the person who submitted the comment, or any other interested party, may submit a petition to the agency, with substantiating information, requesting definition for these terms.

195. A few comments disagreed with the idea of defining "light" and "lite" as synonyms. One comment suggested that sound alike spellings for "light" (e.g., "lite") should be prohibited. Another comment suggested that the term spelled "l-i-t-e" should be used to refer to calorie reductions and the spelling "l-i-g-h-t" should refer to other product qualities.

The agency does not agree that the terms "lite" and "light" should not be synonymous. The agency points out that the statute required that the agency define "'light' or 'lite'" (section 3(b)(2)(A)(iii)(III) of the 1990 amendments). From this instruction, the agency can reasonably conclude that Congress intended that the two spellings of the term be synonymous. Further, under the statute, to not define both of these terms, the agency would need to find that one of them was misleading under section 403(a) of the act. The comment gives the agency no basis to make this finding, nor is one apparent to the agency. In addition, the agency believes that because of similarity of the terms "lite" and "light," the suggested distinct definitions for the two spellings of the term would cause confusion to consumers and would indeed be misleading. Accordingly, the agency is not changing the status of the terms "light" and "lite" as synonyms.

iv. Dietary Supplement Act

FDA proposed to require in § 101.56(a)(3) that if a food bears a "light" claim, it must be nutrition labeled in accordance with §§ 101.9, 101.10, or 101.36, as appropriate. However, as stated above, the Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. As a result, FDA is not adopting § 101.36 at this time. To reflect this fact, FDA has deleted the reference to § 101.36 from § 101.56(a)(3). FDA has also deleted references to § 101.36 from §§ 101.60(a)(3), 101.61(a)(3), and 101.62(a)(3).

3. "More" claims

Although the 1990 amendments do not require that FDA define the term "more," the agency proposed a definition and requirements (proposed § 101.54(e)) for use of "more" to describe a food in the general principles proposal (56 FR 60421 at 60453).FDA proposed that a comparative claim using the term "more" may be used to describe a food, including a meal-type product, that contains at least 10 percent or more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium than the reference food that it resembles and for which it substitutes (proposed § 101.54(e)(1)(i)).

Further, the agency proposed that when the claim is based on a nutrient that has been added to the food, fortification be in accordance with the policy on fortification of foods in § 104.20 (21 CFR 104.20) (new § 101.54(e)(1)(ii)). Also, the agency proposed to require that 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 be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(1)(iii)).

Further, the agency proposed to permit a comparative claim using the term ' more" on a food to describe the level of complex carbohydrates in a food, including a meal-type product as defined in proposed § 101.13(l), provided that the food contains at least 4 percent or more of the DRV for carbohydrates than the reference food, and that the difference between the two foods is only complex carbohydrates as defined in proposed § 101.9(c)(6)(i). The identity of the reference food and quantitative information comparing the level of complex carbohydrates with the level in the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(2)).

Finally, FDA proposed to permit a comparative claim using the term "more" to describe the level of unsaturated fat in a food, including meal products as defined in proposed § 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. Under the proposal, the identity of the reference food and quantitative information comparing the level of unsaturated fat with that of the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(3)).

The agency specifically requested comments on certain specific aspects of the proposed definitions of "more" for describing levels of complex carbohydrates and unsaturated fatty acids (56 FR 60421 at 60453 through 60454). First, both of the proposed definitions deviated from FDA's past requirements for superiority claims which, as stated above, have been based on a food having 10 percent more of the U.S. RDA of a nutrient per serving than the food to which it is being compared. Secondly, the provision in the "more" definition for unsaturated fatty acids limiting the level of trans fatty acids to 1 percent of the total fat was included because the agency believed that it would be misleading for products containing significant levels of trans fatty acids to bear claims of more unsaturated fatty acids in light of recent data suggesting that trans fatty acids act like saturated fat in raising serum cholesterol.

196. A few comments were opposed to the proposed definition of "more." The comments argued that claims for "more" should not be permitted because the 10 percent eligibility criterion is too small to be of significance to consumers. One comment suggested that claims of "more" be expressed in 5 percent increments to prohibit food companies from rounding up to make the increased nutrient level appear greater than it actually is. A few comments stated that the definition for "more" should be similar to the definition for "less," and that the food should contain 25 percent "more" of the nutrient than the reference food to be eligible to bear the term "more." A few comments were concerned that a 25 percent eligibility criterion may lead to over fortification of foods in order to be eligible to bear this term.

The agency has not been persuaded to change the definition for "more." As discussed in the general principles proposal (56 FR 60421 at 60453), the agency believes that a 10 percent greater level of a nutrient relative to the RDI or DRV in a serving of a food is nutritionally significant and is also necessary to ensure that there is truly a difference in the foods being compared. This level is the minimum level of a nutrient that must be provided by a food for the food to meet the definition of "good source" in this final rule. Consistent with this requirement, a food must provide at least an additional 10 percent of the DRV or RDI compared to the reference food before it can be designated as a better source, i.e., having "more" of the nutrient.

The nutrition labeling regulations allow for the standard practice of rounding values to the nearest percent when determining levels of nutrients (new § 101.9(c)(8)(iii)). However there is no provision in the final rule that allows for inappropriate rounding up of values when making claims.

Additionally, the values represented by a "more" claim must be truthful and not misleading. The agency considered requiring at least a 25 percent increase relative to the RDI or DRV as compared to the reference food in arriving at the proposed definition for the term "more." As discussed in the general principles proposal (56 FR 60421 at 60453), FDA 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. Therefore, the agency is retaining the proposed definition of "more" in the final rule.

197. A few comments disagreed with the proposed requirements for use of the term "more" for complex carbohydrates. The comments generally argued that defining "more" for complex carbohydrates but not defining "high" in this regard is inconsistent, and that further scientific evidence about the benefits of consuming complex carbohydrates is needed.

As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has determined that it cannot presently define, and, therefore is not defining, "complex carbohydrates." FDA has concluded that there is not sufficient consensus about the meaning of the term or appropriate analytical methodology for a specific definition for "complex carbohydrates." Therefore, the agency is not providing for the term "more" for complex carbohydrates in the final rule.

198. Most of the comments disagreed with the proposed definition for "more" for use with unsaturated fat. Most comments expressed the view that "more unsaturated fat" should not be defined until there is more scientific evidence to support the benefits of the claim. The comments were concerned that allowing the claim at this time will confuse consumers about the benefits of increased consumption of unsaturated fat. One comment suggested eliminating the additional criterion for trans fatty acid in the proposed definition because no conclusive evidence exists that trans fatty acids function like saturated fatty acids. One comment requested that the agency define "more" for monounsaturated fat.

The agency agrees that a definition for "more unsaturated fat" is unnecessary. As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has decided not to establish a DRV for "unsaturated fat." FDA has been persuaded by comments that the use of the term "unsaturated fat" is potentially confusing, does not provide useful information, and could result in consumer deception. Therefore, the agency is not defining "more unsaturated fat" or "more monounsaturated fat" in this final rule.

199. A few comments disagreed with the proposed requirement that a food containing added nutrients must be in compliance with the agency's fortification policy to be eligible to bear the term "more" on its label. The comments noted that this policy is only a guideline.

The agency concludes that this requirement is appropriate. As discussed in the general principles proposal (56 FR 60421 at 60453), the fundamental objective of the agency's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. While it is true that the fortification policy is only a guideline, in the context of new § 101.54(e)(1)(ii), FDA has subjected the use of § 104.20 (21 CFR 104.20) to notice and comment rulemaking. Interested persons were given notice that FDA intends to use that provision as more than a guideline. Such persons had an opportunity to object to provisions of that regulation and explain why such provisions did not provide an appropriate basis on which to limit the use of "more" on food labels. No comments did. Therefore, the fact that part 104 (21 CFR part 104) is generally intended to be used as a guideline has no significance here.

In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In authorizing a claim for "more," the agency is making a finding that the claim will assist consumers in maintaining healthy dietary practices (see section 403(r)(2)(A) of the act). The agency cannot make such a finding for nutrient additions that are not consistent with the fortification policy. Therefore, FDA is retaining the requirement that foods bearing the term "more" comply with the agency's fortification policy.

200. A few comments expressed interest in use of the terms "fortified" and "enriched" as synonyms for "source." The comments were of the view that these terms should be permitted because they are easily understood by consumers as a result of their use in food labeling for many years.

The agency believes that the terms "fortified" and "enriched" are not synonymous with the term "source" but more appropriately may be defined in the same manner as the term "more." "Fortified" and "enriched" convey the meaning that there is "more" or a nutrient in a food compared to another food. This approach is consistent with the agency's fortification policy § 104.20(h)(3), which states that when labeling claims are permitted, the term "enriched," "fortified," "added," or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements. Section 403(r)(2)(A)(i) of the act limits the terms that can be used to those provided for by § 101.54(e).

Therefore, the agency is providing, in this final rule, for the use of the terms "fortified," "enriched," and "added" with the same quantitative definition as the term "more" when these terms are used to describe the level of a nutrient that has been added to a food. However, as discussed in greater detail in the section of this document on reference foods, there are circumstances in which the term "more" is appropriately used but "fortified," "enriched," and "added" are not. These circumstances, which are delineated in new § 101.13(j)(1)(i), turn on whether the comparisons are being made to similar (bread to bread) or dissimilar (bread to rolls) foods.

4. Reference foods

a. Reference foods for "reduced" and "less"

201. Many comments suggested that if "reduced" and "less" were defined in the same manner, they should both be permitted to use the same types of reference foods, i.e., a manufacturer's regular brand or a food in a valid data base in addition to an industry-wide norm.

Because the agency has determined that "reduced" and "less" should have the same quantitative definition, the agency believes that it is appropriate for these two terms to be permitted to have many of the same types of reference foods (see new § 101.13(j)(1)(ii)(B)). In many circumstances, these terms can be used interchangeably.

Consequently, the agency has concluded that the manufacturer's regular brand, another manufacturer's regular brand, and a representative value for a broad base of foods of the particular type, are appropriate reference foods for both "reduced" and "less" claims. Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(B) that "reduced" and "less" claims may use as a reference a food or class of foods whose composition is reported in a representative valid data base.

However, as discussed in greater detail in comment 204 of this document, not all reference foods that are appropriate for "less" claims are appropriate for "reduced" claims. Even though these terms are based on the same percent reduction, reductions from a certain class of reference foods, those foods that are different than the labeled food but that would fall in the same product category (e.g., potato chips as a reference food for pretzels) are not appropriately described, simply as a matter of English, by use of the term "reduced." Claims that are designed to draw consumers' attention to such reductions are more appropriately phrased using the term "less." FDA has reflected this fact in new § 101.13(j)(1)(i) and has modified §§ 101.60(b)(4), 101.61(b)(6) and 101.62(b)(4), (c)(4), and (d)(4) accordingly.

In this context, the agency notes that because it has determined that "light" claims should be subject to a more rigorous standard than the other relative claims, it is limiting the reference foods that are appropriate for use with "light" claims. Under new § 101.13(j)(1)(ii)(A), FDA is requiring that the reference for a "light" claim be limited to a representative value for the type of food that bears the claim. This value may be drawn from such sources as a valid data base, an average of the three top national or regional brands, or a market basket norm.

These determinations are explained in more detail in response to the comments that follow.

202. Several comments stated that use of nutrient values from data bases as references for claims should not be limited to the kinds of data bases cited as examples in proposed § 101.13(j)(1)(iii). They suggested that other published or unpublished data bases should be available for use as a basis for claims because established data bases like USDA's Handbook 8 (Ref. 24) are not updated frequently enough to keep up with product innovation. The comments contended that more flexible data bases should be used. In addition, one comment stated that the established data bases are not truly average values because they do not account for variations in preparation of foods. For example, the comment stated, they do not provide the fat content of potato chips cooked in a variety of oils. Some comments requested clarification, including examples of what constitutes a valid data base. One suggested that there is inadequate control over the quality of the data going into a data base.

The agency recognizes the limitations of data bases. Data bases, as they apply to relative claims, are intended to be used to determine representative values for nutrients in a particular type of food for the purpose of determining nutrient differences on which to base a claim. They are not intended to provide all-inclusive nutrient values, such as nutrient values for potato chips cooked in a variety of oils. The agency recognizes that while published data bases, by their nature, are often not up-

to-date, they do provide a reference that is readily available. Further, the agency advises that while USDA's Handbook 8 (Ref. 24) was cited in the proposal as an example of an acceptable data base, it is not the only data base available for use as a reference for relative claims.

On July 23, 1992, the agency published (57 FR 32796) a notice of availability of a draft document entitled "Nutrition Labeling Manual, A Guide for Developing and Using Data Bases." This draft manual has now been subject to review and comment and is being made available in final form with the publication of the regulations. This manual details the parameters that the agency believes to be appropriate for data bases used for nutrition labeling. Because the use of descriptive terms is directly related to these same nutrient values, data derived from data bases, as described in this manual, would be appropriate for use as a basis for relative claims.

203. Some comments said that products that have been improved in order to bear nutrient content claims, especially those meeting the definition of "light," should not be included in data for reference values to be used as the basis for claims. They stated that if nutrient values of improved products were included, some improved products would eventually be disqualified from bearing claims because the data base would change as additional modified products become available.

The agency believes that all improved foods, including those that bear "light" claims, should be considered when deriving appropriate reference foods on which to base claims. To the extent that the claim is based on a reference food that is representative of a particular type of food, for the claim to not be false or misleading, the reference food should fairly reflect the market. Thus, the effect of improved foods on the market must be reflected in the reference food. The agency agrees that this position may well result in a progression of the overall nutrient values of marketed foods in a direction that is consistent with dietary guidelines, but this result is consistent with the 1990 amendments.

204. Some comments specifically supported basing claims on a comparison of dissimilar products within a product category, e.g., potato chips to pretzels. They said that without the ability to make such claims, there would be no incentive for the industry to develop reformulated products. Several other comments suggested that "reduced" claims should not be based on the difference in amount of a nutrient in dissimilar products, such as a potato chip compared to a pretzel, but that such claims should be limited to comparisons between similar products (potato chips to potato chips).

One comment stated that comparisons between dissimilar products could result in consumer confusion and would increase the possibility of misleading claims. The comment said that consumers view a "25 percent less fat" claim as a comparison to another version of the same type of food as the food that bears the claim. It went on to say that unless all products of a particular type (e.g., pretzels) make the same claim, consumers could be misled into thinking that products making the claim are nutritionally superior to those that do not, despite the fact that such claims refer to a different type of food. The comment suggested that if cross-food comparisons are permitted, additional restraints on their use are needed. As an example, the comment asked whether a "reduced sodium" claim could be made for pretzels simply because they contained 25 percent less sodium than potato chips. The comment stated that using the term "reduced" to represent such a comparison could mislead consumers.

The agency has evaluated these comments and is convinced that comparisons using the terms "light" and "reduced" are only appropriate for use in comparing similar foods, e.g., a reformulated version of a manufacturer's product to the original product (potato chips to potato chips). These terms say that there has been a change in the level of a nutrient in a given food and, therefore, are only appropriate to reflect actual changes in the level of a nutrient. Thus, they are not appropriate for use to reflect differences between two dissimilar foods (pretzels to potato chips).

The term "less," on the other hand, can have the same connotation as "reduced" and "light," or it can denote the existence of a difference between two products without implying that there has been a change in nutrient level in the product that bears the term. For example, a "reduced" claim would clearly be misleading under section 403(a) of the act if it were used on the label of a pretzel to describe that the pretzel had 25 percent less fat than potato chips if there had been no change to the pretzel to achieve the difference in the level of the nutrient, and the pretzel bearing the claim was no different than other pretzels. On the other hand, the agency is also convinced that comparisons between products that are dissimilar but within the same product category, and that can generally be substituted for one another in the diet, are useful to point out alternative food choices. This type of comparison can provide the consumer with valuable information useful in making food selections to achieve a diet consistent with dietary guidelines.

The agency does not believe that the consumer will be led to believe that claims comparing dissimilar products are applicable only to the brand bearing the claim because the use of the claim with the reference food, e.g., "25 percent less fat than potato chips," will adequately characterize the claim. Accordingly, the agency in new § 101.13(j)(1)(i)(A) is providing that the term "less" may be used to compare dissimilar foods within a product category, and in new § 101.13(j)(1)(i)(B) is limiting the reference foods for "light" and "reduced" claims to products similar to the product bearing the claim (e.g., potato chips to potato chips).

In addition, the agency points out that the 1990 amendments repeatedly state that claims provided for in this regulation and other regulations promulgated under this statute must not be misleading (e.g., section 403(r)(2)(A)(vi) of the act and section 3(b)(1)(A)(iii) of the 1990 amendments). In these regulations, FDA has attempted to provide clear guidance to manufacturers on how to state claims and on what foods are appropriate as reference foods. However, these provisions do not mandate precise phrasing for each permissible claim. Particularly for use of dissimilar foods as reference foods, the regulation does not specify what "product category" means. The agency has intentionally used a flexible standard. This flexibility is intended to facilitate useful comparisons on foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims. As a consequence, manufacturers will have to use judgment in developing claims to ensure that the claims comply with the regulations and are not misleading under section 403(a) of the act. The agency advises that it will determine on a case-by-case basis whether a claim is misleading because its overall context or presentation is misleading.

205. Several comments stated that in addition to using the nutrient values of a manufacturer's own brand of food as a basis for a "reduced" or "less" claim, similar claims should also be permitted based on comparisons of the product to another manufacturer's brand of the same food. In addition, comments stated that a recognized regional or national brand, with a significant market share,

that is competitive to the product making the claim should also be an appropriate reference food for "reduced" or "less" claims. They said that allowing for brand-to-brand comparisons would provide incentives for development of new products consistent with dietary guidelines.

The agency has evaluated these comments and has determined that use of a competitor's product as a reference food for "reduced" and "less" claims could be appropriate if done in a nonmisleading manner. A competitor's product used for comparison should be an accurate reflection of the products competing with the labeled product. Using a brand of product that is markedly different from the typical foods of the type that includes the labeled food has a great potential to result in a misleading claim. The agency would not, however, consider comparisons between the labeled product and competing products of the type with which the consumer is familiar (e.g., a market leader) to be misleading under section 403(a) of the act unless the competing product is significantly dissimilar in its nutritional attributes.

Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(A) that for relative claims other than "light," another manufacturer's product may be used as a reference food.

206. A few comments suggested that products that had previously been offered for sale but are not currently being sold should be considered appropriate reference foods for products bearing "reduced" and "less" claims. Comments suggested that such a product should be useable as a reference food for up to 6 months or 1 year after being taken off the market.

The agency agrees that it would not be misleading to highlight changes in the formulation of the labeled food, even though the old version of the product is not being marketed. Such claims could be used to point out changes in the level of a nutrient in the new product that would assist consumers in maintaining healthy dietary practices. However, FDA believes that such comparisons to discontinued products should be limited. The agency advises that it would not consider comparisons to such products misleading, provided the labeling for FDA regulated products is attached to that product no more than 6 months after the product has been discontinued from the product line. Any such comparisons after that time would be misleading because of the absence of the old "regular product" for which the new product is a substitute. As the new product replaces the old product, the new product becomes the manufacturer's regular product, thus eliminating the old product as an alternative food choice. Without this alternative choice, the comparison becomes meaningless. In addition, the agency points out that similar time restrictions are appropriate when comparing a labeled product with a competitor's product. In the event that a competitor discontinued a product, the agency believes that claims using that food as a reference would also only be appropriate for 6 months after discontinuation of the product. After that time such claims would no longer be valid because the old product would have become unavailable for consumers either to purchase or to compare.

b. Reference foods for "added," "enriched," and "fortified"

As discussed in comment 200 of this document, the agency is providing for the additional terms "added," "enriched," and "fortified" (referred to collectively for purposes of this discussion as "added"), which will have the same quantitative definition as the term "more."

The agency believes that the difference in meaning between "reduced" and "less," discussed above, also exists between "added" and "more." Comparison of the level of a nutrient between two dissimilar foods using the word "added" is misleading because the term "added" implies that the labeled food is the same as the reference food except for the addition of the nutrient. On the other hand, like "less," the term "more" would not necessarily be misleading in a comparison of two dissimilar foods within a product category that can generally be substituted for one another in the diet. The term "more" states that there is a difference between the two foods but does not imply that difference is a result of modification of the food bearing the term. Accordingly, the agency is reflecting this distinction in new § 101.13(j)(1)(i).

c. Reference foods for "light" products

In the general principles proposal (56 FR 60421 at 60445 through 60446), FDA proposed that an "industry-wide norm" be the only reference for "light" claims. The agency said that because of the special nature of this term, the reference should take into account all foods of a particular product class so as to provide the broadest base and the least opportunity for abuse of the term. The general principles proposal defined an industry-wide norm as "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."

207. A few comments agreed with the concept of an industry-wide norm, saying that maintaining a high standard for the reference for "light" claims would ensure the term's utility, and that such claims would not be misleading. However, an overwhelming majority of the comments that addressed the issue forcefully disagreed with this concept, especially since the industry-wide norm was the only basis proposed for "light" claims. The comments said that the standard of an industry-wide norm was ambiguous and could lead to erroneous comparisons between foods because of the difficulty in deriving such values. Some comments asked who was going to derive the industry-wide norm, while others, recognizing that manufacturers were responsible for label information, said that because of the difficulty in deriving the industry-wide norm, different manufacturers were likely to reach different nutrient values for similar foods. The comments said that the industry-wide norm was: (1) Too complicated to derive because it encompassed 100 percent of the foods of a particular type; (2) excessively restrictive; and (3) prohibitively expensive because of the cost involved in obtaining all the necessary marketing and nutrition information. The comments went on to say that an industry-wide norm is impractical because of frequently changing formulations, variations in products from region to region, and wide variations within certain food types even within a region.

The agency has reviewed the comments and has concluded that requiring use of an industry-wide norm as proposed would be impracticable because of the amount of data needed to include 100 percent of the foods of a particular type, because such data are not always available and because of frequently changing formulations and product variation. In addition, the agency acknowledges that the cost of acquiring such data would be very high. Accordingly, the agency finds that using the proposed industry-wide norm as a reference is unworkable and is deleting the requirement from new § 101.13(j)(1)(i).

However, because an industry-wide norm was proposed as the sole reference for products making "light" claims, as explained in response to the comments that follow, the agency has developed alternative references for "light" foods.

208. Several comments suggested that a manufacturer's own brand or another version of the food from a different manufacturer or competitor should be

an acceptable reference food for a "light" claim. They said that this reference food is appropriate especially when the labeled food was a "light" version of an existing product.

The agency disagrees. As stated in the proposal, FDA believes that for "light" claims, comparisons to a single food in a product class may be misleading, particularly when the reference food differs significantly from the norm for the product class and contains the nutrient at a level that is at the extreme end of the range for the product, e.g., deluxe chocolate chip cookies. Using such a single product as a reference for a "light" claim would result in skewed comparisons in which a product that would normally be considered average for the product type could qualify to make a "light" claim. Clearly such a claim would be misleading to a consumer who, based on it, concludes that the labeled product has 50 percent less fat or one-third fewer calories, than similar foods of the same type.

Because the comments did not provide information to persuade the agency that a provision permitting use of single foods as references for "light" claims will not result in misleading claims, the agency does not consider a manufacturer's own product to be an appropriate reference food for a "light" claim.

209. A few comments stated that the reference for "light" should be based on a market basket norm or a less comprehensive version of the industry-wide norm, e.g., 70 percent of market volume instead of 100 percent of the product.

Although these alternatives are less comprehensive than the 100 percent of the market share based industry-wide norm, they still present problems in their derivation, either because the marketing data collection and nutrient analyses are expensive especially for small manufacturers, or because they are almost as difficult to derive as the industry-wide norm. Therefore, the agency concludes that such a comprehensive standard is too burdensome to be required as a reference food for products bearing the term "light" and will, therefore, not compel manufacturers to use such a high standard for a reference. However, the agency believes that these composite values would in all likelihood be representative of the market and thus would be an appropriate representative reference for a product bearing the term "light." While the agency is not requiring these specific references, it encourages manufacturers to use them where feasible.

210. Other comments stated that values from a valid data base would be appropriate references for "light" claims.

It is possible that nutrient levels from a data base can provide the appropriate reference against which "light" comparisons could be made. A data base is an appropriate reference if it is representative of the nutrient values for foods that are similar to the food for which the claim is being made and that are currently on the market (see Nutrition Labeling Manual, A Guide for Developing and Using Data Bases). However, the agency cautions that broader, general data bases such as USDA Handbook 8 (Ref. 24) may not be representative of a single food because they may not represent the current market, especially when such data are for a rapidly changing food category such as bakery products or snack foods. Therefore, such data bases should be used with caution.

211. Several comments suggested other types of references for use with "light" claims, such as a leading national brand (e.g., one of the top three brands or a brand with 5 percent or more of the market share), or a top regional brand (for that region only). Comments noted that there needs to be a reference for manufacturers to use who only sell "light" products.

As discussed in comments 209 and 210 of this document, FDA is concerned that when a "light" claim is made, it be based on a reduction in the amount of the nutrient in the product compared to the level of that nutrient in a reference food that is accurately reflective of the foods of that specific type of food on the market. For example, if a "light" claim were made on chocolate ice cream, the agency would expect that reference the nutrient levels would not be derived exclusively or disproportionately from nutrient values from high fat or premium chocolate ice creams. Such a claim would clearly be misleading.

To the extent that values such as those suggested in the comments are representative of the market place, they would be appropriate references for "light" products. The leading national or regional brand also might be an appropriate reference food if the food is firmly and convincingly established as the market leader. However, if there were two market leaders with widely different nutrient profiles, selecting the one with the slightly higher market share for comparison could be misleading.

In summary, the agency has determined that any food or group of foods would be appropriate as a reference for a "light" product if their nutrient levels are convincingly reflective of a broad base of foods of the type that includes the product bearing the claim. Accordingly, the agency is revising new § 101.13(j)(1)(ii)(A) to provide that the reference for a "light" claim must be nutrient values for a food or group of foods whose nutrient values are accurately representative of a broad base of individual foods of the same type as that bearing the claim, e.g., an average value determined from the top three national (or regional) brands of the food, a market basket norm, or from a representative valid data base.

However, when claims are based on reference nutrient values derived from one of a variety of sources, most of which may be unknown or generally unavailable to the average consumer, the agency is concerned that in order for consumers to fully understand such claims, the basis upon which the reference nutrient values are derived be available to consumers on request. Individual reference foods are identified with the claim and thus the reference nutrient value derived from that food would be available by checking its nutrition labeling. In contrast, broad based reference nutrient values derived form average values, market basket norms, data bases, and similar sources are not ordinarily readily available to the public. Therefore, to fully inform consumers, firms that use a broad based reference nutrient value as a basis for a claim must be prepared to make information on how they derived the reference nutrient value available to consumers on request. In addition, the information must also be made available to appropriate regulatory officials on request. This additional requirement will assist regulatory officials in determining compliance with the requirements for appropriate reference nutrient values for products bearing a claim to ensure the claim is not false or misleading. Accordingly, the agency is providing for this requirement in new § 101.13(j)(1)(ii)(A).

5. Accompanying information

In the general principles proposal (56 FR 60421 at 60446), the agency stated that relative claims would be misleading unless they are accompanied by certain material facts that are necessary for consumers to understand the comparisons that are being made. The agency tentatively concluded that the percent and amount of difference of a nutrient in the labeled product compared to the reference food are material facts under sections 403(a) and 201(n) of the act. The agency proposed that this information accompany the relative claim that is in the most

prominent location. The agency also proposed that this information be in type size no less than one-half the size of the claim but no less than one-sixteenth of an inch.

212. A number of comments agreed with the proposed requirement that for a food to bear a relative claim, the product to which the food is being compared must be identified on the label. They said that naming the reference food provides information about the basis on which the claim is made and makes the other required information relevant. In addition, a majority of the comments agreed that the percentage (or fraction) that a nutrient in a product is changed should also be stated. However, a few comments stated that none of this type of information was necessary.

Because the latter comments did not present information to support their assertion, the agency concludes, that consistent with the proposal, the percentage difference of the nutrient compared to a reference food and the identity of the reference food are facts material to the claim under section 201(n) of the act. Without this information the consumer cannot fully evaluate the claim or understand the utility of the food that bears the claim in maintaining healthy dietary practices. Therefore, a claim without declaration of the percentage difference and the identity of the reference food would be misleading under section 403(a) of the act. Accordingly, the agency is retaining this requirement.

213. The comments were less in agreement regarding the necessity of retaining information about the amount of the nutrient in the product compared to the amount in the reference food. Although many comments agreed that this information was useful in assisting a consumer to evaluate the claim and to understand the role of the food in maintaining healthy dietary practices, many felt that the information was not necessary because it could be ascertained from other information on the label, such as the percentage that the nutrient in the labeled food was different from that in the reference food. Others stated that the amount of the nutrient in the labeled food compared to the amount in the reference food was redundant of the information indirectly provided by the minimum difference in the amount of the nutrient that must be achieved for the food to qualify to bear the claim.

The agency has reviewed these comments. FDA finds that a quantitative comparison between the labeled food and the reference food is not a redundant requirement. First, as explained in comments 158 and 179 of this document, the agency is not retaining the requirement of a minimum absolute reduction from the reference food because the agency has concluded that such a requirement is not necessary to ensure the validity of the claim and would only serve to deprive consumers of useful information. Consequently, the amount that the nutrient has been reduced will not be redundant of the definition of the claim. In addition, the amount of the nutrient in a food compared to the reference food is not readily discernable from the other information on the label but would be attainable only by a mathematical calculation using the percentage reduction and the nutrition information. Consequently, the agency concludes that the stated amount of the nutrient in the labeled product compared to the amount in the reference food is necessary for consumers to fully and easily evaluate and understand these claims and for it to be useful to them in maintaining healthy dietary practices. Therefore, the agency is retaining this requirement.

214. Several comments agreed with the proposed requirement that the accompanying information be adjacent to the most prominent claim. However, others disagreed. Some stated that the accompanying information should appear wherever the claim is made. A few comments suggested that it should be permitted to be located next to any claim. Others objected to any specific provisions and recommended that there be a general requirement that accompanying information appear prominently and conspicuously. Still others stated that the information could be placed on the information panel with a notation, for example an asterisk, on the PDP to encourage consumers to turn the package to the information panel for the accompanying information.

A larger number of comments took a different approach and suggested that requiring declaration of the absolute amounts of the nutrient in addition to the identity of the reference food and the percentage difference in the nutrient between the two foods resulted in too much information being required to directly accompany the claim. They stated that this information adds to label clutter on the PDP. Comments said that this provision would make it difficult, if not impossible, to provide information necessary to market the product, especially for multi-language labels. They suggested that all or part of this information, particularly the absolute amount of the nutrient in the product compared to the reference food, should be placed on the information panel. On the other hand, other comments suggested that the amount of the nutrient in the labeled food compared to the reference food was more important than the other accompanying information, and it should be retained on the PDP.

The agency has reviewed these comments and has reconsidered the proposed requirement that all the accompanying information be next to the most prominent claim. FDA evaluated the need for each of the three components of the explanatory information for the consumer to understand the claim at the point of purchase and has concluded that because the relative claim describes a difference in nutrient content between two foods, the identity of each food is essential for the consumer to understand the claim. In addition, a description of the difference in nutrient content between the two foods is needed with the claim because such a description actually defines the relative claim. The agency concludes that the most readily understood description of the difference between two foods is the percentage difference. Therefore, the percentage difference in content of the nutrient appropriately appears with the claim. Accordingly, new § 101.13(j)(2)(i) of the final regulation requires declaration of the identity of the reference food and the percentage difference in content of the nutrient to accompany the most prominent relative claim on the PDP.

However, FDA concludes that the declaration of the absolute amount of the nutrient in each of the two foods provides the type of quantitative information that generally appears on the information panel, and that, therefore, the absolute amount declaration need not directly accompany the claim. In fact, while the absolute amount declaration is a material fact under section 201(n) of the act, FDA finds that it is consistent with the scheme in section 403(r)(2) of the act to place this information on the information panel in conjunction with nutrition labeling. Specifically, if a food that bears a nutrient content claim contains another nutrient in an amount that exceeds the applicable disclosure level, section 403(r)(2)(B)(ii) of the act requires that that nutrient be highlighted in conjunction with the claim, and that the consumer be referred to the information panel for quantitative information about that nutrient. Here, analogously, the comparative percentage differences are to be set forth with the relative claim, and the referral statement will guide the consumer to the information panel for the relevant

quantitative comparison. Accordingly, FDA has revised new § 101.13(j)(2)(iv) to permit declaration of the absolute amount of the nutrient in each food on the information panel. Of course, a manufacturer is free to place this information in direct proximity with the claim.

FDA disagrees with comments that requested that all accompanying information be declared with the claim each time it is stated on the label. In the general principles proposal, the agency tentatively concluded that the consumer will likely read the most prominent claim at the point of purchase, and that if the essential information is declared near that claim, the consumer will receive adequate explanation of the meaning of the claim.

The comments did not explain why this presentation is inadequate. In addition, requiring that accompanying information appear with every claim would add considerably to label clutter. FDA agrees with the many comments that stressed that label clutter should be minimized to the extent possible. The agency concludes that requiring that the information accompany the claim each time it appears would reduce the readability of the label while providing no additional information. Therefore, the agency is not adopting such a requirement.

Finally, FDA concludes that requiring an asterisk on the PDP to guide the consumer to the amount of nutrient information on the information panel is not necessary. The referral statement required to accompany all nutrient content claims (new § 101.13(g)) will be on the label and will direct the consumer to the information panel. Additional referrals to the information panel would be redundant.

215. One comment stated that while the percentage the nutrient differs compared to the reference food and the referral statements were appropriate for single nutrient claims, this same information for multiple claims would clutter the PDP.

The agency recognizes that multiple claims would require more information on the PDP. However, because the absolute amount of the nutrient compared to the reference food will no longer be required to be on the PDP, and because § 101.13(g) requires that there be only a single referral statement when multiple claims are made on the same panel, the label information required to be on that panel is considerably lessened. In addition, although not required, a single reference food will likely be used when multiple claims are made on a particular product. Use of the same reference food will considerably reduce the amount of information on the label. In addition, in light of the changes that the agency is making in this final rule, the percentage that the nutrient has been changed will often be part of the claim, e.g., "25 percent reduced fat cheese cake." Therefore, the agency concludes that no additional changes in declaration requirements are necessary for multiple nutrient claims.

216. Several comments suggested that the percentage declaration that accompanies the claim be in the same type size, style, and color as the rest of the claim. However, many other comments suggested that the proposed type size requirement would make the declaration too large and would leave insufficient label space to effectively convey information about the product. To substantiate this contention, the comments provided mock ups of labels showing how the type size requirements would lead to label clutter. They requested that the type size be reduced.

The agency considered these comments and examined the label examples that were submitted. As a result, the agency has become convinced that the type size requirements for accompanying information may so crowd the PDP that manufacturers may not be able to effectively communicate needed information to the consumer. Therefore, the agency has determined that a different type size requirement is appropriate for this information. Because the accompanying information is adjacent to (although preceding) the referral statement and, like the referral statement, is used to clarify the claim, the agency concludes that the accompanying information should be subject to the same type size and style requirements that it has prescribed for the referral statement. Therefore, the agency in new § 101.13(j)(2)(ii) is cross-referencing the type size requirements in new § 101.13(g)(1) for referral statements. Thus, the accompanying information will be in the type size required by § 101.105(i) for net contents declaration or one-half the size of the claim, as appropriate, but in no case less than one-sixteenth inch.

217. A few comments suggested that the labeling disclaimers for substitute foods that do not have the same performance characteristics as the original food, e.g., "Not for use in cooking," be required on foods that bear "light" claims as well those that bear "reduced" claims.

The agency advises that the requirement for performance characteristic labeling for substitute foods applies to all foods that bear claims that they may be used interchangeably with another food. Therefore, the disclaimer requirement in § 101.13(d) will apply equally to any food in which a nutrient level has been changed and that bears a nutrient content claim including "free," "low," "reduced," "less" (or "fewer"), "light," "more," and "added."

6. Modified

218. Of those commenting on the term "modified," most agreed with the proposed use of the term. However, one comment stated that the term "modified" does not explain whether the nutrient has been reduced or augmented. Another comment suggested that the word "modified" used to compare dissimilar products would be misleading and recommended that foods bearing the term "modified" as part of the statement of identity not be allowed to use a dissimilar food as reference food. It said that a food labeled "modified" should be required to be actually changed as compared to other foods of its type. A few comments said that "modified" should be used only to distinguish chemical changes in a food or to refer to the nutrient character of the food (e.g., "modified fat" or "modified food starch"), not to a change in the amount of a nutrient. A comment suggested that "adjusted" should be used instead of "modified." Another comment suggested that the term "modified" was unattractive for marketing purposes.

The agency points out that the term "modified" is not meant to be used alone, nor was the term meant to be used to describe products that had not been altered. Therefore, as discussed in comment 204 of this document, the term will not be permitted based on a comparison to a dissimilar product.

Additionally, because the word "modified" reflects a change in the food, the reference food used for the "modified" would be one that was appropriate for a "reduced" or "added" claims. For example, a modified fat cheddar cheese would have as its reference a full fat version of cheddar cheese, not some other cheese.

The comment suggesting "adjusted" did not provide any basis to believe that this term is more useful as part of the statement of identity to reflect a change in a food than is the term "modified." In addition, the agency is not persuaded that the term "modified" is an inappropriate term to reflect nutrient changes in a food, or that it should be limited only to uses describing changes in the chemical nature of a food or in the character of the food, such as "modified food starch." Accordingly, the agency is not amending its provision

for the term "modified" and is retaining the criteria as proposed in § 101.13(k).

D. Implied Claims

In the general principles proposal (56 FR 60421 at 60423), FDA proposed to define an implied nutrient content claim as 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"). The agency stated that, under the provisions of the statute, such implied claims are prohibited until they are defined by FDA by regulation.

However, the agency recognized that an argument could be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers about the nature of certain ingredients. Likewise, the agency said that statements that a particular ingredient constitutes 100 percent of the food, e.g., "100 percent corn oil," should not be considered implied nutrient content claims when such statements are the statement of identity for the food. Moreover, the agency reasoned that claims such as "contains no preservatives" could not be characterized as nutrient content claims because they do not relate to nutrients of the type addressed in nutrition labeling.

The agency requested comments on how to draw an appropriate line between implied nutrient content claims and ingredient and other label claims. The agency did not propose regulations that authorized specific implied claims. However, it solicited comments concerning criteria for evaluating whether implied claims are appropriate and not misleading, as well as information on specific implied claims. The agency said that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. The agency said that, alternatively, it would defer action on implied claims until after the rulemaking required by the 1990 amendments is complete and would then consider individual implied claims through the petition process on a case-by-case basis.

1. General

219. The agency received a wide variety of comments on what should constitute an implied nutrient content claim, and on what steps the agency should take to regulate such claims. Some comments stated that FDA must maintain strict control of claims made on food labels in order to prevent misleading nutrient content claims and subsequent consumer confusion. Another comment stated that the agency should develop a list of acceptable implied nutrient content claims and accept others on a petition basis. Several comments asserted that the proposed regulations are too vague and will not allow manufacturers to determine whether or not an ingredient claim will be considered an implied nutrient content claim by the agency. Some of these comments stated that because of the vagueness of provisions that rely on interpreting consumer perception and the criminal nature of violations of the act, it is incumbent on the agency to define with specificity, and through rulemaking, the standards by which implied claims will be judged. Other comments provided a wide variety of suggestions, discussed in detail below, as to what should constitute an implied nutrient content claim, what should not constitute such a claim, and what, if any, implied nutrient content claims should be provided for in regulations.

Other comments suggested that factual statements, particularly ingredient statements, that constitute implied claims and that are found to be misleading should be regulated under the general misbranding provision of section 403(a) of the act. One of these comments asserted that whether a label statement is an implied nutrient content claim can only be determined on a case-by-case basis in which the context of the entire label is considered. The comment stated that it is highly implausible to identify specific words that will always constitute implied claims. Some comments supported such a case-by-case approach on the grounds that a blanket prohibition of ingredient claims that constitute implied nutrient content claims would prohibit the presentation of truthful labeling statements concerning the content of a food product. Another comment stated that affording manufacturers wide latitude in language would better serve to educate consumers about nutrition and the nutrient content of food, because they would not become bored with and disregard a limited number of repetitive descriptors.

The agency disagrees with those comments that said that implied claims should be prohibited and also with those that suggested that all implied claims should be regulated under section 403(a) instead of 403(r) of the act. The language of the statute and the legislative history make clear that implied nutrient content claims are subject to the nutrient content claims regime. Section 403(r)(1)(A) of the act provides that a food is misbranded if it bears a claim that "expressly or by implication characterizes the level" of a nutrient unless the claim is made in accordance with regulations established by FDA. Section 3(b)(1)(A)(i) of the 1990 amendments instructs the agency to establish regulations that identify claims described in section 403(r)(1)(A) of the act that comply with section 403(r)(2). The legislative history (H. Rept. 101-538, supra 19) includes reference to "high in oat bran" as an example of an implied nutrient content claim. This reference to an ingredient claim as an implied claim subject to section 403(r)(1)(A) of the act clearly demonstrates that Congress intended that at least some statements about ingredients be subject to regulation under section 403(r)(1)(A). Accordingly, FDA concludes that it must attempt to define implied nutrient content claims.

The agency examined the comments carefully in attempting to devise a scheme for determining when a label statement is an implied nutrient content claim. The agency agrees with the comment that stated that in many cases whether a label statement is an implied nutrient content claim can only be evaluated on a case-by-case basis, considering the entire label and the context within which the claim is made. However, FDA also agrees with the comments that the definition in proposed § 101.13(b)(2) is too vague. Accordingly, as discussed below, FDA has modified that definition. Moreover, FDA has identified groups of claims that it concludes can be defined and would not be misleading. The agency is providing in new § 101.65(c) definitions for these claims.

However, because of the large variety of statements that can be considered to be implied claims, because of resource constraints, and because of the strict timeframes under which this rulemaking has been accomplished, FDA is unable to adopt a comprehensive set of implied nutrient content claims. Interested persons may provide information to the agency with which it can develop additional definitions, or they may submit petitions requesting approval of specific definitions or brand names.

2. Statements that are not implied claims

The agency has attempted to define as many groups of implied claims as possible so as to permit as many appropriate, nonmisleading implied nutrient content claims as possible in

this final rule. In addition, FDA examined the comments carefully to identify groups of label statements about ingredients and other attributes of foods that are not implied nutrient content claims. The agency finds that it can distinguish several types of statements that can be excluded from the requirements for nutrient content claims. The agency is describing these claims in new § 101.65(b).

a .Statements that facilitate avoidance

220. Several comments stated that some statements of the absence of a substance or an ingredient provide valuable information to consumers who seek to avoid certain substances. The comments noted that statements such as "100 percent milk free" or "contains no milk or milk fat" serve primarily to assist those buyers who adhere to Kosher dietary laws, or those who suffer from lactose intolerance, and wish to avoid dairy products. Other comments noted that statements such as "contains no MSG" or "contains no wheat flour" provide useful, indeed, sometimes vital, information to consumers who are sensitive to these substances. The comment stated that it was not clear from the proposal whether these ingredient statements would be permitted.

The agency has considered these comments and agrees that such statements are not nutrient content claims. Statements of the absence of an allergen are regulated under § 105.62 (21 CFR 105.62), which provides for labeling of foods for special dietary use by reason of the absence of an allergenic property. Statements that declare the absence of other food components or ingredients that are not nutrients of the type required to be declared in nutrition labeling and that are intended to facilitate avoidance of the substance for such reasons as food intolerance, religious beliefs, or dietary practices (such as vegetarianism), e.g., "100 percent milk free," are also not nutrient content claims. FDA has included new § 101.65(b)(1) in its regulations to recognize this fact. However, the agency cautions that such a statement could be made in such a way as to connote a nutrient content claim. For example, a statement such as "contains no milkfat" made in context with other label information about the benefits of reducing fat intake, implies that the product is "fat free." In such a context, the statement would be a nutrient content claim subject to section 403(r)(1)(A) of the act. Also, for example, claims such as "no tropical oils" or "contains no animal fat" are usually made in a context that implies that the product has little or no saturated fat. Therefore, such claims would not be avoidance claims under the provisions of § 101.65(b)(1) but implied "saturated fat free" claims. Thus, they would have to meet the requirements for such claims.

b. Ingredients that do not serve nutritive purposes

221. Several comments stated that factual statements about ingredients, by their very nature, are not nutrient content claims and should be allowed on food labels (e.g., "no artificial colors" and "contains no preservatives"). One comment suggested that this criterion should also apply to nonnutritive or nutritionally insignificant sweeteners such as saccharin, aspartame, and acesulfame-K and to the brand name Nutra-Sweet. Such claims, the comment said, should be accompanied by "not a reduced calorie food" if appropriate, and the label should provide a statement referring specifically to the caloric and sugar declarations in nutrition labeling.

The agency continues to believe, as it stated in the proposal, that claims about the absence of certain substances that do not function as nutrients, such as preservatives and artificial colors, provide information important to certain consumers but are not nutrient content claims because they are not claims about the level of a nutrient. Consequently, such claims are subject to regulation under section 403(a) of the act, to ensure that they are truthful and not misleading, but not section 403(r). Accordingly, the agency is listing in new § 101.65(b)(2) as a second class of claims that are not nutrient content claims, those that are about substances that do not have a nutritive function and do not substitute for nutritive substances, e.g., "contains no preservatives" or "no artificial colors."

However, FDA does not agree with the comment's suggestion that this policy should also apply to label statements referring to the presence of nonnutritive or nutritionally insignificant sweeteners. In the past the agency has regulated statements like "artificially sweetened" and "sweetened with nonnutritive sweetener" as claims of special dietary usefulness (§ 105.66), which in some contexts imply that the food is "low calorie" or "reduced calorie." Elsewhere in this issue of the **Federal Register**, in a companion final rule on revisions to § 105.66 related to the nutrient content claims regulations in this final rule, FDA has discussed its policy on label statements that refer to the presence of a nutritionally insignificant sweetener in a food. In that document the agency reiterated its position that such claims are subject to either new § 105.66(a) and (b), or (e).

c. Ingredients that provide added value

222. A few comments stated that claims about ingredients that provide added value to products convey important information about the quality of the products and should not be considered implied nutrient content claims. The comments suggested that claims such as "made with butter," "contains buttermilk," "made with whole wheat flour," "contains real fruit," or "made with natural, not processed, cheese" would be examples of added value claims.

The agency agrees that some of these claims would be useful as tools for the manufacturer to communicate to the consumer that the product is of high quality because premium or otherwise preferred ingredients have been used. In most instances, statements such as "made with butter," "made with whole fruit," or "contains honey" would not be considered to be a statement about the product's nutrient content. Accordingly, in new § 101.65(b)(3) the agency is listing claims about the presence of an ingredient that is perceived to add value to the product, such as "made with butter," "made with whole fruit," or "contains honey," as statements that are not nutrient content claims. However, there would be cases, such as "made with whole wheat flour," where the added value statement is made in such a context that it could imply not only that a preferred ingredient was used, but also that the product contained a certain level of a nutrient (e.g., fiber). Such statements would be subject to section 403(r) of the act.

d. Statements of identity

223. Some comments agreed with FDA's discussion in the proposal that factual statements that a particular ingredient constitutes 100 percent of the food (e.g., 100 percent corn oil or 100 percent Columbian coffee) are statements of identity and not implied nutrient content claims. In addition, one comment specifically requested that FDA clarify that the names of dietary supplements (e.g., Vitamin C supplements) will not be considered implied nutrient content claims.

The agency concludes that when an ingredient constitutes essentially 100 percent of the food, so that the name of the ingredient is the statement of identity, the name of the ingredient does not constitute an implied nutrient content claim. In such circumstances, the name of the ingredient constitutes

the common or usual name of the product as described in § 101.5 or the identity of the commodity as described in § 101.3. As such it must provide an adequate description of the food.

When the ingredient is not associated with a nutritional benefit (e.g., Colombian coffee), it is clear that the statement of identity does not imply that a nutrient is present or absent in a certain amount. When the ingredient is associated with a particular nutritional benefit (e.g., corn oil), declaring its presence could imply the presence or absence of a nutrient. However, when used as the statement of identity, the name of the ingredient does not imply that the nutrient is present in a certain amount. Rather, it describes the nature of the product and does not specifically characterize the level of the nutrient. Hence, it would not be considered a nutrient content claim. As for the comment that the names of dietary supplements (e.g., vitamin C supplements) are usually not nutrient content claims, FDA intends to deal with this issue in the rulemaking that it will conduct under the Dietary Supplement Act of 1992.

Accordingly, FDA is providing in new § 101.65(b)(4) that the name of an ingredient is not a nutrient content claim when the ingredient constitutes essentially 100 percent of a food, so that the name of the ingredient is the statement of identity of the food. The agency notes, however, that a statement of identity may include an express nutrient content claim (see e.g., the final rule on requirements for foods named by use of a nutrient content claim and a standardized term, published elsewhere in this issue of the **Federal Register**). Such nutrient content claims are fully subject to new § 101.13 and the regulations in part 101, subpart D.

224. Several comments suggested that common names or statements of identity of foods that include terms that relate directly or indirectly to the nutrient content of a food (e.g., "oat bran muffins") should be considered implied nutrient content claims. Other comments suggested that such statements are merely statements of the characterizing ingredient and should not be considered implied nutrient content claims. They suggested that "oat bran muffin" is not different from "carrot spice muffin." One comment stated that truthful statements such as these should be assumed to be nonmisleading unless there is evidence to the contrary and should be permitted as part of the statement of identity.

While FDA agrees that most statements of identity are statements about the character of a food, there are a limited number of statements of identity that contain the name of an ingredient that is associated with a nutrient or a nutritional benefit and that therefore may also be implied nutrient content claims, depending on what other statements are made on the label or in labeling. Examples of such statements of identity would be "corn oil margarine," "oat bran muffins," and "whole grain bread." The agency will evaluate such claims on a case-by-case basis in the context of the entire label and the labeling to determine whether they are nutrient content claims. For example, if the labeling of oat bran muffins includes a discussion of the importance of fiber in the diet, FDA believes that the "oat bran muffins" name is an implied claim that the muffins are high in fiber. If the labeling is devoid of such information, FDA is not likely to consider the name to be an implied nutrient content claim. Accordingly the agency is providing in new § 101.65(b)(5) that a statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels") is not an implied nutrient content claim unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount.

Statements of identity that are provided by a standard of identity subject to section 403(r)(5)(c) of the act are not subject to definition under section 403(r) of the act and are therefore not considered nutrient content claims.

e. Statements of special dietary usefulness

225. One comment requested that the agency clarify that FDA will not deem a statement of special dietary usefulness made on the label or in labeling of a food in accordance with part 105 of FDA's regulations to be an implied nutrient content claim solely because it represents the food to be for special dietary use.

The agency has considered this comment. As stated in the general principles proposal (56 FR 60421 at 60457), FDA views claims on a food relative to special dietary needs to be different from claims made on a food relative to the nutrient content of the food. The agency would not consider claims made solely to portray the usefulness of the food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 to be a nutrient content claims subject to new § 101 13. A claim such as "use as part of a weight reduction program" in and of itself, would not be considered to be a nutrient content claim.

However, there are circumstances in which a claim that a food is useful in a special diet may be made in a context that portrays a nutritional aspect of the food relative to the general population. If, for example, in addition to including a claim that the food was part of a weight reduction program, the label said that the food was "low calorie," or the label contained other statements of specific nutritional information, then such statement would be subject to the requirements for nutrient content claims because the label contained information directed toward the general population. Accordingly, the agency is providing in new § 101.65(b)(6) that label statements made in compliance with part 105 solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition where the claim identifies the special diet of which the food is intended to be a part, is generally not a nutrient content claim.

3. Single nutrient implied claims

a. Ingredient statements

226. Many comments addressed how requirements for implied claims should be applied to ingredient statements like "contains oat bran" and "corn oil margarine." Some stated that ingredient statements should not be considered implied nutrient content claims. Other comments stated that even though there are good reasons for having ingredient statements on labels, the fact that a declaration is an ingredient statement does not preclude the possibility that it is also an implied claim. Some said that claims such as "contains no tropical oils" and "made with 100 percent vegetable oil" would be misleading to consumers who would be led to assume that such a product is low in or free from saturated fat, when that is often not the case. A few comments stated that to prevent ingredient claims from being misleading nutrient content claims, all ingredient statements should be subject to the provisions of section 403(r) of the act.

The agency disagrees both with the comments stating that no ingredient claims should be considered to be implied nutrient content claims, and with those that want all ingredient claims to be regulated under section 403(r) of the act. As discussed above, some ingredient statements clearly are not implied nutrient content claims, and

some clearly are, while other ingredient statements will have to be evaluated on a case-by-case basis to determine whether they are implied claims. The agency will evaluate ingredient statements in the context of the total label to determine whether they are implied claims and therefore subject to section 403(r)(1)(A) of the act. The agency's focus will be on whether the ingredient statement identifies a nutrient explicitly or by implication, and whether it states or implies that the nutrient is absent, or that it is present in a certain amount.

227. One comment disagreed with FDA's definition for single nutrient implied claims in proposed § 101.13(b)(2), stating that the phrase "leads a consumer to assume" should be changed to "consumers acting reasonably under the circumstances." This phrase is preferable, the comment said, because it requires that the label be interpreted reasonably, rather than in an arbitrary, unusual, or unreasonable fashion. The comment asserted that a standard that is based on the interpretations of a few credulous people is not legally sustainable. The comment stated that the phrase "consumers acting reasonably under the circumstances" correctly takes into account the context in which the statement is made.

The agency has considered the comment and disagrees that "consumers acting reasonably under the circumstances" is a more valid standard for implied nutrient content claims than the one proposed by the agency. The focus of FDA's definition of implied claims is on what the claim suggests. The definition is not intended to be a quantitative standard to determine the number of consumers who have a particular conception about an individual claim but is intended to focus on what the claim is saying. To clarify the intent of the definition, FDA is striking the phrase in question and replacing it with the word "suggests."

228. A few comments said that FDA should evaluate, on a case-by case basis, whether a manufacturer intends a particular label statement to make an implied nutrient content claim, and whether consumers perceive the statement to be that claim. The comments asserted that a similar approach has been supported by the courts in determining whether a product is sold as a food or a drug.

In making an evaluation of a label statement within the context of the labeling as a whole, FDA agrees that it should consider both the manufacturer's intent and consumer perception. However, it notes that intent means more than the manufacturer's subjective intent. See *National Nutritional Foods Association* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its label, labeling, promotional materials, advertising, and "any other relevant source." Id.

FDA advises that it will evaluate ingredient label statements on a case-by-case basis using the definition of implied claims in new § 101.13(b)(2) and the other provisions of the regulations to determine whether a label statement is an implied nutrient content claim. As stated above, the agency's primary focus will be whether the statement identifies the nutrient explicitly or by implication, and whether it states or implies absence of that nutrient or its presence in a certain amount.

229. Several comments suggested that the agency should consult popular media, scientific articles, and consumer surveys to determine when an ingredient claim constitutes an implied nutrient content claim. Several of these comments suggested that implied claims should not be allowed on food labels unless there is scientific consensus as to what these terms mean. On the other hand, a few comments suggested that a statement about an ingredient is not an implied nutrient content claim, unless there is direct consumer survey evidence that a substantial number of consumers understand the statement to imply a specific nutrient claim. The comment contended that any other position would create chaos because manufacturers would continually be in doubt as to whether an ingredient claim would be interpreted by the agency to be an implied nutrient content claim.

Another comment asserted that claims must be interpreted in their historical context. The comment stated that "high in oat bran," implying "high in fiber," for example, is taken out of context. The comment stated that at the time the claim became widely used, consumers believed that they needed to eat oat bran, not soluble fiber, to lower cholesterol. The comment further stated that consumers wanted to know the amount of oat bran in a product in order to follow a diet high in oat bran. However, current scientific evidence may not substantiate this early finding, and the necessity for consuming large amounts of oat bran may not currently be supported by scientific data. Therefore, for an implied claim to be considered valid, the comments said, current scientific data must be considered.

The agency agrees that nutrient content claims should be defined so as to be meaningful to consumers. It has attempted to ensure through the definitions established in these regulations that permitted claims will assist consumers in maintaining healthy dietary practices. In addition, where possible, FDA has used information on consumer understanding of terms. However, the agency is not persuaded that direct consumer survey information is always needed for it to provide clear guidance to manufacturers on whether an ingredient statement is an implied nutrient content claim. As discussed above, FDA is describing in this document some label statements that clearly are nutrient content claims, and others that clearly are not. For those label statements not addressed in this document, manufacturers who wish guidance can submit a petition requesting approval of a claim. The minimum requirements for information needed to support such a request are described in new § 101.69. Petitioners are welcome to provide consumer survey information as well as other types of information in support of a petition.

230. Some comments asserted that FDA's definition of implied nutrient content claims should be limited to those statements that either expressly or by implication describe the level of a nutrient present in a food, as opposed to simply describing the food's composition. One comment stated that such an approach is consistent with Congressional intent as recorded in the House Report, which states:

> An example of an implied claim covered by this section 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, or "high oat bran" which conveys an implied high fiber message.

(H. Rept. 101–538, 101st Cong. 2d sess. (June 13, 1990).)

Another comment asserted that it would be inconsistent with the language of the 1990 amendments to regulate claims about an ingredient that do not characterize the level of that ingredient as implied nutrient content claims. The comment requested that FDA specifically exempt ingredient claims that do not directly or indirectly refer to the level of a nutrient (e.g., "contains oat bran" and "made with vegetable oil").

As already discussed, FDA agrees that statements that describe (expressly or by implication) the level of a nutrient present in a food are nutrient content claims. In addition, for ingredients with nutrient implications (e.g., "bran" implies fiber and "tropical oils" implies saturated fat), a claim that describes the

level as "high," "low," or "free" clearly constitutes a nutrient content claim.

The agency does not agree, however, that claims such as "made with oat bran" and "contains vegetable oil" should be exempt from the regulations. It is not clear to FDA that such claims describe the nature of the food and not the level of a nutrient. The agency notes that it is providing in new § 101.54 that a claim that a food is a "good source" of a nutrient can only be made if the nutrient is present at 10 percent or more of the RDI or the DRV per serving of the food. The agency is also providing for use of the terms "contains" and "provides" as synonyms for "good source." As a result, "contains fiber" is a defined expressed claim that must meet the 10 percent of the DRV criterion.

The question then becomes whether "contains oat bran" and "contains whole wheat" imply that the food is a "good source of fiber." Some comments state that such claims are implied nutrient content claims, while others argue that they are statements about an ingredient and not the level of a nutrient. The agency concludes that, in certain contexts, these statements would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient. For example, if a label declared "Joe's Oat Bran Muffins" or "Joe's Muffins, made with oat bran" the prominence of "oat bran" may not call attention to it is a way that proclaims its nutritional value. However, if "Joe's Muffins" bore a bright banner with "oat bran" in large, bright letters, the emphasis on "oat bran" would likely place it in the overall context of a nutrient content claim. However, FDA will evaluate these claims on a case-by-case basis, taking into account the entire label and the labeling, including the placement and prominence of the claim as well as the text of label statements.

231. Some comments asserted that FDA should narrow the definition of nutrient content claims to include only those claims specifically mentioning a nutrient of the type addressed in section 403(q) of the act and of the type appearing as part of the nutrition panel (e.g., fat or cholesterol). Similar comments asserted that any statement regarding an ingredient, as opposed to a nutrient, should not be considered an implied claim. One comment asserted that even those ingredient claims that imply that a nutrient is absent or present in a certain amount are not implied claims. Rather, according to these comments they are more appropriately considered statements of identity or parts of ingredient claims. Some comments specifically disagreed with the House report and FDA that the phrase "high in oat bran" should automatically constitute an implied fiber claim. These comments argued that this claim, as well as others that simply describe the ingredients present in a product in a truthful and nonmisleading manner, should be considered ingredient statements. One comment supported this position by stating that these claims do not automatically lead a consumer to assume that fiber is absent or present in any amount. The comment asserted that such a statement simply advises consumers that oat bran is used as a significant ingredient in the product. The comment went on to say that while oat bran does have some relationship to fiber, consumers will not automatically associate the two. A similar comment requested that FDA alter proposed § 101.13(b)(2) to read, "e.g., high in oat bran, which may imply that a food is also high in fiber."

The agency does not agree that nutrient content claims under section 403(r)(1)(A) of the act are limited to label statements that specifically identify a nutrient, e.g., fat or cholesterol. The legislative history identifies the term "high in oat bran" as an example of an implied nutrient content claim (H. Rept 101–538, 101st Cong. 2d sess. 19 (June 13, 1990)). This statement provides strong evidence that when Congress said that "a claim * * * which expressly or by implication—characterizes the level of a nutrient * * * must be made in accordance with section 403(r)(2)," it intended to include ingredient claims that imply that a nutrient is present at a particular level in, or is absent from, the food. Accordingly, FDA rejects the comment that objected to this interpretation.

The agency advises that there are long established relationships between ingredients and nutrients that are covered under the definition of implied nutrient content claims. Some of these ingredient-nutrient relationships have been regulated as claims for special dietary use. For example, terms like "sugar free" have been regulated by FDA as implying that the product is low or significantly reduced in calories (§ 105.66). In addition, FDA has issued warning letters regarding foods that contain tropical oils (which contain significant levels of saturated fat) when they bear label statements, like "100 percent vegetable oil," that imply that these ingredients have low levels of saturated fat.

Consequently, FDA is not granting the request to exempt from the nutrient content claim requirements ingredient claims that do not explicitly identify a nutrient. However, as discussed in the previous comment, the agency acknowledges that some statements that name ingredients that have nutritional relevance are not nutrient content claims. The agency will evaluate such claims on a case-by-case basis. In addition, where appropriate, manufacturers may submit petitions under new § 101.69 requesting approval of specific claims.

232. A few comments suggested that only those ingredient statements that meet the definition for a defined nutrient content claim should be considered implied nutrient content claims, and that all other ingredient claims should not be considered nutrient content claims. However, several other comments suggested that all ingredient claims that imply that a nutrient is either absent or present at a particular level, whether or not they met the definition of the expressed term, should be considered implied nutrient content claims.

Some of the latter comments said that only those implied claims that meet the requirement for an analogous expressed claim should be permitted on the label or in labeling. For example, several comments said that a statement that a product "contains oat bran" implies that the product is a good source of fiber and should, therefore, only be permitted on foods that meet the definition for "good source of fiber." The comments said that requiring that the expressed claim be met in order to make an implied claim would be effective in preventing manufacturers from using claims on food that may not meet appropriate nutritional standards. Another group of comments stated that any "no [ingredient]" claims (e.g., "contains no tropical oils") that imply that the product is free of a nutrient, but that disparage the absent ingredient, could be misleading if there is inadequate scientific support for health concerns about the ingredient and therefore should be prohibited. The comments presented various other examples to either support or oppose a requirement that an implied ingredient claim that meets the requirements for an explicit nutrient content claim should be permitted.

The agency agrees that ingredient claims that make implied representations about the level of a nutrient in a food, whether or not they meet the definition of the expressed claim, should be considered implied nutrient content claims. This conclusion is consistent with section 403(r)(1)(A) of the act, which states that a food can be misbranded by a statement that

expressly or by implication characterizes the level of a nutrient in a food. An ingredient claim that implies that a nutrient is present in the food at a particular level, but that fails to meet the requirements for the equivalent express claim, will misbrand the food under section 403(r)(1)(A) of the act.

The question of whether claims like "contains no tropical oil" should be prohibited as misleading because they disparage the ingredient will turn on what the scientific evidence shows about the ingredient. If it is commonly known that the ingredient for which absence is claimed is a source of a nutrient for which the current dietary guidelines recommend decreased or moderated intake, then there is no reason for the agency to refuse to permit the claim. The fact that FDA would permit such a claim, however, would in no way represent a disparagement of the ingredient. The claim provides a means by which a manufacturer could highlight the saturated fat content of its food. It does not imply that the ingredient in question is a "bad" food.

233. One comment suggested that FDA allow companies to use expressed or implied nutrient content claims (in brand names or otherwise) that have not been defined or specifically approved by the agency if the claim is not false and misleading and is consistent with, and explained by, an immediately adjacent term that is defined in the agency's regulations. Alternatively, the comment requested that FDA permit ingredient claims that did not meet the expressed nutrient content claims definition but require them to be followed by a factual statement clarifying the nutrient content implication (e.g., "no tropical oils—this product contains 2 g of saturated fat" or "contains oat bran—not a significant source of fiber"). The comment stated that, in effect, companies would be allowed to define certain ingredient claims as implied nutrient content claims. Such a process would be in addition to the petition process established by FDA, thus allowing a company to choose whether to determine its own definition of an expressed or implied nutrient content claim or to petition the agency for a codified definition. The inclusion of a self-definition procedure would, the comment contended, be more in keeping with Executive Order 12630. Also, according to the comment, under such a policy, companies would not be forced to abandon nonmisleading implied claims and brand names, as they would under FDA's proposed rule. Companies would also not be made to change labels repeatedly, once by the effective date of the regulations and again after each new implied nutrient content claim is approved. Finally, the comment stated that the rule proposed by FDA would lead to a proliferation of unexplained terms that have been defined by FDA in the regulations but which have little or no meaning to consumers, whereas the procedure suggested in the comment would require the use of a defined term on the label to explain the intended meaning of the implied claim, adding significantly to consumer understanding. The comment asserted that the alternative method is fully consistent with the language and the intent of the 1990 amendments.

The agency does not agree that allowing manufacturers to use undefined claims that do not meet the definition for an expressed claim to be accompanied by a defining statement is consistent with either the intent or the letter of the 1990 amendments. The act provides that claims that characterize the level of a nutrient either expressly or by implication "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary" (section 403(r)(2)(A)(i) of the act). Thus, Executive Order 12630 is not relevant to the approach that FDA is required by statute to take on this matter. To do as the comment requests and allow manufacturers to continue using any label statements they choose (provided they add a defining statement as explanation) would be inconsistent with the letter and spirit of the act. The agency points out that under section 403(r)(4)(A) of the act, any person may petition the agency for permission to use terms that are subject to section 403(r)(2)(A)(i). This section also provides timeframes in which the agency must act on these petitions. Thus, there should not be any undue delay in obtaining a determination as to whether the claims can be used. Because the act specifically provides a mechanism by which use of claims can be authorized, the agency concludes that it would be inappropriate for FDA to establish an alternate mechanism by which such claims can be used.

The agency disagrees that companies would be required to make frequent label changes because of the approval of each new term. The company could decide what term it wants to use, determine whether the use of the term has been authorized, and if it has not been, petition for such authorization. Once the use of a term is authorized, the firm would be free to use it. Any change in the company's labeling made after that point because FDA approved a new term would occur because the company wanted to take advantage of the term, not because FDA compelled a change.

The agency also disagrees that there would be a proliferation of unexplained terms defined by FDA that would have little meaning to consumers. The agency is establishing only a distinct group of terms and synonyms with well defined meanings that may be used as nutrient content claims. Any additional terms that are included in response to a request of a petitioner will have been shown to be as well supported as those terms originally defined.

The agency concludes that the approach to regulating implied nutrient content claims suggested by the comment is not consistent with the structure established by 1990 amendments and will not promote better consumer understanding of label claims. Accordingly, FDA is not permitting use of undefined nutrient content claims accompanied by an explanation.

234. Many comments asserted that factual declarations of the amount of an ingredient (e.g., "160 mg of sodium," or "contains less than 300 calories") do not constitute implied nutrient content claims. Other comments maintained that statements concerning the percent of a nutrient (e.g., "9 percent fat") should also not be considered implied nutrient content claim.

The agency advises that declarations of the amount of a nutrient or the percent of a nutrient are provided for in new § 101.13(i). That provision, pursuant to section 3(b)(1)(A)(iv) of the 1990 amendments, states that such statements must meet the definition for a defined term or must be accompanied by a statement that the food does not meet the appropriate definition. Comments 16 through 19 of this document contain a full discussion of such claims.

235. One comment suggested that "equivalent" be defined as a nutrient content claim so that comparisons could be made to indicate that a food had the amount of a nutrient equivalent to a reference food, e.g., "contains as much fiber as an apple." The comment stated that this type of claim was particularly appropriate for dietary supplements.

The agency advises that it considers the example given in the comment to be an implied claim about the fiber content of the food. "Contains as much dietary fiber as an apple" implies that one apple is a good source of fiber, and that by being equivalent in fiber to an apple, th labeled food is also a good source of fiber. Such a claim can be used to provide valid, valuable information to the consumer about the nature of a

product in terms of another product that the consumer already understands. However, the agency believes that such a statement would be misleading if the labeled food was compared to the level of nutrient in a food that was not consistent with dietary guidelines, namely the amount of nutrient in a food which is "free," "low," a "good source," or "high." Likewise such a claim would be misleading if comparisons between the foods were not made on a common basis. Because a serving of the product is the amount customarily consumed in one eating occasion (a value which is applicable to all foods), the agency concludes that comparisons using this type of claim should be made on a per serving basis.

Accordingly, the agency is providing in new § 101.65(c)(2) for the use of equivalence claims using the phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" to imply that the reference food is a good source of specified nutrient, and that on a per serving basis, the labeled food is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "contains the same amount of Vitamin C as a glass of orange juice").

236. Several comments requested that the agency define specific implied claims so that their use would be permitted in labeling. Claims that were suggested included "high in oat bran," "contains no oil," "no tropical oils," and "contains canola oil." While the comments suggested definitions for the claims, they were not always in agreement on what the definitions should be.

The agency has carefully considered these terms and is providing its interpretation of the nutrient content implied by the label statement. Label statements about oils like corn, sunflower, safflower, and canola generally refer to the oils' fatty acid content. Accordingly, FDA considers a statement about a type of oil as an ingredient, such as "made with canola oil" or "contains corn oil," to generally imply that the oil in the product was low in saturated fatty acids. The statement "made only with vegetable oil" implies that because vegetable oil was used instead of animal fat, the oil component was low in saturated fat.

A claim that a product contains "no tropical oils," including a statement about the absence of a specific tropical oil, assumes that the consumer understands that tropical oils have a large amount of saturated fats. Such a claim would imply that another oil had been used that did not have a large amount of saturated fat. Consequently, a claim that a product "contains no tropical oils" would imply that the product is "low in saturated fat."

The agency considers that a statement that a product "contains no oil" implies that the product is not made with lipids (fat). Accordingly, such a claim would imply that the product was "fat free." Such a claim on a product that contained another source of lipids (e.g., animal fat) would be misleading.

Further, the agency considers that a claim that a product is made with or otherwise contains a whole grain, a bran, or any type of dietary fiber (such as soluble fiber), implies that the product is a good source of total dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber derived largely from the sources of fiber mentioned such that the product met the definition for "good source of dietary fiber." However, a claim naming these ingredients that also used the term "high" or a synonym thereof would be misleading if the product was not "high in dietary fiber."

The agency would generally not consider ingredient claims that are consistent with the meanings that it has outlined above to be misleading under section 403(a) of the act. However, as with any implied claim, the agency will consider the appropriateness of the use of the claim in the context in which it is made.

The agency advises that it does not consider that the terms that it has mentioned provide an all-inclusive list of those ingredients that imply the level of a nutrient. Claims for other nutrients will be considered on a case-by-case basis.

In conclusion, a claim that states or implies a characteristic that distinguishes a particular nutritional attribute of an ingredient will generally be considered an implied nutrient content claim. Whether or not it is a nutrient content claim will depend on the context in which it is presented, taking the entire label into consideration. The level of the ingredient may be implicit or explicit. The agency has described generically in new § 101.65(c)(3) circumstances under which such implied claims can be made. The regulation states that claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either low in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

The agency believes that the approach that it is taking in § 101.65(c)(3) strikes an appropriate balance between the interest of industry in making claims and the consumers' interest that claims that appear on the label accurately and fairly characterize the level in the food of the nutrient that, either explicitly or implicitly, is the subject of the claim.

b. Accompanying information

237. One comment suggested that implied nutrient content claims should be accompanied by appropriate referral statements that are consistent with the requirement for such statements to accompany nutrient content claims.

The agency advises that implied nutrient content claims that are defined in new § 101.65 (a)(2), must comply with all of the requirements for nutrient content claims described in new § 101.13. Among the requirements is the requirement for referral statements. In addition, FDA advises that as with other nutrient content claims, labels bearing such implied claims must also bear nutrition labeling in accordance with the requirements of new § 101.9 or, where applicable, new § 101.10. For clarity, the agency is listing the latter requirement in new § 101.65(a)(3).

4. General nutrition claims

In the general principles proposal (56 FR 60421 at 60423) FDA proposed to include in § 101.13(b)(2) a provision that label statements that imply that a product would be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") are implied nutrient content claims.

a. General comments

238. Many comments asserted that FDA's definition of implied nutrient content claims should not include claims that imply that a "food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., healthy)."Some of these comments stated that Congress showed no interest in regulating such claims but instead was concerned only with regulating those statements that characterize the level of a nutrient present in a food. One such comment noted that neither the act nor the legislative history contains any

language addressing general nutrition claims.

The agency does not agree with these comments. First, the reading of section 403(r)(1)(A) of the act suggested by these comments is clearly too narrow. A claim that a food, because of its nutrient content, may by useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health.

Moreover, Congress was clearly concerned with such claims. The October 24, 1990, proceedings in the Senate show that one purpose of the 1990 amendments was to regulate the use of nutrient content claims that appear on food labels and labeling in order to help consumers make appropriate dietary choices (136 Congressional Record S16610 (October 24, 1990)). In addition, section 403(r) of the act itself, repeatedly uses the phrase "* * * will assist consumers in maintaining healthy dietary practices" to describe the information for which provision is being made (see e.g., section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the act).

The agency is therefore not persuaded that this aspect of the proposed definition of implied nutrient content claims is inconsistent with the language of the act, the intent of Congress, or the goals of the 1990 amendments. However, FDA is modifying § 101.12(b)(2)(ii) to replace the phrase "* * * achieving a total diet that conforms to current dietary recommendations" with the statutory phrase "* * * maintaining healthy dietary practices."

239. Some comments objected to regulating terms such as "nutritious," "healthy," and "wholesome" under section 403(r) of the act because they have different meanings depending on their contextual use and would be difficult to define. These comments asserted that the agency should instead regulate the use of such terms on a case-by-case basis under section 403(a) of th act. The comments asked for assurance that these terms would not be regulated under section 403(r) of the act.

Other comments asserted that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" are implied nutrient content claims and should be banned from food labels. A few of these comments suggested that such terms are more appropriately used to describe an overall diet and should not be used on the labels of individual foods. One of these comments cited a poll that was conducted for them in February 1992, in which 1,007 individuals were interviewed concerning their interpretations of the terms "wholesome" and "nutritious." The comment reported that, other than the 55 percent who responded that the term "wholesome" on a food label meant that the product was "good for you," none of the possible responses for the meaning of either term garnered more than 23 percent of the respondents. Some comments, however, suggested that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" could be defined as synonyms for "healthy." Some of these comments supported such a definition only as a secondary option to banning the terms, while other comments stated that the terms should be allowed but controlled. One comment stated that if terms such as "healthy" are held to be implied nutrient content claims, then other suggestive words having to do with a product's quality, such as "beneficial" and "hearty," must similarly be defined or banned.

Some comments expressed concern about continued use of such terms in brand names grandfathered under section 403(r)(2)(C) of the act. One of these comments stated that leaving the terms undefined allows companies that used the claims before October 25, 1989, to continue to use them on foods that may not meet appropriate standards. The comment stated that if FDA chooses to define such terms, then the definition must include strict and comprehensive criteria.

One comment stated that the proposed definition for general nutrition claims could have an impact on many proprietary trademarks or slogans such as "Keeping Fit!", "Stay 'n Shape," "Product 19," "Breakfast of Champions," "Eat Right and Look It," and "Right Choice." Although the comment maintained that Congress did not intend these terms to be regulated, it acknowledged that these brand names serve as a beacon to consumers to indicate that there is something nutritionally desirable about the product.

FDA disagrees that terms such as those cited in the comments should be automatically excluded from regulation under section 403(r) of the act. The agency believes that these terms can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling. FDA advises that it will consider these terms to be in a nutritional context when they appear in association with an explicit or implicit claim or statement about a nutrient. For example, in the statement "nutritious, contains 3 g of fiber," "nutritious" is an implied nutrient content claim because it suggests that the food may be useful in maintaining healthy dietary practices. Accordingly, the agency is providing in new § 101.65(d)(1) that such statements are implied nutrient content claims and are subject to the requirements of section 403(r) of the act.

However, the agency also believes that when a term such as "healthy," "wholesome," and "nutritious" appears on a food label in a context that does not render it an implied nutrient content claim, it is not subject to the requirements of section 403(r) of the act. Under such conditions, the use of th term is subject to section 403(a) of the act, and FDA will determine whether it is misleading on a case-by-case basis.

The agency further advises that, except for "healthy," it does not have enough information to decide if definitions for the terms mentioned in these comments are needed, and if so, what those definitions should be. In a tentative final rule published elsewhere in this issue of the **Federal Register**, the agency is providing its tentative position on an appropriate definition for "healthy" based on information received in the comments. In addition, because of the time constraints of this rulemaking, FDA has been unable to develop information with which to make such a decision. The agency solicits information on whether such definitions are appropriate, and if definitions are appropriate, what they should be. Interested persons may submit appropriate petitions under new § 101.69 with accompanying substantiating information to initiate this process.

E. Use of Nutrient Content Claims with Meal-type Products

1. Definition of meal-type products

In the general principles proposal (56 FR 60421 at 60455), FDA proposed a definition for a "meal-type product" for the purpose of regulating nutrient content claims for these products on a different basis than for individual foods. The proposal cited the many comments that the agency received in response to the ANPRM (54 FR 32610), and during the public hearings that followed, that requested that FDA define and allow for the use of nutrient content claims for meal-type products. FDA proposed in § 101.13(l), to define a "meal-type product" as a food that: (1) Makes a significant contribution to the diet either by providing at least 200 calories per serving (container) or by weighing at least 6 ounces per serving (container);

(2) contains ingredients from 2 or more of 4 food groups; and (3) is represented, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. The four food groups in § 101.13(l) were: (1) Bread, cereal, rice and pasta group; (2) fruits and vegetables group, (3) milk, yogurt, and cheese group; and (4) meat, poultry, fish, dry beans, eggs, and nuts group. The agency recognized that current guidelines for daily food intake specify five food groups, distinguishing between fruits and vegetables. However, FDA proposed to combine the fruits and vegetables groups for regulatory purposes.

FDA requested 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 ounces) and specific product types (e.g., "main dish") used as a basis for this definition.

The agency received many comments on the need for separate criteria for meal-type products and the definition of meal-type products. After reviewing these comments, the agency continues to believe that separate criteria for meal-type products are needed but is revising the definition of a "meal-type product" to establish separate definitions for meal products and main dish products for the purpose of regulating claims (these products will still be referred to collectively as "meal-type products" in this preamble).

246. The majority of comments supported separate criteria for meal-type products as compared to individual foods. Two comments, however, stated that FDA should not create separate nutrient content claim definitions for these foods because meal-type products contain no more food or calories than ordinary foods. One of these comments also stated that FDA's proposal arbitrarily sets up a double standard for nutrient content claims in the marketplace. Alternatively, these comments recommended that the criteria for claims such as "low," "source," and "high" on all food products be based on specified nutrient levels per serving and per reference amount, or specified nutrient levels per 100 calories (or per 100 nonfat calories in the case of sodium and cholesterol). For example, for "low fat," one comment suggested that the criteria be no more than 3 g of fat per serving and per reference amount, or no more han 20 percent of calories from fat. For "low cholesterol," the comment suggested that the criteria be no more than 20 mg of cholesterol per serving and per reference amount, or no more than 15 mg per 100 nonfat calories. The comments stated that the alternative criteria would allow foods that are high in calories to make "low" claims for certain nutrients.

The agency acknowledges the complexity in defining a meal-type product for the purpose of regulating claims and agrees that, with any such definition, there is the potential for certain requirements that may result in similar food products having different bases for claims. The agency carefully considered the suggestion that it establish a single set of criteria for all types of food products but concluded that it was not appropriate to do so. This approach would generally result in the application of the per 100 calorie criterion rather than the per serving and per reference amount criterion to meal-type products, because the former would permit products to contain greater amounts of nutrients per serving. For example, a 400 calorie product could have as much as 9 g of fat if "low fat" was defined as not more than 20 percent of calories from fat. However, the agency concludes that the primary criterion for all "low" definitions for nutrients should be based on nutrient levels per 100 g as proposed, rather than on specified nutrient levels per 100 calories (or per 100 nonfat calories). The agency concludes that it is inappropriate to have as a primary basis for "low" claim a criterion that considers total fat levels in a food in addition to the levels of another nutrient that is the subject of the claim. For example, given the suggested criterion of no more than 15 mg of cholesterol per 100 nonfat calories, a 400 calorie dinner with 40 percent of the calories contributed by total fat could have only 36 mg of cholesterol, whereas another dinner with the same number of calories but only 20 percent of the calories contributed by total fat could have as much as 48 mg of cholesterol. The agency further believes that it would confuse consumers to have a criterion that links the amount of total fat in a product to the product's ability to make a "low" claim about another nutrient such as cholesterol or sodium. Accordingly, the agency is not persuaded to adopt this alternative set of criteria for meal-type products and individual foods.

However as discussed in comment 52 of this document, the agency has concluded that it is appropriate to have for "low" claims for fat and saturated fat, a second criterion that considers their caloric contribution to a meal-type product.

247. Some industry comments supported the proposed definition of a meal-type product, whereas others stated that the definition was too broad with respect to the minimum requirement of either 200 calories or 6 ounces and with respect to the inclusion of main dishes, entrees, and pizzas in this category.

One comment said that the 200 calorie level is an insufficient amount of food for a "meal-type product," even as part of a reducing diet, and that those who purchase such food could easily be misled that such foods will provide them with a filling, balanced meal. Other comments maintained that 200 calorie food items are meal segments, not meal replacers, for the vast majority of consumers and should not be included in a definition for a "meal-type product." Some comments recommended that a minimum of 500 calories be used. These comments maintained that a 500 calorie minimum would be a more accurate reflection of the calorie content of an individual's meal. They stated that foods that contain this higher calorie level still comprise less than one-third of the calories consumed by the segment of the population that consumes the fewest calories, and that this level would comprise about one-fourth of the typical consumer's daily caloric intake. One comment suggested that 350 calories be the minimum level, while another comment suggested that 300 calories be the minimum requirement.

These comments acknowledged, however, that a minimum calorie requirement, whether at 200 calories or 500 calories, could result in similar products slightly below or above these levels having very different outcomes with respect to claims. For example, it was stated that with FDA's proposal, a 200 calorie serving of soup could qualify for a "low fat" claim with 6 g of fat, whereas a 190 calorie soup that contained only 4 to 5 g of fat could not.

The agency acknowledges that the 200 calorie level is about equal to or less than one-tenth of the National Research Council's recommended energy allowances for adults (Ref. 28). The agency further agrees with the comments that a number of individual foods would meet this minimum caloric level. In addition, the agency has noted that, with this proposed minimum caloric level, it would be possible for meal-type products below the 300 calorie range that met the 3 g per 100-g criterion for "low fat" to contain more than 30 percent of calories from fat. This result would not occur if the agency adopted a higher minimum caloric level, such as 500 calories. However, this higher minimum caloric level would exclude a number of meal products that for some consumers are

appropriate for weight maintenance and for other consumers are appropriate for intended weight reduction.

The agency also considered whether to adopt the suggested levels of 350 or 500 calories. However, as pointed out in the comments, using a 350 or 500 calorie minimum requirement would not eliminate the problem of similar products having different outcomes for claims.

For these reasons, the agency is persuaded that a minimum calorie requirement is not an appropriate basis on which to define meal-type products, and that another product type category that would make the meal-type product category less broad is necessary. Accordingly, the agency has dropped a minimum calorie requirement from the definition of a "meal product" in § 101.13(l) and is not including one in the definition of a "main dish product" in § 101.13(m) (discussed below).

248. A few comments addressed the proposed requirement in the definition of a meal-type product that the food be represented as, or in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. These comments stated that there needed to be a clear distinction in the regulations of the types of foods that are eligible to bear claims as "meal products." One comment raised the question of whether foods such as a danish, fruit sweetened yogurt, or a bowl of cereal could be a breakfast entree, or whether pasta, beans in tomato sauce, soup, or a baked potato with topping could be a lunch or dinner entree. Another comment suggested that entrees including pizza have a different basis for claims than meal products, and that this basis should be the reference amounts for mixed dishes.

These comments further demonstrate that the proposed category of a meal-type product is too broad for the purpose of regulating claims, and that an additional category needs to be established. The types of products that the agency intended to include in meal-type products, besides meal products, included foods that are often represented as main dish products and, thus, represent only a portion of the complete meal. Based on the comments, however, the agency is persuaded that it would be inappropriate to apply the same criteria to a product that represents a meal and to a product that represents a significant portion of a meal. Thus, the agency is persuaded that separate criteria for claims should be established for meal products and for main dish products. Accordingly, FDA is revising proposed § 101.13(l) to define a "meal product" and is defining a "main dish product" in § 101.13(m). The requirements in these definitions are discussed in comments 249, 251, and 252 of this document.

249. Some comments agreed with the 6-ounce minimum requirement, while other comments stated that this minimum requirement was too low. One of the latter comments stated that this minimum would be met by such products as canned soups, pastas, beverages, and most containers of yogurt, and that even the skimpiest meals or entrees weigh closer to 10 ounces. Another comment suggested that the minimum weight requirement should be at least 7 ounces per serving.

The agency acknowledges that the minimum 6-ounce weight is low for many meal products, even though it is within the range of main dish products that are now marketed. USDA has required that frozen products labeled as "dinner" or "supper" weigh at least 10 ounces (Ref. 29). Thus, FDA concludes that it is appropriate to require that products represented as meals weigh, at a minimum, 10 ounces to be consistent with USDA. Further, FDA believes that products weighing between 6 and 10 ounces which were defined as meal-type products in the proposal, generally are marketed as entrees and side dishes. Thus, the agency finds that because of their contribution to the overall diet and because of consumer expectations, it is appropriate to require that main dishes weigh at least 6 ounces.

Accordingly, for the purpose of making a claim, FDA is defining a "meal product" in § 101.13(l)(1) as a food that makes a major contribution to the total diet by weighing at least 10 ounces per labeled serving. Likewise, for the purpose of making a claim, FDA is defining a "main dish" in § 101.13(m)(1) as a food that makes a major contribution to a complete meal by weighing at least 6 ounces per labeled serving.

Consistent with these provisions, the agency is also revising proposed § 101.13(l)(3) (redesignated as new § 101.13(l)(2)) to provide that to qualify as a "meal product" the food b represented as or be in a form commonly understood to be, a breakfast, lunch, dinner, or meal. The agency is retaining the provision that such representations may be made either by statements, photographs, or vignettes. The agency is aware that some products currently available in the marketplace are represented as meals but weigh somewhat less that 10 ounces. Should these products make nutrient content claims, the agency advises that such claims should comply with the provisions established for main dish products in § 101.13(m)(2). This will ensure the application of appropriate disclosure levels for such products (see comment 273 of this document).

The agency is requiring in new § 101.13(m)(2) that to qualify as a "main dish" the food be represented as, or be in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). The agency has cited beverages and desserts in this provision because they are not commonly understood to be a main dish and thus are appropriately excluded. However, foods that may be marketed as main dishes in the future are not categorically excluded from being main dishes but will be considered by the agency on a case-by-case basis. 250. A few comments objected to use of the term "container" in the agency's proposed requirement that a meal-type product weigh at least 6 ounces per serving (container). The comments maintained that the term "container" effectively equates meal-type products with single-serving containers, whereas meal-type products are packaged in both single-serve and multiple-serve containers. One comment stated that it makes no sense to have a provision that would allow a product in a single-serve container to make a claim but not an identical product packaged differently.

The agency agrees with the comments that the term "container" may inappropriately equate meal-type products with single-serving containers. This was not the intent of the proposal. Therefore, the agency is deleting the term "container" from new § 101.13(l)(1)(i) and (m)(1)(i).

251. Some comments suggested revisions to FDA's proposed requirement that a meal-type product contain ingredients from two or more of four food groups. Several comments supported a requirement that the product contain at least 3 different foods. A few comments suggested that a specified number of food servings be required rather than ingredients, because, according to one comment, the requirement for two "ingredients," irrespective of their amount, was meaningless. Another comment suggested that a serving be at least one-half the reference amount.

Given the decision to provide separate criteria for meals and main dishes, the agency is persuaded that a meal product should contain at least three different foods from at least two of four food groups and is revising new § 101.13(l)(1)(ii) accordingly. Dietary guidance recommends that Americans assemble daily diets by selecting a variety of foods from the various food groups. Because meals are large

segments of the diet, it is appropriate to expect that meals would include at least three different foods from at least two food groups. Main dishes, on the other hand, are combined with other foods to create a meal and thus may contain as few as two foods from two food groups. Therefore, the agency is requiring in § 101.13(m)(1)(ii) that a main dish product contain at least two different foods from two of four food groups.

The agency also agrees that the requirement for a specified number of foods may be problematic without a minimum weight requirement. FDA considered whether there should be a requirement based on a minimum percentage of a reference amount such as 50 percent. The agency has concluded, however, that such a requirement would be difficult to implement and may not in the end be meaningful. Different reference amounts could be applied to a food in a meal-type product depending on how the food was prepared (e.g., with or without sauce), how it was used in a product (e.g., as a major component or a garnish), or whether the food is subject to a mixed dish reference amount.

Therefore, the agency has developed an alternative approach that derives from the comment that suggested that a serving be at least one-half of the reference amount, the aim of which would be to prevent an ingredient that is present in small amounts from counting toward the requirement that a meal product and a main dish product contain a minimum number of foods from at least two food groups. Thus, FDA has revised new § 101.13(l)(1)(ii) and (m)(1)(ii) to require that a meal product contain not less than 40 g each of the minimum number of different foods.

The 40 g minimum requirement is about one-half of the reference amount for fish, shellfish, or meat/poultry substitutes without sauce (reference amount is 85 g) and is about one-half of the reference amount for drained vegetables (reference amount is 85 g). The 40 g amount is also within the middle range when comparing one-half the reference amount of foods with large reference amounts (e.g., 140 g is the reference amount for pasta) to products with small reference amounts (e.g., 30 g is the reference amount for cheese); that is, 40 g is about midway between 15 g and 70 g. The 40 g amount should not be confused with the reference amounts for individual foods.

252. One comment stated that FDA's proposed requirement that a meal-type product contain ingredients from at least two food groups sets up an artificial distinction between foods. The comment asked, for example, would breaded fish, but not unbreaded fish, be considered as consisting of two food groups?

The agency finds that it is inappropriate to include certain types of foods when determining the number of foods from the four food groups because such foods cannot be considered to contribute a recommended serving of food. These type of foods are gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes. The agency also believes that it is inappropriate to count sauces toward this requirement because of their high water content. However, a food that is in a sauce and that belongs to one of the four food groups can be counted toward the requirement for the particular food group if the food weighs a minimum of 40 g (e.g., 40 g of tomatoes in tomato sauce). The agency believes that a requirement for a minimum amount of a food in a meal or main dish product should be determined by the weight of the food and not by the way in which the food is presented in the product (i.e., an ingredient in a sauce).

Accordingly, the agency is providing for a meal product in § 101.13(l)(1)(ii)(E) and main dish product in § 101.13(m)(1)(ii)(E) that gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes can not be counted as foods to meet the requirement for a specified number of foods from at least two food groups. This provision also excludes sauces except for foods in the four food groups that are in the sauces.

253. One comment suggested that there be separate food groups for fruits and for vegetables. It pointed out that such a separation would be consistent with the food groups recommended in current dietary guidelines.

FDA endorses the five food groups recommended in current dietary guidelines. For this particular regulatory application, however, the agency believes fruits and vegetables should not be treated as separate groups. While the agency acknowledges the important and distinct contributions each makes to the diet, FDA is concerned that a combination of a fruit and a vegetable could be classified as a main dish. The nutritional contribution of each, while not the same, is more similar than any other two food groups. These products would contribute only a limited number of calories and would fail to contribute as diverse a range of nutrients and food components as a combination of two other food groups.

2. Definition of "free" for meal-type products

In the general principles proposal (56 FR 60421 at 60473), FDA proposed definitions of the term "free" to describe the content of sugar and sodium in a food. The agency also proposed in the fat/cholesterol proposal (56 FR 60478) definitions of the term "free" to describe the content of fat and cholesterol in a food. These proposed definitions applied both to individual foods and to meal-type products, and for meal-type products, were based on specified nutrient levels per reference amount and per labeled serving. The rationale proposed for the definition of "free" was based on the finding that this nutrient content claim is an absolute term implying absence of a nutrient. The agency further stated that the definition considered the level of a nutrient that is at the reliable limit of detection and that is dietetically trivial or physiologically inconsequential.

254. One comment supported the use of the same criteria for "free" claims for individual foods and for meal-type products. Another comment suggested that all nutrient content claims for meal-type products should be based on nutrient levels per 100 g of food.

The agency continues to believe, as it stated in the general principles proposal (56 FR 60421 at 60433), that the term "free" is an absolute term implying absence of a nutrient in a serving of a food, whether it is an individual food or a meal-type product, not absence of a nutrient in a specified weight of food such as per 100 g. Therefore, the agency rejects the suggestion that it base "free" claims for meal-type products on nutrient levels per 100 g.

255. One comment stated that the proposed requirement of less than 2 mg per serving in the definition of "cholesterol free" for meal-type products is unreasonable. This comment stated that 2 mg of cholesterol in a 9-ounce serving is less than 0.008 percent, whereas in a small serving product such as crackers, the same amount of cholesterol represents 0.015 percent. This comment suggested raising the cholesterol free level for meal-type products to 5 mg per serving. The comment stated that at the 5 mg level, 60 servings of a meal-type product would be required to be consumed to meet the DRV and thus would result in ample protection for the consumer.

This comment has not convinced the agency to raise the level for "cholesterol free" for meals and main dishes. The agency acknowledges that 2 mg of cholesterol in a meal/main dish product will be a much smaller percentage by

ight than a small serving size product ut points out that these percentage differences also occur with individual foods that vary considerably in serving size weight. The agency continues to believe that the same cholesterol level for the definition of "free" should be used for meal-type products as for individual foods, because it is defining "free" as an absolute term implying absence of a nutrient in a serving of food, irrespective of the serving size of the food in question. Accordingly, the agency has retained the proposed cholesterol levels in the final rule, including the disclosure statement allowed for ingredients commonly understood to contain the nutrient in question.

3. Definition of "low" and "very low" for meal-type products

a. Basis for claims

In the general principles proposal, FDA proposed that the definition of "low" and "very low," when describing the content of single nutrients in meal-type products, be based on nutrient levels per 100 g. The proposal stated that this approach would alleviate the need to accommodate the variations in serving size for the various types of meals. The agency proposed that the nutrient levels per 100 g, except for calories, be the same levels for meal-type products as for individual foods. As part of the rationale for proposing specific levels of nutrients for the "low" definition of individual foods (56 FR 60421 at 60440), the agency considered that the "low" definition should be 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.

256. Many comments supported using amounts of nutrients per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. One of these comments stated that this is the only workable approach because of the wide variety of products and the range in net weights encompassed within meal-type products. However, another comment stated that meal-type foods should have to meet the same criteria (i.e., a per serving rather than per 100 g basis for claims) as single item foods to qualify for nutrient content claim. An additional comment expressed the view that an approach based only on nutrient amounts per 100 g would allow many claims on meal-type products that would be prohibited on individual foods. This comment and two other comments suggested, for example, that FDA consider requiring that a meal-type product obtain no more than a certain percentage of its calories from fat (e.g., 20 percent) in order to qualify for a "low fat" claim. Two other comments supported upper limits for "low calorie" claims, with one comment recommending an upper limit of 300 calories and another recommending an upper limit of 350 calories.

FDA agrees with the majority of comments that support the use of per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. FDA does not agree with the comment that meal-type products should have to meet the same criteria as single foods because meal/main dish products are generally a larger part of the total diet than single foods.

The agency has not been persuaded by these comments that there is a need or an appropriate basis for establishing upper limits for absolute amounts of calories or nutrients per serving when a claim for "low" is made. Rather, the agency believes that providing for the level of the nutrient per 100 g of food is generally sufficient to prevent misleading claims on meal-type products. While FDA has usually assumed that food consumption patterns generally reflect 3 meals per day and a snack (with about 25 percent of daily intake for each), the agency notes that even if a meal-type products weighs as much as 400 g, the absolute amount of a nutrient or calories consumed would be relatively low and thus consistent with the claim. For example, a 400 g meal could contain no more than 12 g of fat, which is only about one-fifth of the DRV.

Moreover, meal size will increase and decrease as a function of the number of servings of individual foods in the meal-type product. Larger persons in need of more calories and greater amounts of nutrients are expected to select a meal comprised of more servings of an individual food or of more servings of different foods (hence a larger meal) than would be expected to be selected by a smaller person. Thus, a basis for determining an absolute amount of a nutrient that would preclude the product from being considered "low" in a particular nutrient is problematic.

However, FDA is persuaded by comments that it is appropriate to require that meal-type products contain no more than a certain percentage of calories from fat. The agency recognizes that it is possible for certain meal-type products to contain no more than 3 g of fat per 100 g of product and still derive more than 30 percent of their calories from fat. FDA is concerned that claims be consistent with dietary guidance. Current recommendations are that 30 percent or less of calories from fat and less than 10 percent of calories from saturated fat. These recommendations are targeted toward the total diet, and the agency has stated in this document several times that they should not be applied to individual foods. However, the agency believes that a meal-type product makes a significant contribution to the diet and, thus, finds that it is appropriate to apply these total diet-oriented recommendations to meal-type products. By their nature, meal-type products are not single foods but combinations of foods intended to contribute a larger amount to the diet than a single food.

FDA has therefore concluded that "low fat" or "low saturated fat" claims on meal-type products that have more than 30 percent of calories from fat or 10 percent or more of calories from saturated fat are misleading to consumers and inconsistent with dietary guidance. Accordingly, the agency is providing in new § 101.62(b)(3)(i) that meal-type products that contain 3 g or less of fat per 100 g and derive 30 percent or fewer of their calories from fat may bear a "low fat" claim. Likewise, the agency is providing in new § 101.62(c)(3)(i) that meal-type products that contain 1 g or less of saturated fat per 100 g and derive less than 10 percent of their calories from saturated fat may bear a "low saturated fat" claim.

b. "Low calorie"

257. In the general principles proposal, FDA requested comments on whether the criterion of 105 calories per 100 g of product for "low calorie" meal-type products was too low. A few comments from industry recommended that the level be raised from 105 calories per 100 g to 120 calories per 100 g. One of these comments was submitted by the organization that had previously suggested the 105 calories that became the level in FDA's proposal. At least one comment suggested that FDA not establish an upper limit for calories in a serving. However, a foreign government suggested an upper limit of 300 calories, and a well-known health organization suggested 350 calories as the upper limit. Another comment maintained that the proposed criterion of 105 calories per 100 g was arbitrary and did not bear any relation to the definition of "low calorie" for individual foods. This comment further maintained that a weight-based criterion was not necessarily relevant, that a "low calorie meal" was a contradiction in terms, and that consumers did not need this provision because of the availability

of comparative claims. An additional comment recommended that the number of calories be disclosed next to the nutrient content claim for meal-type products.

First, FDA disagrees with the comment that the agency should not provide a separate definition for "low calorie" for meal-type products because of the availability of comparative claims. Obesity is a major public health concern and the agency has long acknowledged that the availability and marketing of low calorie food products helps to promote weight control among American consumers. The agency has made provisions for absolute claims (such as "low") as well as comparative claims (such as "reduced") on individual foods, and, given that meal-type products are combinations of individual foods, finds no reason why such claims on meal-type products would not be helpful to consumers.

Secondly, as discussed in response to the previous comment, the agency has established no upper limit for nutrient or calorie levels in meal-type products making nutrient content claims, but instead believes that the amount per 100 g of food provides sufficient control so that claims are not misleading to consumers and are consistent with current dietary recommendations.

The agency acknowledged in its general principles proposal (56 FR 60421 at 60455) that establishing a definition for "low calorie" meal-type products was problematic but accepted the suggestion put forth in a comment that 105 calories per 100 g of food was reasonable and consistent with market practices. FDA specifically asked for comments on this issue. Little support was expressed for this level, while several comments suggested that the level be raised from 105 calories to 120 calories per 100 g.

FDA finds that it is appropriate to increase the definition to this level. The agency notes that 120 calories per 100 g of food is low enough to allow consumers to select different types of meal-type products during the day, including some that are "low" in calories and some that are not "low," and still consume calories at a level consistent with weight control goals. For example, even if a meal product weighs 400 g it would be limited to no more than 480 calories. This calorie amount is less than one-fourth of the average recommended energy allowance for most adult age/sex groups (Ref. 28). Accordingly, FDA is revising new § 101.60(b)(3)(i) to provide that to qualify for a "low calorie" claim, a main dish or a meal product contain 120 calories or less per 100 g.

c. "Low sodium"

258. Several industry comments supported raising the level of sodium that would justify a "low sodium" claim on meal-type products to 200 mg per 100 g. One comment stated that the 140 mg per 100 g level is more appropriate for medically supervised therapeutic diets to manage serious health conditions than for the general population or for many individuals on restricted diets. The comment further stated that the 140 mg per 100 g level would inhibit, if not effectively preclude, the marketing of meal-type products to persons interested in restricting sodium intake. Another comment stated that they knew of no products that would qualify for "low sodium" at the 140 mg per 100 g level, while other comments maintained that products below the 140 mg per 100 g level would have an unacceptable flavor profile. Still another comment stated that for a 10 ounce product, the 200 mg per 100 g level would represent one-fourth of the sodium DRV. The comment further stated that this definition for "low sodium" is reasonable because it provides sufficient room for consumption of other sodium-containing foods during the day while remaining within the DRV. Additional comments stated that current USDA guidelines for low sodium meals require that sodium content be no more than 560 mg for a four component dinner (minimum weight 10 ounces), which is a level to which consumers have grown accustomed.

The agency is not persuaded that the 140 mg of sodium per 100 g level for meal-type products should be raised, or that the level is too restrictive for products marketed to the general population. This level is consistent with the level for individual foods. Further, FDA believes that meal products labeled "low" should be low enough in a nutrient to allow a consumer to eat several such products and still have a significant reduction in total daily intake in the particular nutrient when compared to the DRV for that particular nutrient. The agency notes that with the 140 mg/100 g level, a meal product that weighs as much as 400 g could have no more than 560 mg of sodium. However, with the higher suggested level of 200 mg/100 g, a meal product at this weight could have as much as 800 mg of sodium, which is one-third of the sodium DRV (i.e., 2,400 mg). This level would be too high for a low sodium claim on a meal product, given the assumption of a daily food consumption pattern that includes three meals and a snack (with about 25 percent of daily intake contributed by each).

The agency acknowledges that many products now on the market would not qualify for "low sodium" with the criterion of 140 mg per 100 g but does not believe that currently marketed foods should be the driving force for a "low" definition. Accordingly, FDA has retained the 140 mg per 100 g level in new § 101.61(b)(5)(i).

d. Other sodium claims

259. One comment recommended that in addition to "low sodium," "moderate sodium" be defined as a nutrient content claim on meal-type products for levels of sodium higher than "low." This term was recommended to allow consumers interested in modifying sodium intake a wider choice of products.

The agency believes that the existing nutrient content claims "low sodium" and "very low sodium" are adequate to provide information about sodium content to consumers wishing to limit their sodium intake. The comments did not provide any support for an additional term. The agency believes, for reasons discussed above, that the number of nutrient content claims should be limited. The additional term suggested in the comment is likely to confuse the consumer and possibly reduce the effectiveness of the other nutrient content claims for sodium. Furthermore, consumers interested in modifying their sodium intake will be able to refer to the nutrition label to determine if the product meets their personal dietary needs. Accordingly, the agency is not defining "moderate sodium" for meal-type products.

e. "Low fat"

260. Two industry comments supported defining "low fat" for meal-type products as no more than 3.5 g per 100 g instead of no more than 3 g per 100 g as FDA proposed. One of these comments stated that most meal-type products contain meat or poultry, and in order to use these ingredients, even lean cuts, the fat content will often be greater than 3 g per 100 g because of the meat requirements. The 3.5 g level, it was argued, would provide consumers with a greater number and variety of products available to them.

As it stated in the general principles proposal (56 FR 60421 at 60455), the agency believes that the fat level for meal products and main dish products should be consistent with the level for individual foods. Such consistency will minimize consumer confusion and assist consumers and health professionals in recalling and using

these definitions. The agency acknowledges that a number of meal-type products may not be able to make "low fat" claims. However, the term "lean" will be available to these products. FDA has retained the proposed level of 3 g or less per 100 g for a "low fat" claim in new § 101.62(b)(3)(i).

f. "Low saturated fat"

261. A few comments supported the proposed "low saturated fat" definition of no more than 1 g of saturated fat per 100 g for a meal-type product. Two comments, however, recommended that "low saturated fat" for all food products be defined as no more than 1 g of saturated fat per serving or no more than 7 percent calories from saturated fat.

As discussed in comment 256 of this document, the agency believes that nutrient amounts per 100 g should be the basis for regulating "low" claims on meal-type products. However, as discussed in comment 256 of this document, the agency is establishing an additional criterion in new § 101.62(c)(3)(i) that a meal-type product derive less than 10 percent of its calories from saturated fat in order to bear a "low saturated fat" claim.

g. "Low cholesterol"

262. Two comments recommended that FDA define "low cholesterol" for all meal-type products as no more than 20 mg of cholesterol per serving or no more than 15 mg cholesterol per 100 nonfat calories.

The agency is not persuaded to adopt this alternative criterion because, as previously stated, it believes that it is inappropriate and would confuse consumers to have a primary criterion for a "low" claim that links the amount of total fat in a food to the food's ability to make a "low" claim for another nutrient. However, the agency is including in the "low cholesterol" definition of meal-type products in new § 101.62(d)(3) a criterion that requires that a meal product contain no more than 2 g of saturated fat per 100 g. The agency has established this additional criterion under the authority in the 1990 amendments to establish a saturated fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." As discussed above in response to comment 116 of this document, the agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the health and dietary guidelines to lower blood cholesterol levels by limiting cholesterol and saturated fat intake. Thus, with respect to "low cholesterol" claims on meal-type products, the agency concludes that consumer expectations regarding blood cholesterol levels are met as long as the food contains 20 mg or less of cholesterol and 2 g or less of saturated fat per 100 g.

4. Definition of "percent fat free" for meal-type products

263. A few comments supported the proposed requirement that a meal-type product meet the "low fat" definition to make a "percent fat free" claim, whereas another comment stated that "percent fat free" claims can be particularly deceptive on meal-type products because many of these products, such as frozen dinners, have a high moisture content. The latter comment further stated that because moisture contributes significantly to a product's weight, foods with a high moisture content can make higher (more impressive) "percent fat free" claims than foods with lower moisture levels. The comment pointed out that a label on an 18 ounce frozen dinner containing 15 g of fat could make a "97 percent fat free" claim.

The agency is not persuaded by the latter comment that a "percent fat free" claim on an 18-ounce dinner that meets the "low fat" definition would be deceptive. Regardless of the total weight of the dinner, it still contains 3 g or less fat per 100 g, is a "low fat" meal-type product, and would assist consumers in limiting their fat intake. Thus, the agency finds that a percent fat free claim on meal-type products that meet the "low fat" definition, regardless of the serving size of the product, is not deceptive and can be useful in assisting consumers in meeting their dietary goals.

5. Definition of "high" and "good source"

In the general principles proposal (56 FR 60421 at 60457), FDA proposed that for meal-type products, the nutrient levels for "high" and "good source" be the same percentages of the DRV or RDI as for individual foods, but that the basis for these nutrient levels be per 100 g, not per serving. The agency proposed in § 101.54(b)(2) that "high" be defined as 20 percent or more of the DRV or RDI per 100 g of product, and in § 101.54(c)(2) that "good source" be defined as 10 to 19 percent of the RDI or DRV per 100 g of product.

While one comment supported the use of a per 100 g basis for the definitions of "high" and "good source," a few comments opposed this basis. For the reasons cited below, the latter comments have persuaded the agency to reconsider the basis for "high" and "good source" claims for meal products and for main dish products.

264. One comment recommended that FDA base its definition of "high" and "good source" for all foods including meal-type products on a criterion that considers the nutrient/caloric contribution of a food. This comment proposed that "good source" be defined as at least 10 percent of the DRV or RDI per serving and at least 10 percent of the DRV per 200 calories. Similarly, "high" would be defined as at least 20 percent of the DRV or RDI per serving and at least 20 percent of the DRV or RDI per 200 calories.

The agency rejects this alternative because it could result in plain vegetable products being able to make a claim for "high in vitamin C," but a similar product with these vegetables in a sauce not being able to make this claim. The additional calories contributed by the sauce would cause the product not to meet the minimum DRV level per 200 calories. Such an approach to defining these claims would create inconsistencies in the use of the claims and could cause consumer confusion.

265. Several comments stated that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products eligible to make "high" or "good source" claims. For example, it was stated that to make a "high in fiber" or "high in vitamin C" claim, a 10-ounce frozen dinner would be required to contain over one-half of the DRV or RDI. The comments stated that products that contain a smaller percent of the DRV or RDI still may be considered excellent nutrient sources. Alternatively, one comment recommended that the basis for the definitions of "high" and "good source" for meal-type products be per labeled serving rather than per 100 g of food.

FDA is persuaded, for the reasons given in the comments, that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products. The per 100 g basis would require that a 10-ounce meal-type product have at least 30 percent of the DRV to be labeled a "good source" of a nutrient, or at least 60 percent of the DRV or RDI to be labeled "high" in a nutrient. The agency acknowledges that some meal-type products on the market meet these definitions, but it is

concerned that the proposed levels may encourage increased fortification of these products, with little benefit to the consumer.

Furthermore, the agency is not persuaded to adopt the suggested alternative to define "good source" and "high" using the same percentage levels as individual foods per labeled serving because it would be misleading to state on a label that a three component meal is "high" in a nutrient, when each of the three components may only have 6 percent of the DRV or RDI.

Having considered the alternatives for defining "high" and "good source" claims for meal-type products and finding inadequacies in each, FDA now concludes that such claims should not be defined for meal-type products. FDA is, therefore, not providing definitions for "high" and "good source" claims for meal products and main dish products. The agency concludes that it would not be misleading, however, to state on a label that a specific individual food in a meal-type product is a "good source" of a nutrient or is "high" in a nutrient if that food meets the individual food criteria for these claims.

Accordingly, FDA is revising new § 101.54(b)(2) and (c)(2) to allow "high" and "good source" claims for a food contained in the meal product or main dish product provided that the food meets the individual food criteria for these claims and provided that this food is identified with the use of the nutrient content claim (e.g., "The serving of broccoli in this product is high in vitamin C;" "The serving of sweet potatoes in this product is a good source of dietary fiber").

6. Relative claims for meal-type products

FDA also proposed definitions for "less" and "fewer," "more," "reduced," and "light" for individual foods in the general principles proposal (56 FR 60421 at 60456). With the exception of the terms "reduced" and "light," FDA proposed that the provisions for individual foods apply to meal-type-products.

Some of the comments, as discussed below, have persuaded the agency to change the basis for "less," "fewer," and "more" claims and to provide for "reduced" and "light" claims on meal products and main dish products.

a. "Less," "fewer," and "more"

FDA proposed requirements for "less" and "fewer" claims on meal-type products that were consistent with the requirements for these claims on individual foods. The proposed provisions included a requirement that the product have a minimum percentage and absolute reduction of a nutrient per labeled serving size compared with the reference food that it resembles and for which it substitutes. For "more" claims, the proposed requirements included a provision that the product contain at least 10 percent more of the DRV or RDI for a nutrient per labeled serving than the reference food that it resembles and for which it substitutes.

However, information provided in comments has persuaded the agency to revise the proposed requirements for the percent nutrient reduction and absolute nutrient reduction for the use of the comparative claims "less" and "fewer" on meal-type products. The agency has also revised new § 101.13(j)(1) with regard to reference foods, as previously discussed in this document. This revision applies to meal products and main dish products as well as to individual foods.

266. One comment suggested that the criteria for comparative claims on meal-type products should be based on a percentage difference in a nutrient per 100 g of food compared with per 100 g of the reference food. This comment pointed out that meal-type products include a wide variety of types of foods and a range of serving sizes. It further stated that claims that compare dissimilar products, such as a two component product to a three component product or spaghetti and tomato sauce to macaroni and cheese, would only lead to consumer confusion and misinterpretation of the claim.

The agency agrees that both the meal and main dish categories include products that vary substantially in the number of foods, type of foods, and size of the labeled serving, and that claims that compare dissimilar products on a per labeled serving basis have the potential to confuse consumers. For example, the only difference between two products that may bear a comparative claim under the proposed criteria may be the amount of the food components. The agency has also considered that comparative claims based on FDA's proposed labeled serving size may encourage manufacturer manipulation of serving size to make these comparative claims, given the fact that the labeled serving size for many of these products is the single serve container rather that the reference amount.

Thus, the agency finds merit in the comment's suggestion to base a comparative claim for meal-type products on a per 100-g criterion rather than per labeled serving size. A per 100 g basis reflects the composition of the product based on an absolute amount and not a serving size that can vary from one product to another. Moreover, a per 100-g criterion is likely to not encourage manipulation of serving size because the serving size will have no bearing on whether the food qualifies to bear the claim. Thus, a claim will result in more meaningful comparisons of dissimilar products.

Accordingly, the agency is establishing a per 100 g basis for the use of these comparative terms on meal/main dish products in new §§ 101.54(e)(2)(i), 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). Like other relative claims, a statement that identifies the reference food and the percentage change in the nutrient must be declared in immediate proximity to the most prominent claim (e.g., Contains 33 percent less fat per ounce than Brand Y meal product.). Moreover, quantitative information comparing the level of the nutrient that is the subject of the claim in the labeled food to the level of that nutrient in the reference food must be declared either adjacent to the most prominent claim or on the information panel (e.g., Fat content has been reduced from 2.5 g per ounce to 1.7 g per ounce.). In addition, consistent with the use of relative claims on individual foods, meal or main dish products may not bear comparative claims if the level of the nutrient that is the subject of the claim in the reference foods meets the definition for a "low" claim for such nutrient.

267. One comment contended that the agency's published correction (57 FR 8189, March 6, 1992) of the minimum absolute reduction criterion in the definition of "fewer calories" from "more than 40 calories" to "more than 105 calories" must be withdrawn from this rulemaking because it changes the substance of the proposal, and the agency is not permitted to make a substantive proposal in a notice of correction.

The agency disagrees with the comment. In proposing the absolute minimum reduction criterion for making comparative claims, the agency concluded that the amount of nutrient in the food bearing the claim should reflect a nutritionally significant reduction in the amount of that nutrient when compared to the reference food. The agency recognized, however, that no guidelines or definitions were available to determine the amount of reduction in a nutrient that would be nutritionally significant. Thus, the agency tentatively concluded that such a criterion should be based on the amount specified in the definition of "low" for the nutrient in question. The

agency applied this rationale to individual foods as well as to meal type products. The amount specified in the proposed definition of "low calorie" for meal-type products was 105 calories per serving. Thus, it was clear that the intent of the agency was to propose an absolute minimum reduction criterion for comparative claims for decreased levels of calories for meal-type products as "more than 105 calories." Therefore, the notice of correction did not make a substantive change in the proposal but only an editorial change.

b. "Reduced"

FDA proposed not to provide for the use of "reduced" claims on meal-type products because it was of the opinion that there was an insufficient basis on which to establish a reference criterion. In the general principles proposal (56 FR 60421 at 60456), the agency stated that meal-type products may have the same basic ingredient, e.g., fish, but may differ in their preparation and in added ingredients. Consequently, the agency expressed concern that such a provision could result in inappropriate comparisons of dissimilar products.

268. One comment agreed that FDA should not allow "reduced" as a nutrient content claim for meal-type products, whereas a few comments recommended that the term be permitted. One of the latter comments recommended that a single set of criteria for all comparative terms be applied to meal-type products. Thus, the same definitions would be used for "reduced," "less," "fewer," and "light." Another comment was specifically concerned that there was no definition for "reduced fat" and "reduced cholesterol" meal-type products. An additional comment stated that manufacturers should be permitted to make a "reduced" claim for a meal-type product if the recipe has been changed to effect a meaningful reduction in a nutrient from the previous recipe, and that to disallow "reduced" on these products would be a serious disincentive for manufacturers to improve their products' nutritional profiles and a disservice to consumers.

In response to these comments, the agency has reconsidered its proposal to disallow "reduced" claims on meal-type products. In another section of this document, the agency has concluded that comparisons using the term "reduced" are only appropriate for use in comparing similar foods, i.e., a reformulated version of a manufacturer's product to the original product (e.g., a lasagna meal-type product that uses low fat ricotta cheese and lean meat may bear the claim "reduced" when the original product uses regular ricotta cheese and meat, whereas a lasagna with low fat ricotta cheese that substitutes spinach for the meat portion could not bear a "reduced" claim but may bear a "less" claim with respect to the original product). This revised position of the agency is consistent with the comment that recommended that "reduced" be allowed on meal-type products that have been reformulated and addresses the agency's earlier concerns, as stated in the general principles proposal (56 FR 60421 at 60456), that "reduced" not be used to compare dissimilar products. Accordingly, the agency is establishing similar provisions for use of the term "reduced" on meal-type products in new §§ 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). In addition, the agency advises that if the manufacturer should discontinue the original product used as the basis for the "reduced" claim, the use of the "reduced" claim is limited to a maximum of 6 months after the original product has been removed from the market. As with other comparative claims such as "less," these provisions will require that the comparisons be based on per 100 g of the product, so that "reduced" claims will not be subject to manipulation by reducing the label serving size (e.g., reduced fat—33 percent less fat than our former recipe. Fat content has been lowered from 1.7 to 1.1 g per ounce).

c. "Light"

FDA did not propose a definition for "light" for meal-type products in its general principles proposal because, similar to "reduced" claims, the agency could not identify appropriate reference foods to permit this use of the claim (56 FR 60421 at 60456). However, the agency tentatively concluded that the term "light" could be useful to consumers in selecting products that contain fewer calories than would be expected in a normal meal and asked for comments on the need for, and definition of, this term on meal-type products. The agency stated that it was considering allowing the term "light" to be used if a meal-type product met the criteria for a "low calorie" claim, provided that the product did not contain more than one-fourth of the DRV for fat, saturated fat, sodium, or cholesterol. The agency noted that the proposed "low calorie" level for a 10-ounce meal product (i.e., 105 calories per 100 g or 300 calories per 10 ounces) was nearly one fourth of the calorie intake in a calorie-restricted diet of 1,200 calories a day. FDA further stated that the requirement that these four nutrients not exceed one-fourth of the DRV would ensure that "light" meal-type products would not contribute amounts of these nutrients that would cause total daily intake to exceed recommended values.

269. One comment agreed with FDA's suggested definition of "light" for meal-type products (i.e., a "low calorie" meal-type product that contained no more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium). Several comments, however, offered alternative definitions for the use of the term on meal-type products. A few comments suggested that comparative criteria be used to define "light" for meal-type products. One comment recommended that the definition for "light" for meal-type products be consistent with the definition of "light" for other foods. In addition, this comment stated that meal-type products should meet the per 100-g criterion. Other comments recommended that a "light" claim be permitted on meal-type products if a food product meets the definition for a "low nutrient" product, or if the product achieved a reduction of at least 25 percent of calories. One of these comments stated that there may be some instances when there will be an appropriate reference food to which a comparison could be made.

The agency's general approach in defining nutrient content claims is to try to define terms as consistently as possible for all types of food. Thus, if the agency were to adopt comparative criteria for "light" claims for meal-type products, it would be consistent with the criteria that it has established for use of this term on individual foods. However, the agency believes that in the case of meal-type products, there is only a limited group of appropriate reference foods for use with comparative claims. Meal-type products vary greatly in the number and type of ingredients as well as in labeled serving size, and as one comment stated, meal-type products, other than reformulated meal-type products do not truly "substitute" for a definable reference food as do individual foods. The agency is providing for the use of "reduced" on those meal-type products that are reformulated, and it considered whether the term "light" might also be appropriately used on these products. Limiting the use of "light" on meal-type products to only reformulated products would, however, greatly limit the number of such products that could bear this term. The agency has concluded that because of its widespread appeal and its potential usefulness in denoting foods that can assist consumers in maintaining healthy dietary practices,

the use of this term should not be so limited. Accordingly, the agency has rejected the suggestions to use criteria that compare a product with a reference food in defining "light" for meal-type products.

270. A few comments recommended that the term "light ' not be permitted on meal-type products. Two of these comments stated that products meeting the criteria for a low calorie meal would already meet consumer expectations, and therefore a "light" claim is unnecessary. Comments further noted that eliminating unnecessary terms and different criteria for the same term would help reduce consumer confusion.

The agency does not agree with the comments that contended that the use of the term "light" is without value on meal-type products. As explained above in the section on "light" claims for individuals foods, the terms "light" and "light in sodium" in comment 185 are terms that have special usefulness as marketing tools for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in fat, calories, or sodium. Furthermore, available data and comments show that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines.

Thus, the agency has concluded that provisions for the use of the terms "light" and "light in sodium" on meal products and main dish products that require (as discussed below in comment 272 of this document) that meal-type products bearing such claims meet the definition of "low calorie," "low fat," or "low sodium" will assist consumers in implementing dietary recommendations with respect to limiting caloric, fat, and sodium intake. Further, as reflected in the legislative history (136 Congressional Record 16609 (October 24, 1990)), Congress' intent was to permit the use of the comparative claim "light" for entrees, meals, dinners (i.e., meal-type products). Accordingly, the agency rejects the suggestion to not allow this term on meal-type products.

271. One comment contended that FDA's calorie criterion for "light" (i.e., no more than 105 calories per 100 g) was too restrictive. This comment recommended that "light" be allowed on products that contain no more than 450 to 550 calories (or about one-fifth to one-fourth of a 2,350 calorie diet).

FDA has made a number of changes that have had the effect of making this criterion not as restrictive as this comment contended. The agency has modified the criterion, as discussed above, to 120 calories per 100 g and is basing its dietary calculations on a 2,000 calorie diet, as discussed in the document on RDI's and DRV's, published elsewhere in this issue of the Federal Register. Thus, a "light" claim will be allowed on a 300 g (approximately 10 oz) meal if it contains no more that 360 calories.

272. Some of the comments also addressed what nutrients in addition to calories should be limited for a meal-type product to qualify for a "light" claim. One comment suggested that the term "light" as applied to meal-type products should focus on healthfulness rather than low calorie, while another comment stated that the conceptual basis of "light" should be different from "healthy." The latter comment stated that "light" claims should be allowed on meal-type products that are "low calorie," "low fat," or both, with the relevant expressed claim (e.g., "low in calories) appearing in close proximity to the "light" claim. This comment stated that the term has been widely used to enable consumers to select products that contain less fat or fewer calories than would be expected in a normal meal. However, this comment specifically objected to the proposal's suggestion of not allowing more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium for a "light" claim to be made. Other comments agreed that there should be no restrictions on these four nutrients, whereas another comment stated that the restrictions should correspond to one-eighth of the DRV, rather than one-fourth, because the maximum permitted level of about 300 calories for a 10 ounce product would correspond to one-eighth of the reference caloric intake of 2,350 calories.

FDA has reconsidered what nutrients should be limited in a meal-type product for it to be permitted to bear a "light" claim. FDA is persuaded by the comment that an unqualified "light" claim on meal/main dish products may appropriately refer to fat, calories, or both. However, as discussed in comment 269, the agency has determined that for meal-type products, "light" should not be limited to reductions in the level of nutrients in existing foods. Rather, the agency is persuaded by the comments that the term should denote those meal-type products in which the level of the nutrients are particularly useful in constructing a diet that is consistent with dietary guidelines, that is, the term should be permitted on foods that are "low in calories," "low in fat," or both. The agency notes that a provision for "light" to refer either to calories or to fat is consistent with the definition of "light" for individual foods that have less than 50 percent of calories from fat. It is also consistent with consumer understanding of this term. FDA is also persuaded, however, that a statement that explains whether "light" is used to mean "low in fat," "low in calories," or both should appear on the principal display panel to clarify the nature of the claim for consumers who may be interested in limiting only calories, only fat, or both (§ 101.56(d)(2)(i)). Furthermore, to ensure that this explanatory statement is sufficiently prominent relative to the "light" claim, FDA concludes that it should be in no less than one-half the type size of the "light" claim (new § 101.56(d)(2)(ii)). This requirement is also consistent with the final rule on "light" claims on individual foods that requires that qualifying statements of sufficient type size must accompany the claim.

Accordingly, FDA is defining "light" for meal products and main dish products in new § 101.56(d). To meet this definition, a meal product or main dish product must meet the definition of "low" for calories, fat, or both (new § 101.56(d)(1)). Further, the agency believes that for consistency with individual foods, it should provide for use of the additional claim "light in sodium" on meal-type products. As with individual foods, the agency has determined that the words "light in sodium" or "lite in sodium" is a single descriptive term, presented in the manner described above, that should all be presented in the same type size, style, color, and prominence. Further, the agency believes that such a "light in sodium" claim for meal-type products should be based on the same criteria as the "light" claim for other nutrients for meal-type products, i.e., it should be based on the "low" definition for the specified nutrient. Accordingly, the agency is defining "light in sodium" for meal-type products in new § 10.56(d)(2). To qualify to make this claim, a meal product or a main dish product must meet the definition of "low" for sodium (new § 101.61(b)(5)(i)). However, because the nutrient that is the subject of the claim is identified as part of the claim i.e., the defined term is "light in sodium," the agency believes that the additional defining label statement (i.e., "low in sodium") that is required with other "light" claims on meal-type products would be redundant. Therefore, the agency is not requiring this additional information to be stated adjacent to the claim.

FDA has also reconsidered whether the definition of "light" should require that fat, saturated fat, cholesterol, and sodium not exceed specified levels i

product. The agency has no evidence that would suggest that consumers who use "light"roducts expect these products to have restricted levels for all of these nutrients, especially if the "light" claim is clarified by a statement that identifies the nutrients that are the subject of the claim. Further, if the levels of any of these nutrients were sufficiently high in a product, the product will have to bear a disclosure statement referring the consumer to the nutrition information panel that discloses the amount of the nutrient (new § 101.13(h)(2) and (h)(3)). Accordingly, the agency is not including in the definition of "light" restrictions on the amount of saturated fat, cholesterol, or sodium.

7. Definition of "lean" and "extra lean" for meal-type products

As discussed elsewhere in this document, although FDA did not propose to define "lean" or "extra lean" in the general principles proposal, the comments have persuaded the agency to adopt the provisions that the FSIS is establishing for "lean" and "extra lean" for meat and poultry products, including meal-type products, regulated by USDA. FDA is providing for the use of the term "lean" and "extra lean" to describe FDA regulated products comparable to those covered by the FSIS regulation. The criteria that FDA is adopting for "lean" as used to describe meal and main dish products are provided in new § 101.62(e)(2) and "extra lean" as used to describe meal and main dish products are provided in new § 101.62(e)(4).

Accordingly, the provisions in new § 101.62(e)(2) require that for the term "lean"o be used on the label or in labeling of a meal product or main dish product that product must contain less than 10 g of fat, less than 4 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving. The provisions in new § 101.62(e)(4) require that for the term "extra lean" to be used on the label or in labeling of a meal product or a main dish product that product must contain less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

The agency recognizes that the definitions for "lean" and "extra lean" for main dish products allow for use of the claim when levels of cholesterol exceed FDA's disclosure levels for this nutrient in a main dish product (i.e., 90 mg). It considered whether to prohibit the claim on products that contained greater than 90 mg of cholesterol. However, the agency has concluded that it would be more beneficial to consumers to allow the claim on meal-type products whose cholesterol content exceeds the disclosure level because the claims identify foods relative to other foods in this broad category of foods that contain lower amounts of fat and saturated fat. Consequently, these changes will assist consumers in selecting such foods. Furthermore, when the level of cholesterol exceeds FDA's disclosure level, the food will be required to bear a disclosure statement that refers the consumer to the nutrition information panel for additional information about cholesterol content.

8. Disclosure statement

In the general principles proposal (56 FR 60421 at 60457), the agency applied the concept of disclosure levels for individual foods to meal-type products. However, the agency did not propose specific disclosure levels for meal-type products and solicited comment on whether the disclosure levels should be different for meal-type products than for individual foods, and if so, what the levels should be and why.

273. FDA received comments recommending that it provide separate disclosure criteria for meal-type products. Several comments argued that the single food disclosure levels were too stringent to be applied to large quantities of food such as meal-type products. Two comments suggested that a specified amount of the designated nutrient per 100 g of product was the most appropriate basis for a criterion.

The agency considered whether to retain the disclosure levels for individual foods as the disclosure levels for meal-type products but on a per 100 g basis rather than per serving (i.e, 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol and 480 mg sodium). On this basis, a meal weighing 10 ounces (280 g) would be subject to the disclosure requirements if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 12 ounces (336 g) would be subject to the disclosure requirement if it contained about 44 g of fat or about 67 percent of the DRV for total fat. If it is assumed that a "meal constitutes one-fourth of a total day's nutrient/calorie intake, this criterion appears to be too high in that such a meal could contribute more than half of the total amount of the nutrient (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake, not be required to bear a disclosure, yet still be able to bear a health claim.

The comments received offered no alternatives to the per 100 g basis for disclosure levels for main dishes and meal products. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meal products. This approach allows a greater percentage of the DRV for main dish products and meal products than for individual foods.

In arriving at specific percentage levels for disclosure nutrients, FDA considered that the amount of a nutrient in the total daily diet that may increase the risk of a disease may be between 100 percent and 200 percent of the DRV for that nutrient. The agency then considered that if three meals and a snack were consumed during the day, and each contained 40 percent of the DRV for a particular disclosure nutrient, and if foods that sometimes accompany meals such as beverages, breads, and desserts were also consumed and contributed an additional 40 percent of the DRV for that nutrient, then the total daily intake of the nutrient would not exceed 200 percent of the DRV, the level the agency used to establish disclosure levels for individual foods (see the final rule on health claims that appears elsewhere in this issue of the Federal Register). Thus, the agency is adopting 40 percent of the DRV as the disclosure level for meal products in this final rule.

The agency further considered that the contribution of main dish products is generally between meal products and individual foods (for which a disclosure level of 20 percent of the DRV is established in this final rule). Thus, the agency chose 30 percent of the DRV, the mid-point between meals and individual foods, as the disclosure level for main dish products.

Based on the comments received, the agency has established separate disclosure criteria for meal/main dish products. For meal products, new § 101.13(h)(2) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving. These levels correspond to no more than 40 percent of the DRV per labeled serving. For main dish products, new § 101.13(h)(3) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg cholesterol, or 720 mg of sodium per labeled serving. These levels correspond to no more than 30 percent of the DRV per labeled serving.

9. Other

275. The agency received a comment that recommended that the term "controlled" be defined as an implied

nutrient content claim for meal-type products. This comment asserted that this term would be very useful in describing carefully established levels of nutrients and has historically referred to established levels in a line of products designed to be used regularly within the context of a total diet that met dietary guidelines. The recommended criteria for the term "controlled" recommended by the comment were: (1) Less than 300 calories, (2) less than 30 percent of calories from fat, (3) no more than 65 mg cholesterol, and (4) less than 600 mg of sodium.

The term "controlled" has traditionally been used in the marketplace (especially on products marketed for special dietary use) to refer to designated size portions of foods and not to levels of nutrients. Thus, the agency has not defined the term "controlled" as suggested in the comment. However, the agency advises that individuals who believe that there is a need for additional terms for the use of implied claims on meal-type products may petition the agency under the provisions of § 101.69.

IV. Restaurant Foods

A. Nutrient Content Claims for Restaurant Foods

FDA received many comments regarding the proposed nutrient content claims criteria as they would apply to restaurant foods and to foods sold in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are discussed separately below.

276. Several comments stated that because the 1990 amendments are silent with respect to requiring restaurant foods to comply with the requirements for nutrient content claims, FDA is not legally required to regulate such claims for restaurant foods in a manner identical to that proposed for packaged foods.

FDA disagrees with the comments that the 1990 amendments do not apply to nutrient content claims made for restaurant foods. As explained in the general principles proposal (56 FR 60421 at 60428) the 1990 amendments, fully support the agency's proposal in § 101.13(o)(5) (redesignated as new § 101.13(q)(5)) that a nutrient content claim may not be 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, unless the claim is used in a manner that is authorized by a definition that FDA has adopted. However, FDA agrees that under section 403(r)(2) of the act, it is not required to regulate claims on restaurant foods in a manner identical to that for packaged foods. In fact, restaurants are exempt from the referral and disclosure requirements in section 402(r)(2)(B) of the act and certain of the requirements in section 402(r)(2)(A). FDA's regulations incorporate these exemptions. While the regulatory criteria governing claims for restaurant-type foods need not be identical to those governing other foods, if claims on foods are to be useful for consumers, the criteria for those claims must be consistent.

277. Several comments stated that restaurant foods should be required to comply with the proposed requirements for nutrient content claims. Some comments stated that many restaurant foods are centrally manufactured and conform to system-wide composition and quality standards. Therefore, many restaurants and restaurant chains, especially the larger ones, already have access to the nutrition information necessary to verify claims about their products. Finally, these comments stated that portion control of foods is practiced by many restaurants to control their food costs, and that this control will facilitate compliance by the industry.

Some comments stated that the proposed regulations governing nutrient content claims would be impracticable for the restaurant industry because packaged foods and restaurant foods differ markedly in the way they are prepared and sold. For example, variability in the nutrient level of individual foods sold in restaurants occurs as a result of: (1) Seasonal, regional, and market variations in ingredients; (2) differences in preparation methods of similar foods; and (3) consumer preferences in terms of how food is prepared. The comments pointed out that these variabilities would require repeated costly analyses to determine if each food meets the criteria for the content claim. The comment cited additional, complicating factors such as: performance of 100-g calculations for meal-type products; inadequacy of current data bases on nutrient levels in many foods for validating nutrient content claims; and variations in recipes for restaurant foods. One comment estimated the cost of compliance in terms of redoing printed materials in the commercial sector of the food-service industry to be more than $500 million. Additionally, the comments assert that costs associated with product development, testing, preparation, marketing, and staff training will be required. For these reasons, these comments requested that FDA exempt restaurant foods from the requirements for nutrient claims it is establishing in this final rule.

Several comments stated that the proposed regulation for nutrient content claims for restaurants is not the least restrictive alternative available to FDA, in accordance with Executive Order 12291, because it would essentially eliminate a foodservice operator's ability to communicate meaningful nutrition information to consumers and create a disincentive for foodservice operators to develop healthful foods. These comments said that substantial costs of compliance with the new regulations would be passed on to consumers, and the small business segment of the industry would be especially adversely affected. The alternatives suggested by the comments are: (1) Develop definitions for foodservice oriented nutrient content claims; (2) develop voluntary guidelines for foodservice that specify how foodservice operators should provide nutrition information, or (3) establish a standard set of criteria concerning a recommended daily diet so that foodservice operators could flexibly and reliably design meals that may be promoted as healthful.

Several comments specifically addressed the use of the term "light" on restaurant foods. One of these comments said that "light" used on a restaurant food or meal should have the same meaning as when placed on a packaged food. Another comment said that "light" should mean only a reduction in calories, and that it should be restricted to use on meal-type products, on salt substitutes, and for describing physical or organoleptic attributes. One comment said that "light" as used in a restaurant can mean a wide variety of things from lighter texture, color, or consistency to overall healthiness, and that the proposed definition was too restrictive. A comment from a restaurant chain recommended that the term "light" should be used to refer to total meal packages that have at least 25 percent less fat, cholesterol, sodium, or calories than the traditional menu selections. This comment contended that a

restaurant meal will take the place of at least three servings, and that a 25 percent reduction would be significant in terms of total diet.

Other comments were less specific in addressing the issue of restaurant foods or meals bearing relative claims. One of these comments said that relative claims should be permitted for total meal packages at restaurants. Another of these comments said that for relative claims, a restaurant should compare a product to the restaurant's own product.

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet cannot be ignored. Further, FDA believes that dietary information provided to consumers at point of purchase in restaurants and other food service operations can be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such dietary information. However, FDA firmly believes that consumers expect, and deserve, that the claims made at point of purchase are truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Statements such as "lightly breaded," "light crust," or "in a light sauce" on a sign or placard are not nutrient content claims covered by the 1990 amendments. Moreover, because of the importance of context, statements such as "Light Fare," "Lite Bites," or "Light Entrees" will not be considered nutrient content claims if the sign or placard on which the statement appears offers an explanation of the basis for the terms that makes clear that they are not intended to characterize the level of a nutrient. For example, a term such as "Lite Fare," on a sign or placard followed by an asterisk referring to a note that makes clear that in this restaurant the term means dishes with smaller portion sizes than normal would not be considered a nutrient content claim under section 403(r) of the act. In most cases, a prominently displayed disclaimer or information that clearly explains the basis for the use of the term, and that does not characterize the level of a nutrient in the explanation, will be sufficient to remove that use of the term from the coverage of the 1990 amendments.

Similarly, a restaurant may be able to use symbols next to the listing of an item on a sign or placard where the symbols are clearly explained in terms that would not subject the claim implied by the symbol to the 1990 amendments. For example, the use of a star symbol next to the name of an entree, where the symbol is explained in a footnote stating that the item is broiled instead of fried, would not be subject to the 1990 amendments.

Also, a restaurant may use symbols or make reference on a sign or placard to the criteria of a health professional organization or accrediting group and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the general dietary guidelines of the AHA will be considered dietary guidance and not a nutrient content or health claim subject to section 403(r) of the act, provided the explanation does not characterize the level of a nutrient.

Finally, a restaurant also may be able to devise foods or complete meals that are formulated in complete accordance with the Dietary Guidelines for Americans (e.g., moderate calories, less than 30 percent calories from fat, less than 10 percent calories from saturated fat, emphasis on vegetables, fruits, and grain products, moderate use of sugars and sodium). FDA encourages such actions because a meal, especially a restaurant meal, represents a significant portion of the day's consumption, as compared to an individual food product. A restaurateur may signal to customers by the use of a term or symbol on a sign or placard that the meal is formulated in accordance with dietary guidelines, and FDA will consider such indications to be dietary guidance and not nutrient content claims under the 1990 amendments.

FDA is including a provision in new § 101.13(q)(5)(iii) that describes when such indications will be considered to constitute dietary guidance and not nutrient content claims. The agency will evaluate the validity of such guidance on the basis of its being truthful and not misleading under section 403(a) of the act. However, if the restaurateur goes on to characterize the level of nutrients in the food, it would subject the food and the claims for the food to the nutrient content claim regime. When a restaurant uses a defined term such as "low calorie," uses the term "light" without further explanation, or uses a term or symbol that is explained in such a way that states or implies levels of nutrients in the food, it must comply with FDA's definitions of those terms.

How the restaurant demonstrates compliance with those definitions is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels as a result of seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making claims or to prevent the agency from being able to assure consumers that the nutrient content claims that appear on restaurant foods reasonably reflect the nutrient content of the food. Thus, FDA is providing in new § 101.13(q)(5)(ii) that, except if a claim is made on a menu, a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim that FDA has established under section 403(r)(2)(A)(i) of the act. Thus, if a restaurateur labels a fish dish as "low fat," on a sign or a placard he or she must have a reasonable basis for believing that the dish complies with FDA's definition for "low fat," that is it contains less than 3 g of fat per 100 g. The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guideline on nutrient levels in seafood (56 FR 60880, Appendix B, November 27, 1991) shows that the fish contains less than 3 g of fat per 100 g, and that the method of cooking and other foods used in the dish would not add fat. In addition, the restaurateur could show that he or she relied on a reliable cookbook that gave values for fat in the finished food that were less than 3 g per 100 g. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients or inappropriate substitutions of ingredients), FDA will

find that there is a reasonable basis for believing that the food meets the criteria for a defined nutrient content claim.

Upon request, the restaurateur will be expected to present the basis on which he or she believes that the pertinent nutrient levels are present in the foods. In addition, the firm must be prepared to demonstrate that it adhered to the information that provides the basis for its belief, i.e., to the recipe, use of certain types and amounts of ingredients, or preparation methods in preparing the food. The agency will then determine whether the basis cited by the restaurant reasonably supports its use of a nutrient content claim such as "low calorie" or "low fat."

This reasonable basis for belief standard for restaurant nutrient content claims will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that such claims are truthful and not misleading and in accordance with FDA regulations. FDA does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

The agency notes, however, that while restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the nutrient content claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 34). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt nutrient content information to their individual food selection and preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time, for the reasons discussed above, small restaurants will be placed at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about their foods. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make § 101.13(q)(5) effective with respect to such establishments until February 14, 1995.

While the statute will be in effect during that period, FDA will not enforce the statute's nutrient content claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that States will refrain from enforcing any nutrient content claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State's resources can best be used during this initial period in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with nutrient content labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating nutrient content claims in restaurants. As the comments have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to nutrient content claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for nutrient content claims on restaurant foods, other than the exclusion of menus, FDA does not consider the problem of assuring the useful and reliable provision of nutrient related information in restaurants to be solved. It is possible that there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. If this is the case, a different glossary of terms for use in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how terms are used on restaurant foods and whether such terms are appropriate. For example, with FDA's cooperation, the National Restaurant Association is planning to undertake a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for nutrient content

claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared, and that for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims based on nutrient levels drawn from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

278. One comment stated that the use of the terms "healthy" or "healthful" on meal-type products is necessary for restaurants to assist the consumer in identifying the choices that fit an eating pattern consistent with reducing the risk of certain chronic diseases. This comment further stated that disqualifying levels for fat, saturated fat, sodium, and cholesterol should be set in order to prevent inappropriate foods from bearing this claim.

The agency is publishing a proposed rule concerning use of the term "healthy" as an implied nutrient content claim elsewhere in this issue of the Federal Register. Any comments and information with respect to whether the agency's tentative definition of "healthy" is appropriate for restaurant meals and main dishes will be considered in that rulemaking.

B. Nutrition Labeling of Restaurant Foods

279. Several comments agreed that FDA has authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should be required on restaurant foods bearing claims. These comments generally contended that restaurants should be required to follow the same nutrition labeling requirements as food manufacturers when nutrient content claims are made.

Many comments expressed the opinion that FDA does not have authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should not be required on restaurant foods bearing nutrient content claims. These comments generally contended that since the act exempts restaurant foods from nutrition labeling, FDA should allow for the nutrition labeling of restaurant foods on a voluntary basis.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general principles proposal (56 FR 60421 at 60427). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

280. A few comments stated that if nutrition labeling were required for restaurant foods bearing nutrient content claims, restaurants would not make such claims because restaurant foods are not standardized, and it would be too costly to provide accurate nutrition information for these foods. The comments also stated that mandatory nutrition labeling (when a claim is made) would inhibit restaurants from making frequent and more healthful changes in food.

Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal (56 FR 60421 at 60427), the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable nutritional characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a nutrient content claim is made for restaurant foods. It is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained in the response to the next comment. The agency does, however, encourage the voluntary provision of full nutrient information for restaurant foods, even when claims are not made.

281. Some comments stated that if nutrition labeling were required for restaurant foods bearing a claim, restaurants could utilize available nutrition software programs and recognized databases to provide the necessary information for the nutrition label. One comment stated that FDA should develop educational materials for restaurants that explain their obligation not to make nutrient or health claims without providing nutrition labeling. A few comments stated that before requiring mandatory nutrition labeling of restaurant foods bearing nutrient content claims, a pilot study should be done to determine the cost and feasibility of such labeling, and that more study is needed before the agency requires labeling on restaurant foods.

FDA believes that consumers should have access to information about the nutrient content of restaurant foods for which nutrient content claims or health claims are made. The agency is requiring in new § 101.10 that such information be available upon request by a consumer. However, because FDA recognizes the difficulty of providing nutrition labeling for restaurant foods, at this time it will allow such information to be conveyed either by nutrition labeling as described in new § 101.9 or by the provision of information to the consumer about the level of the nutrient for which the claim is made in a serving of the food upon request by the consumer. Under the latter alternative, for example, if a 333 g meal is characterized as being "low fat," the consumer could be informed that the meal contains less than 10 g of fat. Therefore, under this alternative the restaurateur need not state the actual amount of the nutrient present in a serving of the food but may simply state that the nutrient is present at "less than" or "greater than" the amount that would enable the serving of the food to make the claim. Thus, the agency is not requiring that the firm conduct an analysis of the food in order to provide this information. On the contrary, this information should be readily available to the firm from its determination that the food conforms to the criteria for the

claim. For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

Further, the considerations discussed in the previous section concerning the effective date for small restaurants that make nutrient content claims also apply with respect to nutrition labeling when a nutrient content claim is made in those restaurants. Therefore, FDA is also deferring the effective date of § 101.10 for 1 year for small restaurants.

FDA agrees with the comments that educational programs and further study will be helpful. However, the statutory timeframes imposed on the agency by the 1990 amendments do not afford FDA the luxury of deferring until some future time all rulemaking on restaurant foods. The agency recognizes the limitations in the approach that it is taking and encourages the restaurant industry to continue to work with FDA to devise a program that will provide consumers with truthful and accurate nutrition information, without at the same time inhibiting the flow of such information or the development of healthier foods. The agency points out that the conduct of feasibility and consumer studies is more properly the responsibility of the regulated industry, and that FDA is currently working with the industry to do such studies.

282. One comment stated that § 101.10 should be deleted because it would be outdated if nutrition labeling requirements are imposed for restaurant foods bearing claims.

For the reasons discussed above, FDA is deleting current § 101.10. However, FDA is replacing it with a new provision that sets forth how nutrient information is to be provided when a claim that is subject to section 403(r) of the act is made for restaurant foods. The agency believes that information in § 101.10 was useful in advising firms about alternatives for declaring nutrition information when a claim is made, and as revised, § 101.10 will continue to serve this purpose.

283. Other comments addressed specific issues of nutrition labeling for restaurant foods, such as whether the requirement for nutrition labeling of restaurant foods should apply only to large restaurants with fixed items, and whether the content or format of nutrition labeling should be different for the foodservice industry than for packaged foods.

FDA will address these issues in its further deliberations and in its continued interactions with the regulated industries. The agency is likely to seek comment on a number of these issues in the future.

V. Petitions

In the general principles proposal (56 FR 60421 at 60458), FDA proposed to establish procedural regulations to govern the submission, content, and agency review of the three types of petitions authorized by section 403(r)(4) of the act (i.e., petitions for nutrient content claims, for synonymous terms, and for the use of an implied claim in a brand name). The agency also proposed to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition (CFSAN) all of the functions of the Commissioner of Food and Drugs relating to petitions for label claims under section 403(r) of the act involving noncontroversial issues. Further, the agency reiterated its interim policy on petitions submitted pursuant to the 1990 amendments that it announced in a notice published in the Federal Register of March 14, 1991 (56 FR 10906), i.e., that the agency intends to defer or deny action on all such petitions until it establishes the final procedural regulations for the submission, content, and review of these petitions.

284. One comment stated that the 1990 amendments do not require FDA to establish procedural regulations for petitions, and that the agency does not have the authority to defer or deny any petition submitted to the agency on the basis that the agency has not established regulations.

Although the 1990 amendments do not require FDA to establish procedural regulations for the petitions prescribed therein, FDA stated in a notice in the Federal Register of March 14, 1991, (56 FR 10906) that the most efficient way to manage a large influx of petitions likely under the 1990 amendments and to utilize agency resources is for FDA first to establish procedural regulations for handling petitions, and secondly to make them final at the same time as the other substantive regulations implementing the 1990 amendments. The agency continues to believe in the wisdom of this approach. Obviously, it will be more efficient for the agency to be able to simply review petitions to determine whether the petitioner has provided an appropriate basis to justify a claim, than to have to first determine whether a petition has provided the appropriate information and then to review it substantively. FDA believes that adopting new § 101.69 will greatly increase the likelihood that the petitions it receives are adequate.

Also, as explained in the general principles proposal (56 FR 60421 at 60458), the need to promulgate procedural regulations necessitates that the agency defer or deny petitions submitted before such regulations are finalized. Therefore, the agency concludes that the promulgation of procedural regulations for petitions submitted pursuant to the 1990 amendments, and its procedure for handling petitions before the final regulations are established, is appropriate.

285. Another comment urged that FDA not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner of Food and Drugs concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning nutrient content claims and health claims will involve controversial issues that will require a response from the Commissioner of Food and Drugs.

FDA does not agree with this comment. Based on its experience with other types of petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate the denial of the petition or that result in the petition being put in a "not-filed" status until all deficiencies have been resolved. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of such a petition) in the most resource efficient manner.

Although the agency agrees that many petitions concerning label claims will indeed involve controversial issues, no basis was provided by the comment to support the contention that all such petitions will be controversial, and the agency does not believe that it should make this assumption. If a petition does not involve a controversial issue, the redelegation of the functions provision will enable the agency to take action in the most resource efficient manner. Therefore, the agency is retaining the redelegation provision in this final rule.

286. One comment stated that FDA should include a list of terms and synonyms in the final regulation so that the petition process would not be necessary.

This final rule is not intended to define by regulation all conceivable terms that may be used now or in the future to make nutrient content claims The 1990 amendments included the petition process to enable FDA to amend the regulations to provide for

new terms and synonyms that may be presented to the agency with appropriate justification. Thus, this final rule does not render the petition process unnecessary.

287. Several comments were concerned that the requirements established for the petition process are ambiguous and should be streamlined. A few other comments suggested that the petition process would impose a significant burden on manufacturers.

The agency has reviewed these comments and has concluded that, in some cases, changes should be made to the requirements to clarify and simplify the petition process and eliminate unnecessary elements. The specific revisions in the final rule are discussed below.

288. One comment suggested that FDA should use the criteria established in section 403(a) and (r) of the act for determining when to deny or grant a petition. This comment also implied that no other requirements are necessary for the agency to use as a basis to determine whether to deny or grant a petition.

The agency does not agree with this comment. While it is true that section 403(a) and (r) of the act are the statutory provisions upon which the proposed procedural regulations are based, these statutory provisions do not provide petitioners with a clear description of the types of information and scientific data that would be necessary for a petition to be acceptable.

Given the large influx of petitions that the agency anticipates receiving, and the statutory time constraints placed on the agency regarding the review of these petitions, it is in the best interest of petitioners and of the agency for FDA to establish procedural regulations that clearly delineate the requirements that petitioners must satisfy when submitting a petition to FDA for consideration. This course will lead to the most efficient use of the petitioner's and the agency's resources because the data requirements for petitions will be clearly stated, and, as stated above, less agency resources will be expended in reviewing deficient petitions.

289. A number of comments expressed concern that the petition process will prevent manufacturers from developing innovative ways to convey nutrient levels in foods, retard product development, and serve as a disincentive for the development of new healthful foods. One comment suggested that the petition process will stifle product innovation because new marketing claims will need agency approval. This same comment also stated that one way to somewhat alleviate this problem would be for the petition that is under review to remain confidential until it is approved by the agency.

As stated above, FDA has in some cases made changes in the final rule to clarify, simplify, and eliminate unnecessary petition requirements. However, the agency's procedures must be consistent with the statutory requirement that all nutrient content claims used on food labels use terms that are defined in the regulations of the Secretary as provided in section 403(r)(2)(A)(i) of the act. Thus, the requirement of agency approval of a claim, and the petition process by which that approval is obtained, derive directly from the act itself.

Furthermore, section 403(r)(4)(A) of the act requires that nutrient content claim petitions that are filed for further action after 100 days and brand name petitions be made available to the public. Because of this requirement in the statute, FDA is retaining the provisions concerning the public availability of these petitions. However, the availability of information in these petitions will be determined in accordance with § 20.61 (21 CFR 20.61). This regulation provides that trade secrets and commercial or financial information that is confidential or privileged are not to be made available for public review.

290. A small number of comments stated that some specific requirements that the agency proposed for nutrient content claim petitions and synonym petitions (e.g., submission of consumer survey data and submission of data to demonstrate that consumers will understand the meaning of the proposed term) should not be included in the petition requirements. Most of these comments regarded the proposed petition requirements as unduly burdensome. Some of the comments stated that the proposed petition requirements command more information than FDA cited in issuing the proposed regulations for nutrient content claims.

FDA has reviewed the proposed requirements and has concluded that it is not necessary (as was proposed under format item B) for descriptor petitions and synonym petitions (proposed § 101.69(m)(1) and (n)(1)) to include data and information to demonstrate that consumers can be expected to understand the meaning of the proposed term under the proposed conditions of use. The agency believes that it can make a rational determination concerning the ability of consumers to understand a term without requiring such data and information, and, therefore, this requirement would impose an unnecessary burden on the petitioner. However, the inclusion of such information in a petition would, if it shows that consumers do correctly understand the term, enhance the persuasiveness of the petition.

The petitioner will still be required to address why the proposed use of the term will not be misleading (format item A). In this regard, if any concerns arise during the agency's review concerning the ability of consumers to understand the meaning of the proposed term, the agency is likely to deny the petition. Therefore, the agency is removing from new § 101.69(m)(1) and (n)(1) the provision stating "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."

291. Some comments that addressed synonym and brand name petition requirements stated that the agency should delete the requirements in proposed format item C (proposed § 101.69(n)(1) and (o)(1)) that the petitioner provide a detailed analysis of the potential effects of the use of a proposed claim on food consumption and any corresponding changes in nutrient intake when requesting approval for a synonym or for a brand name containing an implied nutrient content claim. These comments stated that the burden imposed by this requirement guarantees that no petition will be successfully submitted. They also argued that such requirements treat synonyms as nutrient content claims rather than as alternative terms for claims that have already been approved by the agency.

The agency has considered this comment and agrees that synonym and brand name petitions need not include detailed analyses of food consumption and nutrient intake effects associated with use of the petitioned term. These matters will have been considered by the agency in approving the primary term with which the petitioned term is claimed to be consistent.

The agency is, therefore, deleting proposed format item C from the requirements for synonym and brand name petitions (new § 101.69(n)(1) and (o)(1)) in the final rule.

292. A comment stated that it is not necessary for FDA to publish a Federal Register notice informing the public of the agency's decision on whether to deny or to grant a synonym petition because it is not required by the statute.

FDA continues to believe that publishing a notice announcing the

agency's decision to either grant or deny a synonym petition will provide useful information to the public. Such decisions have relevance to persons interested in the outcome of the agency's review of the petition, because a synonym, if approved, may be used by any firm and, if denied, may not be used on labels or in labeling. Further, such action is appropriate because the granting of a synonym petition is an agency decision that has the force and effect of law. Public notice of the agency's action will notify all potentially affected parties of the legal status of the synonym. FDA is therefore retaining this provision in the final rule.

However, FDA is correcting an error in the proposed codified language. Proposed § 101.69(n)(4) should have stated that FDA will publish a notice in the Federal Register "As soon as practicable following the agency's decision to grant or deny the petition, * * *" as indicated by the preamble discussion. However, the proposed codified text only referred to the "granting" of the petition. FDA is making the appropriate revision in the final rule.

293. One comment stated that the petition process is unnecessary for the use of a nutrient content claim in a brand name if the term has been defined by the agency.

FDA agrees with this comment. In cases where a nutrient content claim has been defined by regulation or provided for under the regulations for implied nutrient content claims in new § 101.65, the term may be used in a brand name in accordance with the provisions of the applicable regulation. However, a brand name petition would be required for the use of a proposed term in a brand name that has not been defined by the agency by regulation or provided for under new § 101.65, but where the petition could establish that the proposed term is consistent with a defined term.

VI. Constitutional Issues

A. The First Amendment

294. A number of comments from trade associations and individual companies argued that truthful nutrient content claims are protected speech under the first amendment. Many comments contended that food labeling, including nutrient content claims, is commercial speech and argued that FDA's proposed regulations do not pass the Supreme Court's test for regulation of commercial speech. Comments asserted that any suggestion that consumers should be screened from truthful information for their own good is the kind of paternalism rejected by the Supreme Court in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976), and that the idea that the public cannot be trusted to make judgments based on truthful information contravenes the basic principles of the first amendment. Comments maintained that the public has an interest in obtaining useful information, and that the Government's interest is best served by allowing the free flow of truthful information. FDA also received a comment expressing the opinion that the proposed rule does not violate the first amendment and urging the agency not to change its position on first amendment grounds.

FDA believes that its nutrient content claim regulations are consistent with the first amendment, and that the act, as amended by the 1990 amendments, does not violate the first amendment. The act has withstood numerous first amendment challenges. See, e.g., *United State* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States v. 8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951).

Parts of the 1990 amendments and these regulations have an incidental effect on speech in a narrowly defined area, food labeling. See *NAACP* v. *Claiborne Hardware* Co., 458 U.S. 886, 912 (1982). The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d 365, 372-73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC* v. *Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the first amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir.) ("[R]ules restricting speech do not necessarily abridge freedom of speech."), cert. denied, 434 U.S. 829 (1977).

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. See *Ohrali*, 436 U.S. at 456. FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. See 79 Congressional Record 4734 (1935), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label."). In such an area of extensive Federal regulation, the Government may place restrictions on speech by a regulated party where the speech relates directly to the Government's objectives. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. See id. at 373.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of [s]peech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the first amendment, even though in another context the book might be protected. See *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963). "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *Kellogg Co.* v. *Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law), aff'd without opinion, 940

F.2d 1530 (5th Cir. 1991). "The substantial government interest in the goals of the Act justifies this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." *Kellogg*, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern nutrient content claims, Congress sought to put an end to the proliferation of confusing and contradictory nutrient content claims. 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch); 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). In order to assist consumers in improving their eating habits, Congress devised a scheme to ensure that nutrient content claims in food labeling will help consumers to make good nutrition choices, not mislead them. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Under this scheme, only those claims that FDA has defined by regulation, see section 343(r)(2)(A)(i) of the act, or approved pursuant to a petition, see section 343(r)(4)(A), are permitted, and a food that bears an unapproved nutrient content claim is misbranded. Since FDA case law makes clear that a label statement that misbrands a food product is not subject to first amendment protection, an unapproved nutrient content claim on a food label would not be protected speech. See *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963).

Congress considered existing labeling practices to be harmful to the public because of the "confusing" and "misleading" nutrient content claims made by many manufacturers. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); see also 136 Congressional Record H5843 (July 30, 1990) (statement of Rep. Madigan); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity."). Congress dealt with this problem by crafting a system to permit certain useful information to appear on the food label, while ensuring that the information is not misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Congress considered these restrictions on speech necessary to further the government's interest in ensuring that nutrient content claims on food labeling would not mislead consumers. The government's action in regulating the food label does not offend the first amendment simply because speech is involved. *Ohralik*, 436 U.S. at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372–73; see also *Dun & Bradstreet, Inc.* v. *Greenmoss Builders*, 472 U.S. 749, 758 n.5 (1985); *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978).

295. Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985), labeling does not fall clearly within the bounds of commercial speech. The agency does not consider it necessary for first amendment analysis, however, to determine whether or not food labeling fits the definition of commercial speech. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Rather, the agency considers labeling on foods to form "a distinct category of communications in which the Government's power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373. Nonetheless, recognizing that at least one court has categorized labeling as commercial speech, General Nutrition, 638 F. Supp. at 562, FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, these regulations do not violate the first amendment. First, speech that is misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 563–564 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566. These regulations govern a kind of speech that is inherently misleading and that, in Congress' judgment, has been used to mislead the American public for years: Unregulated, nonstandardized nutrient content claims on the food label. However, even if such claims are considered only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the first amendment. See, e.g., *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983). For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563–64. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771 n.24 (1976). These regulations will have the effect of ensuring that the nutrition claims that appear in food labeling are not misleading. See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (because FDA regulation was based on the agency's conclusion that "labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," the regulation did not violate the first amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that which "experience has proved * * * is subject to abuse." In re *R.M.J.*, 455 U.S. 191, 203 (1982). For example, in *Friedman* v. *Rogers*, 440 U.S. 1, 14–15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding State bar's rules against in-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that food labeling, including express and implied nutrient content claims, would be accurate, uniform, and "based on science." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of

Sen. Hatch). With respect to nutrient content claims, the principal problem that Congress sought to correct was the use of ambiguous, undefined claims like "light" and "low." See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). Experience had shown that consumers were being misled because these terms were being used differently by different manufacturers. Id.; 136 Congressional Record H12, 953–954 (Oct. 26, 1990) (statement of Rep. Madigan). Congress recognized that consumers were being hampered in their attempts to achieve a healthy diet by confusing implied nutrient content claims like "light." 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley).

Because of the misleading character of unregulated, nonstandardized nutrient content claims, Congress legislated that any claim that is not consistent with FDA regulations misbrands a food. Section 403(r)(2)(A)(i) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the level of any nutrient * * * of the food *unless* the claim" complies with regulations promulgated by FDA (emphasis added). Section 403(r)(1)(A) of the act. By taking this approach, Congress chose to permit only those nutrient content claims that FDA defines or approves, effectively recognizing that unregulated claims mislead the public.

Particular attributes of unregulated nutrition claims on the food label make them inherently misleading. Because nutrition claims are of great importance to the public, they have a greater potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce purchases may take on exaggerated importance in the public mind and thus be more likely to mislead. *FTC* v. *Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they "played on the average consumer's well-founded fear of cancer"). In addition, nutrient content claims on food labeling are difficult for consumers to verify independently. See *American Home Products* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel* v. *Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct. 2281, 2288 (1990) (a lawyer's certification is a "verifiable fact"). Finally, consumers place great reliance on the portions of the food label that they believe to be regulated by the Government. FDA's 1990 Health and Diet Survey, Division of Consumer Studies, CFSAN. Unapproved nutrient content claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive Government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products* v. *FTC*, 695 F.2d at 697.

296. Many comments argued that nutrient content claims are only potentially misleading, pointing out that the Government may not absolutely prohibit potentially misleading speech if it can also be presented in a nondeceptive way. *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2287 (1990); In re R.M.J., 455 U.S. 191, 203 (1982). The preferred remedy for potentially misleading speech, these comments stress, is not a prohibition but a requirement of disclaimers or explanation. In re *R.M.J.*, 455 U.S. at 203 (citing *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 375 (1977)); see also *Peel*, 110 S. Ct. at 2292 (referring to "[t]he presumption favoring disclosure over concealment"). Comments argued that given the constitutionally based preference for more speech, rather than less, FDA should require disclaimers or explanations rather than prohibiting unapproved claims.

Even if unregulated nutrition claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions must directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to nutrition information that is truthful, reliable, understandable, scientifically valid, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates* v. *Tourism Co.*, 478 U.S. 328, 341 (1986). Moreover, consumers have a first amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978) "The fact that health is involved enhances the interests of both consumers and the public in being assured 'that the stream of commercial information flow[s] cleanly as well as freely.'" Id. (quoting *Virginia State Board of Pharmacy*, 425 U.S. at 772); *American Home Products*, 695 F.2d 681 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys." *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 553 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will define a nutrient content claim by regulation or make an administrative determination that a suggested claim is synonymous with a previously defined claim before permitting the claim to be used. In this way, the regulations will ensure that such claims are consistent, understandable, and do not confuse or mislead consumers. The regulatory scheme will also encourage companies to provide consumers with information that will enable them to improve their diets. There is an "immediate connection," *Central Hudson*, 447 U.S. at 569, between nutrient content claims on food labels and consumers' food choices.

Finally, these regulations are no more extensive than necessary to serve the Government's interest. Under *Board of Trustees* v. *Fox*, regulations that are narrowly tailored to serve the Government's interest will meet this prong of the *Central Hudson* test. 109 S Ct. 3028, 3032–35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "Not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035; see also *Ward* v. *Rock Against Racism*, 109 S. Ct. 2746, 2758 (1989) (a regulation is narrowly tailored if Government interest would be achieved less effectively without the regulation). These regulations reasonably and effectively ensure that nutrient content claims on food labels will be informative, consistent, and not misleading. Thus, they meet the third prong of the *Central Hudson* test and do not violate the first amendment.

FDA recognizes that the Government may not absolutely prohibit potentially misleading information if the information can also be presented in a

nondeceptive way. See In re *R.M.J.*, 455 U.S. 191, 203 (1982). The agency further acknowledges that the preferred remedy for potentially misleading speech is a disclaimer or explanation rather than a prohibition. Consequently, these regulations impose only those restrictions that are necessary to ensure that nutrient content claims are presented in a nondeceptive way. Conceding for the sake of argument that some unapproved claims are only potentially misleading, FDA has not outlawed the information conveyed by such claims; instead, the agency has prescribed that the information be presented in standardized form, using uniform, terms defined by the agency, so that consumers will not be misled.

297. Some comments argued that nutrient content claims, which help consumers to achieve healthy eating habits, convey information of general interest about nutrition and health. Thus, the comments argued, nutrient content claims are "pure" speech, not commercial speech, and as such are entitled to full first amendment protection.

FDA disagrees with these comments. As discussed above, FDA believes nutrient content claims belong to a distinct category of communications in which the government's power to regulate is broad. Under the comprehensive Federal scheme for the regulation of food and drugs, the Government has authority to impose incidental restrictions on food labeling, including nutrient content claims. As between commercial speech and "pure" speech, however, FDA believes nutrient content claims should be categorized as commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction. See *Bolger* v. *Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas* v. *Public Service Commission*, 447 U.S. 557, 562 n.5, 100 S. Ct. 2343, 2349 n.5 (1980). A label is not entitled to the protection due noncommercial speech simply because it relates to an issue of broad public interest. See *Board of Trustees* v. *Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct. at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. In determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct. 2265, 2274 n.7 (1985). Just as informational pamphlets were considered commercial speech in *Bolger*, so too nutrient content claims on food labels, as between pure speech and commercial speech, should be considered commercial speech. See *Bolger*, 463 U.S. at 66–68, 103 S. Ct. at 288–81.

298. Several comments argued that the requirement that nutrient content claims be approved by FDA before they may be used places an unconstitutional prior restraint on expression. The agency, the comments reasoned, would be banning speech not previously determined to be false or misleading. The speech would remain banned until the agency defined the term at issue. Some comments further complained that the petition process is too burdensome. Citing *Space Age Products* v. *Gilliam*, 488 F. Supp. 775 (D. Del. 1980), one comment argued that "the public has an interest in minimizing the frequency and duration of erroneously imposed prior restraints on commercial speech." Id. at 784. This interest, according to *Gilliam*, mandates narrow tailoring of prior restraints on commercial speech and "such traditional safeguards with respect to these restraints as are not inconsistent with its ability to achieve its important and legitimate objectives." Id.

The Supreme Court has said that because commercial speech is not easily chilled, the heavy presumption against prior restraints may not apply to commercial speech. *Virginia State Board of Pharmacy*, 425 U.S. at 772 n.24. The Court has repeated its position on this subject since *Space Age Products* was decided. In Central Hudson, the Court remarked that the State could have required that ads for electricity be approved by the state before being used and reiterated that traditional prior restraint doctrine may not apply to commercial speech. *Central Hudson*, 447 U.S. at 571 n. 13.

Even assuming for the sake of argument that the presumption against prior restraints does apply to commercial expression, the agency believes that its regulations are constitutional because, as discussed more fully above, they limit only speech Congress has already determined to be misleading. This speech is therefore unprotected. See *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (FDA regulation based on agency's conclusion that labeling that fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act was no unconstitutional prior restraint). In addition, the regulatory scheme incorporates procedural safeguards that provide for a prompt determination of whether a particular claim is permissible. The agency is required to act on nutrient content claim petitions expeditiously. See section 403(r)(4)(A) of the act.

299. Some comments argued that the requirement that the proponent of an undefined claim submit a petition for its approval unconstitutionally shifts the burden of distinguishing misleading and nonmisleading speech from the Government to the speaker. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985). Even a showing that the speech has the potential to mislead does not allow the Government to shift that burden, one comment contended, citing *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2292 (1990).

As discussed above, the Government has met its burden of showing that the speech being restricted is misleading. Congress made specific findings that both nutrient content claims in general and particular terms, such as "light," have misled the public. See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman); id. at H5843 (statement of Rep. Cooper); 136 Cong. Rec. S16609 (Oct. 24, 1990) (statement of Sen. DeConcini). In addition, the comment misconstrues *Peel*. In that case, the Supreme Court said that a mere potential to mislead did not justify prohibition of the speech at issue. The Court did not say that the Government could not, based on a showing that a particular kind of speech had the potential to mislead the public, require preapproval of the speech.

300. Some comments suggested that the nutrient content claims regulations are unconstitutionally overbroad because, according to the comments, they reach a substantial amount of protected speech.

FDA disagrees. As discussed in detail elsewhere in this document, these regulations are narrowly tailored to meet a substantial government interest and do not "sweep[] within [their] prohibitions what may not be punished under the First * * * Amendment[]." *Grayned* v. *City of Rockford*, 408 U.S. 104, 115 (1972). In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); *Central Hudson*, 447 U.S. at 565 n.8.

301. One comment cited several lower court decisions involving food labeling and the first amendment to support its argument that these regulations are

unconstitutional. *Lever Bros.* v. *Maurer*, 712 F. Supp. 645 (S.D. Ohio 1989); *Taylor Wine Co.* v. *Department of the Treasury*, 509 F. Supp. 792 (D.D.C. 1981); *American Meat Inst.* v. *Ball*, 424 F. Supp. 758 (W.D. Mich. 1976); *Anderson, Clayton & Co.* v. *Washington State Dep't of Agric.*, 402 F. Supp. 1253 (W.D. Wash. 1975).

FDA disagrees with the comment's interpretation of these cases. *Anderson*, which predated *Virginia Pharmacy* and the Supreme Court's other commercial speech cases, struck down a State law prohibiting use of dairy terms in the advertising of margarine. The court mistakenly applied strict scrutiny to the statute, holding that the State must show a *compelling* government interest to justify restrictions on speech. 402 F. Supp. at 1257 (emphasis added). As discussed above, under current Supreme Court jurisprudence the Government need only demonstrate a substantial interest in regulating potentially misleading speech. *Central Hudson*, 447 U.S. at 564. If the speech is actually or inherently misleading, it may be prohibited or restricted on that basis alone. See *Peel*, 110 S. Ct. at 2292–93; In re *R.M.J.*, 455 U.S. at 203.

In *Lever Bros.* v. *Maurer*, which involved a similar statute prohibiting the use of "butter" in advertising for products intended as imitations of or substitutes for butter, the court held that prohibition of the term "butter" without regard for whether the term was used in a misleading way violated the first amendment. 712 F. Supp. at 652–653. Here, Congress has already found the labeling practices at issue to be misleading. In addition, here the Government's interest is not merely in accuracy, but also in uniformity. Standardizing the nutrition information that appears in food labeling, including nutrient content claims, will make it easier for consumers to find, understand, and compare the information they need to make healthy eating choices. No such government interest was present in *Lever Bros.*

Taylor Wine is also inapposite. That case involved a regulatory scheme that required preapproval of wine labeling. The challenge was not to the preapproval requirement itself, as here but to the agency's refusal to approve a claim that it had conceded would not confuse or mislead consumers of the plaintiffs' wines. 509 F. Supp. at 795. In addition, the agency had conceded that the claim, which used the term "light," met the requirements established by the agency for use of that term. Id. at 793. Under the regulatory scheme at issue here, FDA will allow use of terms defined by FDA in nutrient content claims without preapproval.

Finally, in *American Meat Institute*, there was no first amendment challenge to the legislation at issue; rather, the first amendment was used to uphold the legislation against a preemption argument. The challenged legislation required meat producers whose products did not meet Michigan standards to notify Michigan consumers of that fact. The court upheld the law in part on the basis of the consumers' first amendment right to receive information. 424 F. Supp. at 769. The court further found that the State had a strong interest in consumer education and protection and suggested that striking down the statute might limit the State's communications with its citizens in violation of the first amendment. Id. at 767. The court said that the first amendment question that would arise if the Michigan law were preempted provided additional support for its holding that the notices required by the State were not "labeling" as defined in the Federal Wholesome Meat Act (21 U.S.C. 678). Id. at 769. Thus, far from serving to undermine the nutrient content claim regulations, *American Meat Institute*, if anything, supports them, since it recognizes consumers' strong interest in receiving accurate, useful information about food and the government's strong interest in ensuring that such information will be provided.

302. A number of comments argued that the rule prohibits certain nonmisleading uses of particular terms ("fresh" or "light") and types of claims (comparative statements or amount statements), and that such nonmisleading uses cannot constitutionally be prohibited.

FDA disagrees with the premise of these comments. As explained more fully above, Congress found that the unregulated use of undefined nutrient content claims is inherently and actually misleading. This final rule allows use of the referenced terms and types of claims, but only in ways that will inform the public rather than mislead it. The agency's response to the comments' suggestions concerning particular terms and types of claims can be found elsewhere in this document.

303. Two comments contended that with respect to certain types of nutrient content claims, FDA should use its authority under section 403(a)(1) of the act to regulate false and misleading claims on a case-by-case basis, rather than issuing regulations under the 1990 amendments. Specifically, the comments argued that statements of the amount or percentage of nutrients in foods (e.g., "contains 160 mg sodium") and certain ingredient claims that FDA has classified as implied nutrient content claims (e.g., "high in oat bran") should be regulated under section 403(a)(1) of the act rather than under the 1990 amendments.

FDA disagrees. Congress enacted the 1990 amendments because it found that existing law was insufficient to protect consumers from misleading food labeling practices. While FDA could have regulated deceptive nutrient content claims, including ingredient and amount claims, under section 403(a)(1) of the act, Congress considered FDA's authority to do so unclear and in need of strengthening. H. Rept. 101–538, 101st Cong., 2d sess. 7 (1990). Consequently, Congress passed new legislation directing FDA to issue new regulations that would curb deceptive food labeling. Congress specifically authorized FDA to issue regulations governing amount claims, see section 3(b)(1)(A)(iv) of the 1990 amendments, and also provided more generally for the issuance of regulations limiting the use of claims that expressly or by implication characterize the level of a nutrient required to be on the food label. See section 403(r)(1)(A) of the act. A claim that a food contains an ingredient associated with a particular nutrient by implication characterizes the level of that nutrient.

It is entirely appropriate for FDA to regulate ingredient and amount claims under the new regulations, which specifically target these claims, rather than under section 403(a)(1) of the act; indeed, FDA had no choice but to do so, given the congressional mandate. Moreover, the regulations themselves are narrowly tailored and do not prohibit nondeceptive speech.

304. Some comments asserted that FDA should not prohibit the use of undefined terms and should allow synonyms of FDA-defined terms as long as the synonyms meet the standard for the defined term.

Section 403(r)(2)(A)(i) of the act states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations by the Secretary (and FDA, by delegation). This rule also applies to synonyms. See section 3(b)(1)(A) of the 1990 amendments. As discussed above, Congress was concerned about the proliferation of confusing and conflicting nutrient content claims; hence, it sought uniformity on the food label. Allowing unapproved terms and synonyms would undermine that goal. The petition process provided for in new § 101.69 allows anyone who wishes to suggest both new terms and

synonyms of already-defined terms. In light of Congress' findings and the availability of the petition process to expand the vocabulary of nutrient content claims, FDA does not believe its regulations unduly burden expression.

305. One comment proposed that FDA permit the use of unapproved nutrient content claims if they are consistent with and explained by an immediately adjacent term that is defined by regulation. The comment argued that this solution would cure the first amendment infirmity caused by the prohibition of unapproved claims yet would fulfill the goals of the 1990 amendments.

The agency rejects this suggestion because it would lead to the same kind of inconsistent use of terms that Congress wanted to eradicate. For example, one company might use "lean" as a synonym for "light," while another might use it as a synonym for "low fat." Thus, "lean" would be used in contradictory ways on different products. Such a result is not permissible under the act. As discussed above, the agency does not believe that its approach is constitutionally infirm.

306. In response to FDA's request for comments as to whether it should define "natural" or ban such claims entirely on the ground that they are false or misleading, one company argued that prohibition of "natural" would be an unconstitutional restriction on free speech. FDA has decided not to define the term "natural" or to prohibit its use. Therefore, this comment is moot.

307. One comment asserted that because those who violate the act are subject to criminal prosecution, FDA must define clearly which nutrient content claims are allowable. The comment further argued that a manufacturer who uses a term no intended as a nutrient content claim may learn, too late, that FDA so interprets it as such.

The comment seems to be invoking the vagueness doctrine, which, in the first amendment context, is generally applied to strike down prohibitions or speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498—99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). That is not the case here. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It should thus be clear which type of speech is prohibited and which permitted. Manufacturers will be on notice that the use of an unapproved nutrient content claim is prohibited conduct.

As to the comment's second point, FDA agrees that it is important to consider intent when determining whether an implied nutrient content claim has been made. However, the agency notes that intent means more than the manufacturer's subjective intent. "FDA is not bound by the manufacturer's subjective claims of intent * * *." *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its labeling, promotional material, advertising, and "any other relevant source." Id.; *United States* v. *An Article * * * Consisting of 216 Individually Cartoned Bottles * * * "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). If a phrase on a food label meets the definition of an implied nutrient content claim, it is such a claim regardless of the manufacturer's subjective intent. The definition of an implied nutrient content claim is clear from the statute as interpreted by the regulations. See section 403(r)(1)(A) of the act; new § 101.13(b). Manufacturers are required to keep abreast of changes in the law and are responsible for scrutinizing their labeling to determine whether it makes nutrient content claims.

B. The Fifth Amendment

These regulations will affect some companies' use of brand names, including names subject to trademarks. A brand name that includes an FDA-defined nutrient content claim, such as "light," will be permitted to appear only on products that meet the regulations' definition of "light." Brand names that include nutrient content claims that FDA has not defined will not be permitted unless they were in use before October 25, 1989, the date the 1990 amendments were reported out of committee, or unless a petition for their use is submitted and approved.

308. Some comments contended that outlawing a brand name could violate the fifth amendment. Because brand names are property, banning their use could constitute a taking without just compensation, these comments argued. The comments suggested that in keeping with Executive Order No. 12630, FDA should conduct a takings analysis to assess whether compensation to owners of affected brand names would be appropriate.

In its November 27, 1991, regulatory impact analysis (RIA), 56 FR 60856 at 60865, FDA stated that any alteration of trade names required by the new regulations would not constitute a taking, and that, as a result, no takings analysis was necessary. In view of the comments and concerns raised about the takings issue, however, the agency reconsidered and decided that it was appropriate to conduct a formal takings analysis pursuant to Executive Order No. 12630. The agency has completed the takings analysis and still believes that there is no regulatory taking under the fifth amendment if a manufacturer is required to alter its brand name when that brand name asserts, expressly or by implication, a nutrient content claim that has not been approved by FDA. The basis for this conclusion is set forth in response to the comment that follows.

309. Comments from industry argued that the regulations' effect on companies' ability to use brand names constitutes a taking without compensation in violation of the fifth amendment of the U.S. Constitution. They point foremost to the financial consequences of losing the use of a valuable brand name. Standing alone, however, diminution in property value does not establish a taking. *Penn Central Transp. Co.* v. *City of New York*, 438 U.S. 104, 131 (1978). Indeed, "[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law." *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 413 (1922).

The Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) the extent to which a regulation interferes with reasonable investment-backed expectations; and (3) the regulation's economic impact. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1005 (1984); *Penn Central*, 438 U.S. at 124. When examined in light of these three factors, it is clear that FDA's regulations do not effect a taking in violation of the Constitution.

With respect to the first factor, courts are more likely to find a taking when the interference with property can be characterized as a physical invasion by the Government than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good." *Penn Central*, 438 U.S. at 124. Courts have accorded particular deference to governmental action taken in order to protect the public interest in health, safety, and welfare. See *Keystone Bituminous Coal Ass'n* v. *DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125; *Atlas Corp.* v. *United States*, 895 F.2d 745, 757 (Fed. Cir.) cert. denied, 111 S. Ct. 46 (1990);

Calvert Invs. v. *Metro. Sewer Dist.*, 847 F.2d 304, 309 (6th Cir. 1988).

With the 1990 amendments and these regulations, Congress and FDA seek to protect the public interest in health by ensuring that consumers who wish to maintain healthy dietary practices may be assisted in doing so by the information on food labels. This action constitutes a reasonable effort by the Government to promote the common good. By defining nutrient content claims, the regulations will "bring a sense of order to the understanding of terms used when describing characterizations of food products." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch). By permitting approved nutrient content claims, the regulations seek to provide useful information to consumers while ensuring that the information is not confusing or misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley). These regulations substantially advance and are rationally related to FDA's legitimate interest in promoting the public health through the food label. See *Keystone*, 480 U.S. at 485; *Monsanto*, 467 U.S. at 1007; see also *Pace Resources, Inc.* v. *Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) ("[T]he governmental action is entitled to a presumption that it does advance the public interest."), cert. denied, 482 U.S. 906 (1987).

Although these regulations will restrict the use of certain defined terms, including terms that appear in some trade names, this restriction does not rise to the level of a taking. Governmental restrictions on the uses individuals can make of their property are "properly treated as part of the burden of common citizenship." *Keystone*, 480 U.S. at 491 (citation omitted). These burdens are "borne to secure 'the advantage of living and doing business in a civilized community.'" *Andrus* v. *Allard*, 444 U.S. 51, 67 (1979) (quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)). Moreover, these regulations are not without benefit to manufacturers. See *Keystone*, 480 U.S. at 491 ("While each of us is burdened somewhat by such restrictions, we, in turn, benefit greatly from the restrictions that are placed on others."); see also *Penn Central*, 438 U.S. at 134 ("preservation of landmarks benefits all * * * citizens and all structures"). By defining certain terms, the regulations will increase the reliability of the food label and thus will bolster consumer confidence in label statements. They will also level the commercial playing field: No manufacturer will be able to use a defined term unless its use is consistent with the definition.

The second factor that courts consider is whether a company has a reasonable investment-backed expectation in continuing to use its brand name. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. *Pace Resources*, 808 F.2d at 1033. Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. "In an industry that long has been the focus of great public concern and significant government regulation," *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be modifications of the regulatory requirements. "Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end." *Connolly* v. *Pension Benefit Guar. Corp.*, 475 U.S. 211, 227 (1986) (citation omitted); cf. *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992) ("[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * * ."). Participants in a highly regulated industry are "on notice that [they] might be subjected to different regulatory burdens over time." *California Housing Secs., Inc.* v. *United States*, 959 F.2d 955, 959 (Fed. Cir. 1992), petition for cert. filed, 61 U.S.L.W. 3083 (U.S. July 22, 1992). In contrast, a regulatory scheme that appears suddenly may interfere with a company's reasonable expectations. Id.

It is not reasonable for a company to expect to be able to continue indefinitely to use a brand name that contains a defined nutrient content claim. Such an expectation would ignore FDA's power to regulate the food label, the regulatory environment of the food industry, and the foreseeability that FDA would regulate health and content claims on the food label.

FDA's authority to regulate the food label is broad and longstanding. Governmental authority to regulate the food label has long been recognized. For example, the Supreme Court stated in 1919 that "it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919). With the 1990 amendments, Congress did not suddenly grant the agency new authority of the sort that interfered with a company's reasonable expectations about the way the food label would be regulated, see *California Housing Secs.*, 959 F.2d at 959, but rather clarified FDA's authority to define nutrient content claims. The authority granted by the 1990 amendments was consistent with FDA's existing power over the food label. For example, FDA already had authority to define common or usual names for food and to set standards of identity. See, e.g., *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977). Moreover, under preexisting authority—e.g., sections 201(f) and (n) and 403(a) and (j)—the agency had regulated or taken steps to regulate nutrient content claims on the food label. Although FDA had earlier regulated the use of certain nutrient content claims, the 1990 amendments gave the agency specific authority to define terms such as "light" and "low" consistently across product categories. See, e.g., 136 Congressional Record H12953–54 (Oct. 26, 1990) (statement of Rep. Madigan).

Moreover, the food industry is highly regulated. Companies are well aware that they operate subject to the restrictions of the act. Like other regulatory schemes, the act has not been static, see *California Housing Secs.*, 959 F.2d at 959, and companies that are subject to the act should understand the possibility that its requirements will evolve over time. The food industry has long been "the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Monsanto*, 467 U.S. at 1009.

Not only was the industry on notice that the regulatory scheme under which it operated might be amended, but it also had specific notice of the type of action FDA might take with respect to the food label. FDA promulgated regulations on the use of certain nutrient content claims years before the 1990 amendments were passed. The terms "sodium free," "very low sodium," "low sodium," and "reduced sodium" are defined in current § 101.13. Current § 101.25 governs information that may appear on food labels regarding fat, fatty acid, and cholesterol content. Current § 105.66 controls the use of the claims "low calorie," "reduced calorie," and "sugarfree." It would be unreasonable for a company to expect that the agency would forever

refrain from further regulation of nutrient content claims.

Thus, companies that use brand names that contain express or implied nutrient content claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. Only with the passage of the 1990 amendments and the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim. See *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. at 1010–1013.

The final factor that courts consider is the economic impact of the governmental action. "There is no fixed formula to determine how much diminution in market value is allowable without the Fifth amendment coming into play." *Florida Rock Industries, Inc.* v. *United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), cert. denied, 479 U.S. 1053 (1987). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915) (reduction in value from $800,000 to $60,000); *Euclid* v. *Ambler Realty Co.*, 272 U.S. 365 (1926) (75 percent diminution in value)). Mere denial of the most profitable or beneficial use of a property does not require a finding that a taking has occurred. *Tirolerland, Inc.* v. *Lake Placid 1980 Olympic Games, Inc.*, 592 F. Supp. 304, 313 (N.D.N.Y. 1984); see also *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979); *Florida Rock*, 791 F.2d at 901. Rather, courts look for extensive or drastic interference with a property's possible uses. See *Pace Resources*, 808 F.2d at 1031.

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable" use of its property. See, e.g., *Keystone*, 480 U.S. at 499. This analysis involves looking not just at what has been lost, but at the whole "bundle" of property rights. *Andrus* v. *Allard*, 444 U.S. at 65–66. Courts focus on the remaining uses permitted and the residual value of the property. *Pace Resources*, 808 F.2d at 1031. Although it is undeniable that compliance with these regulations will cost money and may mean that certain product names must be altered, companies will not be denied the economically viable use of their property.

Many firms will be able to minimize the regulations' impact by reformulating those products that do not meet the regulations' definitions. These reformulated products could continue to bear the original brand name. Reformulation may be costly, but it is not the kind of economic impact that leads to a taking. "Requiring money to be spent is not a taking of property." *Atlas Corp.*, 895 F.2d at 756. Nor may companies argue, as one comment did, that their legal and other costs of seeking compensation for losses from these regulations should be included in the assessment of economic impact. These costs are not included in calculating just compensation under the fifth amendment. *United States* v. *Bodcaw Co.*, 440 U.S. 202, 203 (1979); *United States* v. *101.80 Acres*, 716 F.2d 714, 717 n.5 (9th Cir. 1983).

Other companies may be able to continue using their brand names with some, but not all, of their products. These companies will retain a residual economically viable use of their brand names. These companies will retain the ability to use their brand names on some of their products. Those with trademarks will also retain the important right to prevent other companies from marketing under the protected name. See *PruneYard Shopping Center* v. *Robins*, 447 U.S. 74, 82 (1980) ("[O]ne of the essential sticks in the bundle of property rights is the right to exclude others."). They would, moreover, be able to market new products that meet the applicable definition under the brand name. And finally, those foods that could not be marketed under the original brand name may continue to be sold under another name that does not violate the regulations.

It is unlikely that these regulations will force any company to stop using a brand name entirely. However, even if these regulations do have such an effect, the economic impact of this loss, without more, would not establish a taking: It is also critical to consider the character of the Government's action and its interference with reasonable investment-backed expectations. In addition, a company in this position lacks a property right to continue marketing a product under a defined term that its food does not meet. See 56 FR 60856 at 60865, November 27, 1991. For example, a food that bears a "light" claim but does not meet the definition of "light" and cannot be reformulated as a "light" product is not light and should not be called "light." Such a product is misbranded not only under section 403(r) of the act but also under section 403(a)—that is, even before the passage of the 1990 amendments, its labeling was false or misleading and in violation of the act. See *Lucas* v. *South Carolina Coastal Council*, 112 S. Ct. 2886, 2901 (1992) ("The use of these properties for what are now expressly prohibited purposes was always unlawful * * *.").

310. One comment inquired why, if so many misbranded products were on the market before the 1990 amendments, FDA did not take action to stop the misbranding.

In fact, FDA did send warning letters to a number of manufacturers who were making misleading claims. In virtually all of these cases, the manufacturer removed the misleading claim from the product. The agency would have done more but for lack of resources. In addition, consumer confusion resulted as much from the lack of any defined standards for claims as from individual claims that were objectionable. To solve the problem, it was necessary to address it globally by developing a regulatory scheme designed specifically for nutrient content claims.

311. One comment argued that to avoid an unnecessary taking, the agency should interpret section 403(r)(2)(C) of the act (the grandfather clause) to apply to product line extensions. The comment asserts that section 403(r)(2)(C) of the act is ambiguous and reads FDA's proposed implementing regulation (proposed § 101.13(o)(1)) to extend grandfathering to new products introduced under an existing brand name.

FDA does not believe the grandfather clause is ambiguous but has revised its regulation (new § 101.13(p)(1)) to clarify that the grandfather clause does not apply to product line extensions. The grandfather clause provides that unapproved nutrient content claims that are part of the brand name of a food are permitted if the brand name was in use *on the food* before October 25, 1989—not if the brand name was being used on some other food before that date (emphasis added). Therefore, new products introduced under the same brand name are not covered. Any company that started using a preexisting brand name on a new product after the grandfather date did not have a reasonable expectation of being able to use the name on that product. Therefore, the regulation does not effect a taking.

312. Another comment contended that the wording of the grandfather clause demonstrates that a product whose brand name includes an undefined nutrient content claim is not necessarily misbranded under section 403(a) of the act, which proscribes false and misleading labeling. The comment reasoned that, where there are two brand names that contain the same undefined claim—one grandfathered, one not—it would be absurd to say that

the nongrandfathered brand name is misleading, but that the grandfathered brand name is not.

The agency agrees that a grandfathered brand name is not necessarily false or misleading under section 403(a) of the act, nor is a nongrandfathered brand name that makes the same claim. A product with a nongrandfathered brand name that makes an unapproved nutrient content claim is misbranded under the 1990 amendments, however, because they prohibit the use of undefined claims. See section 403(r)(1)(A) of the act. Moreover, after the claim has been defined, both the grandfathered and nongrandfathered product will be misbranded under both section 403(a) of the act and the 1990 amendments if they do not conform to the definition. (See section 403(r)(2)(C).)

It should be noted that Congress did not make a judgment as to whether grandfathered brand names are misleading or nonmisleading; rather, it decided not to disrupt the market until FDA had a chance to define the terms used in grandfathered brand names. There is no taking of an undefined, nongrandfathered brand name because companies had no reasonable investment-backed expectation of being able to use undefined claims after the 1990 amendments were reported out of committee.

It should be pointed out that it is the statute, not FDA's regulations, that forbids the use of undefined terms in nutrient content claims.

313. The same comment argued that because the Patent Office considers the comment's trademark nondeceptive, the company has a reasonable, investment-backed expectation of being able to use the trademark.

The agency disagrees. FDA, not the Patent Office, has primary expertise in food labeling, and FDA does not consider itself bound by the Patent Office's decision as to whether a trademark is misleading.

314. Two comments argued, citing FTC case law, that the policy of the law to preserve trade names protects them from destruction if less drastic means would prevent deception. See *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 612 (1946); *FTC* v. *Royal Milling Co.*, 288 U.S. 212, 217 (1933). The comments argued that prohibiting certain brand names is inappropriate because deception can be prevented by adding disclaimers or explanations to the brand names. One comment said the cited cases are rooted in takings doctrine. The other asserted that these cases are based on first amendment principles. See *Beneficial Corp.* v. *FTC*, 542 F.2d 611, 620 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977).

FDA disagrees with these comments. According to *Jacob Siegel Co.*, whether prohibition of a trade name is necessary "is a question initially and primarily for the [agency] * * * [which] is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed." 327 U.S. at 612. In another case, the Supreme Court upheld the prohibition of a trade name when, in the agency's judgment, the prohibition was necessary to prevent deception. *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 81–82 (1934). With respect to food labeling, no disclaimer or explanation could eliminate the deceptive effect of a brand name that incorporates an FDA-defined term if the food on which the brand name appears does not meet the definition of that term.

The Supreme Court recently acknowledged the protection given to trade names in *Jacob Siegel* and *Royal Milling*, which were decided under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) (the FTC act), but also recognized that those decisions rested on statutory—not constitutional—grounds. The court made clear that the holdings of those decisions do not carry over to cases decided on first amendment principles alone:

> [T]here is no First Amendment rule, comparable to the limitation on § 5, requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication.

Friedman v. *Rogers*, 440 U.S. 1, 12 n.11 (1979). Like the first amendment, the act contains no limitation comparable to section 5 of the FTC act.

Finally, FDA is not bound to follow FTC case law. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. See *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985). Congress has long recognized the division of roles between the two agencies. See 79 Congressional Record 4749 (1935), reprinted in "Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record" 280–81 (Charles W. Dunn ed., 1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people"). The FTC regulates unfair competition and trade practices, including food advertising. See, e.g., 15 U.S.C. 45 and 52. In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Thus, FTC case law does not govern FDA regulation.

VII. Other Issues

315. One comment stated that because of the range of meanings already attached to terms such as "light," "low," "free," "source of," and "reduced," FDA's attempt to define such terms will not be completely successful at eliminating confusion. The comment suggested that a better approach would have been for FDA to create a set of terms, either chosen from words not currently used in relationship to food or completely made up, to attach to their definitions instead of attempting to define terms already in vogue.

In response to this comment addressing the agency's basic approach to defining terms used to make nutrient content claims, the agency advises that many of the terms that it is defining are those that the 1990 amendments require the agency to define. Section 3(b)(1)(A)(iii) of the 1990 amendments directs the agency to define the terms "free," "low," "light" or "lite," "reduced," "less," and "high" when these terms are used to characterize the level of any nutrient in food, unless it finds that the use of such terms would be misleading. The agency has not found that any of these terms are misleading per se, although some consumer confusion as to their meanings may exist as a result of the variety of ways in which they have been used in the marketplace. Providing regulatory definitions for these terms that must be used by any manufacturers that use these terms in their labeling should alleviate or eliminate confusion. Therefore, the agency does not have the prerogative of creating a set of terms for nutrient content claims that have not previously been associated with claims for food as the comment suggested.

316. One comment stated that nutrient content claims such as "free," "low," and "reduced" should be defined for modified lactose levels in foods.

The agency does not agree with this comment. These regulations are intended to define nutrient content claims for categories of nutrients or individual nutrients that are required for maintaining a diet that meets current dietary guidelines (e.g., fiber, cholesterol, and fat). Lactose, a sugar that occurs in milk, is not a nutrient addressed in current dietary guidelines. However, labeling in regard to the lactose content of a food does have