21 CFR Part 101

[Docket No. 84N-153A]

RIN 0905-AD08

## Food Labeling: "Cholesterol Free," "Low Cholesterol," and "____ Percent Fat Free" Claims

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations 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 is intended to ensure that these terms are not used in a manner that is misleading to consumers. In this document, FDA is also responding to the comments that it received in response to its tentative final rule on cholesterol claims (55 FR 29456, July 19, 1990) that pertain to use of the terms "cholesterol free" (including "no cholesterol" and "free of cholesterol") and "low cholesterol."

**DATES:** Written comments by January 27, 1992. The agency is proposing that any final rule that may be issued based upon this proposal become effective 30 days following its publication.

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

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

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA has had a long interest in the proper labeling of foods with information on fat and cholesterol content. FDA's policies have reflected contemporary knowledge on the effect of these food components on health.

Because there was a lack of agreement on the relationship between fat and cholesterol and good health at the time the agency's current regulations were adopted, FDA limited the amount of information that could be provided on the food label about these food components. The relevant regulations are 21 CFR 101.9(c)(6) (formerly 21 CFR 1.17), which requires that the fat content of a food be included in the nutrition label (38 FR 2132, January 19, 1973; and amended at 38 FR 6951, March 14, 1973), and 21 CFR 101.25 (formerly 21 CFR 1.18) (42 FR 14302, March 15, 1977), which provides for the voluntary listing of cholesterol and fatty acid content as part of the food's nutrition label. No other information on fat or cholesterol content is permitted.

In 1986, however, with the emergence of a consensus that limiting dietary cholesterol would contribute to good health, FDA published a proposal to define terms that describe the cholesterol content of foods, including "cholesterol free" and "low cholesterol" (51 FR 42584, November 25, 1986). FDA also proposed to require that whenever these or other terms describing cholesterol content are used on the label, the cholesterol and fatty acid content of the food must be declared in the nutrition label.

As part of the Secretary of the Department of Health and Human Services' food labeling initiative, FDA issued a tentative final rule on cholesterol labeling on July 19, 1990 (55 FR 29456). In announcing that FDA would publish this document, Secretary Louis W. Sullivan stated: "All of us have been frustrated by the misuse of these terms, and only clear, standardized definitions will help us eliminate misleading claims." (Ref. 1.)

In the document FDA addressed the comments that it had received on the 1986 proposal. Many of the comments requested that FDA limit the amount of fat and saturated fatty acids that could be present in foods on which cholesterol claims are made. FDA agreed with these comments and, in the tentative final rule (55 FR 29456), the agency proposed to limit the fat and saturated fatty acid content of foods bearing such claims.

FDA proposed to limit the use of "cholesterol free" and "low cholesterol" to foods that, in addition to containing the requisite cholesterol levels, contain not more than 5 grams (g) of fat and not more than 2 g of saturated fatty acids per serving. On a dry weight basis, these foods could contain not more than 20 percent fat and not more than 6 percent saturated fatty acids. The agency did not propose to change the requisite cholesterol level for "cholesterol free" foods from the 1986 proposal. However, in the case of "low cholesterol" foods, FDA proposed to change the amount of cholesterol per serving from "less than 20 mg" to "20 mg or less" and to add a second criterion, 0.2 mg or less cholesterol per g of food.

On November 8, 1990, the President signed the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The 1990 amendments made the most significant changes in food labeling law since the passage of the Federal Food, Drug, and Cosmetic Act of 1938 (the act). The 1990 amendments strengthen the Secretary's food labeling initiative by clarifying FDA's legal authority to require nutrition labeling on foods and by defining the circumstances under which claims may be made about the nutrients in foods. Specifically, the 1990 amendments add section 403(r), which deals with claims on foods, to the act. Section 403(r)(1)(A) of the act states that a food is misbranded if a claim is made on the label or labeling that characterizes the level of any nutrient of the type required to be declared in nutrition labeling unless the claim conforms to the specific requirements of the act.

The 1990 amendments directly affect FDA's July 19, 1990 tentative final rule on cholesterol claims. Because of the magnitude of changes needed in the tentative final rule to bring it into conformity with requirements of the 1990 amendments, the agency is issuing a new proposed rule on cholesterol descriptors elsewhere in this issue of the **Federal Register**. The agency is including in that proposal definitions for fat and fatty acid descriptors because of the interrelationship of these food components and cholesterol in the etiology of cardiovascular disease. The 1990 amendments require that FDA propose new regulations by November 8, 1991, and issue final regulations by November 8, 1992. These regulations will go into effect in May of 1993.

As the rulemaking on cholesterol labeling has proceeded, however, FDA has grown progressively more concerned about the "cholesterol free" ("no cholesterol" or "free of cholesterol"), "low cholesterol," and ____ percent fat free" claims that have appeared in the marketplace. The agency's concerns culminated in May of 1991 in an FDA decision to advise a number of companies that the "no cholesterol" claims that they made on their products were misleading (Refs. 1a through 6). Each of the manufacturers that FDA contacted made a product that, while containing no cholesterol, was high in total fat and bore a picture of a heart or some other representation that implied that the food was particularly good for the heart. FDA advised the firms that their products were misbranded under sections 201(n) and 403(a) of the act (21 U.S.C. 321(n) and 343(a)) because their labels failed to reveal that dietary factors other than cholesterol content play a necessary role in achieving a healthy heart, and that the products were high in fat, and excess fat in the diet is a general health

risk. All of the firms that received letters from FDA agreed to modify their labels.

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

> The high number—often 90 percent, 93 percent, and even 97 percent—linked with a desirable characteristic—"fat free"—leads people to conclude that the food itself promotes good health. It can also lead people to conclude that they can eat as much of it as they want. * * * We believe that this kind of assertion confuses and misleads consumers. Foods that derive a high percentage of their calories from fat should not be making low fat claims.
> (Ref. 7)

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

In response to FDA's actions, the food industry has expressed concern about what it perceives as a lack of rules regarding cholesterol and "____ percent fat free" claims. Industry has argued that fairness suggests that FDA should provide a set of rules under which such claims may or may not be made before the agency institutes enforcement actions. FDA is addressing these concerns in this proposal.

The agency intends to act on this proposal in an expeditious manner. The agency intends to publish a final rule in this proceeding as quickly as possible, and that that final rule will establish interim rules until the final rule implementing the 1990 amendments is promulgated.

## II. Basis for Action

FDA has decided that manufacturers should not be permitted to continue to make misleading "cholesterol free" (including "no cholesterol" and "free of cholesterol"), "low cholesterol," and "____ percent fat free" claims while the rulemaking under the 1990 amendments goes forward. The agency has focused on these claims because of the wide industry use of them, and because of the significant effect that they can have on the public health if misused. Therefore, the agency has tentatively decided to adopt interim regulations that lay out the circumstances in which these claims may be made on the food label. Although "reduced cholesterol" and comparative claims were also proposed in the tentative final rule, they are not being addressed in this document because they are rarely found in the marketplace and have not been identified as a source of misleading claims.

The agency is not proposing these rules because it believes that such rules are a necessary prerequisite to enforcement actions against products that misuse "free" and "low cholesterol" and "____ percent fat free" claims. FDA can and will take actions against products that are misbranded at any time.

FDA is issuing these proposed regulations under sections 201(n), 403(a), and 701(a) of the act, and not under the new sections added by the 1990 amendments. FDA believes that these three provisions provide ample authority for the regulations that it is proposing. Section 403(a) of the act states that a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states that labeling may be misleading not only because of representations made on or in the labeling, but also to the extent that the labeling fails to bear facts material in light of the representations made or material with respect to the consequences that may result from use of the article. Finally, section 701(a) of the act authorizes the agency to adopt regulations for the efficient enforcement of the act.

Although the agency is not relying on the 1990 amendments for legal authority to adopt these proposed interim regulations (in fact, the regulations that will be adopted under the 1990 amendments will supersede these proposed regulations if they are adopted by the agency), the agency has reviewed this proposal in light of the 1990 amendments. The agency recognizes that these proposed interim regulations do not exactly track the 1990 amendments. However, because the purpose of these proposed regulations, like that of the 1990 amendments, is to assure that certain cholesterol and fat claims are not made in a misleading manner, the agency is satisfied that these proposed regulations are not inconsistent with the 1990 amendments.

As stated above, elsewhere in this issue of the **Federal Register**, FDA is publishing a document on fat, saturated fat, and cholesterol nutrient content claims under the 1990 amendments. FDA plans to publish, if possible, the final rule in that proceeding so that comprehensive rules on nutrient content claims for these nutrients are in place at the same time.

## III. The Proposed Regulations

### *A. Modifications of Section 101.25*

FDA is proposing to remove § 101.25(a), (b)(2)(ii), (b)(2)(iii), (c)(1), (c)(2)(i), (c)(2)(iii), (d), and (g) because they are out of date. The agency had proposed to delete these provisions of § 101.25 in its proposed rule on cholesterol descriptors (51 FR 42584). The only comments received on these deletions addressed the deletion of percent of calories from fat in § 101.25(c)(2)(i). FDA responded to these comments in the tentative final rule on cholesterol descriptors (55 FR 29456 at 29469).

FDA is also proposing to revise § 101.25(b), (c), and (h) to reflect these deletions and to add a new paragraph (d) as described below.

### *B. Cholesterol Claims*

FDA is proposing to permit "cholesterol free" and "low cholesterol" claims on foods that meet specific requirements that will ensure that these claims are not used in a misleading manner. These requirements, as proposed in § 101.25(d)(1) and (d)(2), are:

(1) That the food must contain no more than the requisite levels of cholesterol;

(2) That the food must contain 2 g or less of saturated fat per serving;

(3) That the label or labeling must disclose the amount of fat per serving in conjunction with the cholesterol claim; and

(4) That, if a food is inherently free of, or low in, cholesterol, the food must be labeled to refer to all foods of that type and not to a particular brand.

#### 1. Definition

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

cholesterol when only "cholesterol free" foods were consumed.

In its tentative final rule, FDA advised that it considered that document to contain the final determination of the agency on all substantive issues other than on the threshold levels of fat and saturated fatty acids above which a "cholesterol free" claim would be misleading, and that a comment would need to be very significant to cause the agency to make any changes in the rule other than to the threshold levels. No new evidence on this issue was presented in comments on the tentative final rule. Therefore, FDA has not revised the definition for "cholesterol free."

This rule applies to all the phrases that mean the product has no cholesterol, such as "cholesterol free," "free of cholesterol," "no cholesterol," and "does not have any cholesterol." It is not possible to list here all descriptive phrases that would lead consumers to believe the product had no cholesterol. This regulation is designed to govern all such phrases.

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

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

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

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

Based on a review of the impact of the agency's proposed rule on serving sizes (55 FR 29517) on content descriptors, the agency has tentatively determined that there continues to be a need for a second criterion based on nutrient density even when FDA's rulemaking on serving sizes is completed (Ref. 8). Accordingly, FDA is carrying forward the second criterion for the definition of "low cholesterol." However, the agency is modifying proposed § 101.25(a)(2)(ii), redesignated as § 101.25(d)(2)(i), to specify the second criterion as 20 mg/100 g of food rather than 0.2 mg/g, an identical amount. The agency believes that expressing the second criterion as per 100 g, rather than as per g, is simpler because it eliminates decimals and makes the amount per serving and per weight identical (i.e., 20 mg of cholesterol per serving and per 100 g).

2. Saturated Fat Thresholds

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

FDA believes there is convincing evidence that dietary intake of saturated fatty acids is related to the risk of cardiovascular disease, the reduction of which is one purpose behind this rulemaking to define cholesterol content claims. This belief is supported by the "Surgeon General's Report on Nutrition and Health" which states: "Excessive saturated fat consumption is the major dietary contributor to total blood cholesterol levels" (Ref. 9, p. 11), and by the National Research Council's "Diet and Health" report which found a strong relationship between blood cholesterol levels and the prevalence and incidence of atherosclerotic cardiovascular disease (Ref. 10). Accordingly, the agency believes that it would be misleading for a food that contains a significant amount of saturated fatty acids to make a cholesterol claim and, thereby, to encourage consumers to buy the product for the purpose of reducing their risk of heart disease.

The agency agrees that consumer education programs are necessary to explain the relationship between saturated fat intake and the risk of cardiovascular disease. However, FDA is not persuaded that such programs can effectively reach and be understood by all consumers. A recent FDA consumer survey found that 40 percent of respondents thought that a "cholesterol free" food would also be low in saturated fat, and another 20 percent were not sure what the claim implies about saturated fat content (Ref. 11). The survey found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart disease (Ref. 11). These findings lead FDA to conclude that a significant number of consumers are likely to perceive that a food that bears a cholesterol content claim will help to lower blood cholesterol levels and to reduce the risk of heart disease. In point of fact, foods containing little or no cholesterol can contain saturated fats at levels that can contribute to high blood cholesterol which, in turn, can contribute to atherosclerotic cardiovascular disease (Refs. 9 and 10). Accordingly, FDA continues to believe that to ensure that cholesterol content claims do not mislead consumers, it is necessary to permit their use only when the foods also contain levels of saturated fats that are below a specified threshold level.

The agency, therefore, is proposing in § 101.25(d)(1)(ii) and (d)(2)(ii) to prohibit the use of "cholesterol free" and "low cholesterol" claims, respectively, on foods that contain more than 2 g of saturated fatty acids.

3. Threshold Level for Saturated Fat

Many comments suggested changing the threshold levels for saturated fatty acids. The agency had proposed levels of 2 g or less per serving and 6 percent or less saturated fat on a dry weight basis. These values were based on

calculations of the maximum amount of saturated fat that could be present in foods bearing cholesterol claims if a person consuming a typical diet of 16 servings of food per day ate only such foods and was to stay within dietary guidelines of less than 10 percent of calories from saturated fat. Most of the comments were opposed to the percent dry weight criterion. They argued that a dry weight limit would discourage the development of new food products with lower fat and cholesterol contents where water is substituted, in part, for fat. Comments stated that the development of new food technologies to develop more healthful foods would be hampered, and that the dry weight criterion was unnecessary and would unfairly penalize foods that have a high moisture content. A few comments also objected to the 2 g criterion and suggested lower levels, generally related to suggested changes in the definition of "saturated fatty acids."

The agency is persuaded by the arguments contained in the comments that the dry weight criterion is not necessary and is possibly counterproductive to the "Healthy People 2000" objective of increasing the availability of processed food products that are reduced in fat and saturated fat content (Ref. 12). Accordingly, FDA is deleting the dry weight criterion and proposing the 2 g criterion as the sole threshold level for foods bearing a "cholesterol free" or "low cholesterol" claim.

In regard to the definition for "saturated fatty acids," the agency noted in the tentative final rule (55 FR 29469) that the definition was the subject of another rulemaking, namely the proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision." FDA recognizes the relationship between the definition of "saturated fatty acids" (i.e., the particular fatty acids that are included in the definition) and the numerical value associated with this threshold level (as well as the values defining "low" and "reduced" saturated fat) and will make adjustments in the proposed threshold level as necessary if it modifies the definition in the nutrition labeling rulemaking. However, for now, FDA is proposing to carry forward the definition of saturated fatty acids in § 101.25(c)(2)(ii) and to adopt a saturated fat threshold of 2 g per serving for "cholesterol free", and "low cholesterol" claims.

4. Total Fat Threshold

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

A few comments argued that even though FDA surveys show that many consumers believe that cholesterol is found in all fats and oils, these findings demonstrate a need for consumer education rather than removal of truthful claims. Such education, the comments suggested, could include declarative statements adjacent to claims informing consumers of the total fat content of the product. Comments also stated that a total fat threshold would be a disincentive to the food industry to formulate low cholesterol and low fat foods, which would hinder the achievement of the "Healthy People 2000" objectives (Ref. 12), as well as international harmonization between the U.S. and Canada. The comments pointed out that Canada only restricts the saturated fatty acid content of foods making cholesterol claims.

FDA does not agree that a threshold for allowing a descriptor supports a "good food/bad food" concept. The agency believes that such a threshold merely restricts the use of descriptors to those foods on which they will not be misleading. However, FDA is persuaded by the comments that a cholesterol claim is not inherently misleading on a food that is high in total fat but low in saturated fatty acids. Accordingly, the agency is deleting the total fat threshold.

5. Disclosure of Fat Content

A "cholesterol free" or "low cholesterol" claim, however, represents and suggests that the product provides a health benefit, and the level of fat in the food has a material bearing on this claim. Excess fat in a food increases the likelihood of cancer, other chronic diseases, and obesity. Thus, a "cholesterol free" or "low cholesterol" claim would be misleading under sections 201(n) and 403(a) of the act if the number of grams of fat in a serving of the food is not presented. Moreover, information on another panel of the food labeling would generally not correct this problem. See *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

Therefore, in § 101.25(d)(1)(iii) and (d)(2)(iii), FDA is proposing to require that the amount of total fat in a serving of food appear in immediate proximity to a "cholesterol free" or "low cholesterol" claim, respectively. "Immediate proximity" is defined as immediately adjacent to the claim and with no intervening material. FDA is proposing that if the food contains less than 0.5 g of fat per serving, the amount of fat may be declared as "0." The agency believes that less than 0.5 g is a negligible amount of fat.

6. Foods Inherently Cholesterol Free of, or Low in, Cholesterol

FDA is proposing in § 101.25(d)(1)(iv) to carry forward that part of proposed § 101.25(a)(2)(i) (55 FR 29456) that requires that if a manufacturer wishes to make a "cholesterol free" claim on a food that contains less than 2 mg of cholesterol per serving without the benefit of special processing or reformulation to alter cholesterol content, the food must be labeled as "____, a cholesterol free food" (e.g., "applesauce, a cholesterol free food"). The agency believes that this requirement is necessary to make clear that all foods of that type, and not merely the particular brand to which the labeling attaches, do not contain cholesterol. Placement of the term "cholesterol free" immediately before the name of the food (e.g., "cholesterol free applesauce.) would imply that the food has been altered to reduce cholesterol as compared to other foods of the same type. Such an implication would be false and misleading.

For the same reasons, FDA is proposing a similar provision in § 101.25(d)(2)(iv), based on proposed § 101.25(a)(2)(ii) (55 FR 29456) for "low cholesterol" claims. Under this provision foods that are inherently low in cholesterol will have to be labeled as "____, a low cholesterol food" (e.g., "lowfat cottage cheese, a low cholesterol food").

C. "____ Percent Fat Free" Claims

As stated above, FDA has significant concerns about " percent fat free" claims, and these concerns are reinforced by the comments that FDA has received that suggest that many consumers do not understand this type of claim. Therefore the agency is proposing to prohibit the use of this claim in those circumstances in which it

would be misleading and thus would misbrand the product.

Claims for "____ percent fat free" emphasize how close a food is to being free of fat, that is, to containing no fat. They imply that the food has a very small amount of fat in it, and that the food is useful in structuring a diet that is low in fat. The impression that the claim gives is misleading, however, if the food despite the percentage calculation, contains a significant amount of fat.

Thus, to ensure that, as the claim implies, the food does in fact contain only a small amount of fat, FDA is proposing to require that such claims can only be made on foods that contain 3 g or less of fat per serving and per 100 g of food. FDA also believes that this level would provide an appropriate basis on which to describe a food as "low fat" or "low in fat." The agency urges that any use of the term "low fat" in labeling be in accordance with these levels. In determining this amount, FDA's starting point was § 101.3(e)(4)(ii), in which FDA defines a measurable amount of an essential nutrient as 2 percent of the U.S. Recommended Daily Allowance (RDA). Although there is no U.S. RDA for fat, most dietary guidance (Refs. 10 and 13) suggests that no more than 30 percent of calories should come from fat. Assuming that the average American consumes 2,350 calories a day (55 FR 29476), the average diet should contain no more than 75 g of fat. Two percent of 75 g is 1.5 g.

The agency is not proposing 1.5 g as the cut off for allowing "____ percent fat free" claims, however, because it believes that to do so would unduly restrict the type of foods that could make such a claim. The agency looked at the distribution of fat in the food supply and found that fat is not ubiquitous. Several food categories, including fruits, vegetables, and grains, are mostly free of fat. To account for this fact, FDA believes that it is reasonable to double the measurable amount of fat to arrive at a content level at which it would be misleading to make a "____ percent fat free" claim. Thus, in § 101.25(d)(3)(i), FDA is proposing to permit such claims only on foods that contain 3 g or less of fat per serving.

The agency believes that in addition to a criterion based on the amount of fat in a serving, a criterion based on density (amount in a given weight of food) is needed to control claims on fat-dense foods that have small serving sizes. Such foods may be consumed frequently resulting in a substantial total daily intake of fat. For example, some powdered coffee whiteners contain less than 3 g of fat per serving but contain 35 g of fat per 100 g of food. In addition, the agency is concerned that "____ percent fat free" claims on such foods could encourage consumers to consume the food in larger amounts and more frequently, significantly adding to the total fat intake in an individual's diet.

A density criterion is consistent with the definition for "low calorie" foods in § 105.66(c)(1)(ii) and the proposed definition discussed above for "low cholesterol" claims. In each of these cases, the second criterion is an amount per 100 g equivalent to the amount per serving. For example, "low calorie" is defined as 40 calories per serving and 0.4 calories per gram. The value of 0.4 calories per gram equals 40 calories per 100 g. Therefore, the definition is also 40 calories per serving and per 100 g. The agency considers this consistency to be helpful to consumers and health professionals in being able to recall and use the definitions. Accordingly, FDA is proposing in § 101.25(d)(3)(i) that "____ percent fat free" claims be permitted on food containing 3 g or less fat per serving and per 100 g.

Finally, a "____ percent fat free" declaration would be misleading if the number of grams of fat in a serving of the food was not presented in conjunction with the claim. As discussed with respect to the "cholesterol free" claim, under section 201(n) of the act, a food label is misleading if it fails to reveal facts material in light of the representations that are made on the label. Clearly, the actual amount of fat in a food is a material fact when a "____ percent fat free" claim is made. Moreover, that information generally must be presented on the same label panel as the claim. *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins," supra.* Therefore, in § 101.25(d)(3)(ii), FDA is proposing to require that the disclosure of the amount of total fat in a serving of food appear in immediate proximity to a "____ percent fat free" claim. FDA is proposing that if the food contains less than 0.5 g of fat per serving, the amount of fat may be declared as "0." The agency believes that less than 0.5 g is a negligible amount of fat.

## IV. References

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

1. Sullivan, Louis W., M.D., remarks given to USDA/FDA Journalists' Conference, Washington, DC, June 26, 1990.

1a. Lake, Robert L., letter to Robert Gillespie, May 14, 1991.

2. Lake, Robert L., letter to Robert M. Harris, May 14, 1991.

3. Lake, Robert L., letter to Edwin L. Artzt, May 14, 1991.

4. Lake, Robert L., letter to Albert J. Crosson, May 17, 1991.

5. Lake, Robert L., letter to James Bell, May 17, 1991.

6. Lake, Robert L., letter to Robert M. Harris, May 24, 1991.

7. Kessler, David A., M.D., remarks given t 20th Anniversary Conference, Center for Science in the Public Interest, Washington, DC, June 6, 1991.

8. Park, Youngmeek, Memorandum to Director, Office of Nutrition and Food Services, February 13, 1991.

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

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

11. Levy, A. S. et al., "Recent Trends in Beliefs about Diet/Disease Relationships: Results of the 1979–1988 FDA Health and Die Surveys," presented at FDA/USDA Food Editors Conference, December 1 and 2, 1988.

12. U.S. Department of Health and Human Services, Public Health Service, "Healthy People 2000, Health Promotion and Disease Prevention Objectives," DHHS Pub. No. (PHS) 91–50213, U.S. Government Printing Office, Washington, D.C., 1991.

13. U.S. Department of Agriculture and U.S Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," Home and Garden Bulletin No. 232, 3d Ed., U.S. Government Printing Office, Washington, DC 1990.

## V. Economic Impact

This proposal defines the terms "cholesterol free" and "low cholesterol" and provides for the proper use of these terms and for the use of "____ percent fat free" claims in the labeling of foods. The costs resulting from this proposed rule are those borne by firms currently using these terms but not as provided for by this proposal. The agency estimates that 3500 labels may need to be redesigned in order to comply with this proposed regulation for an estimated one-time incremental cost of $25 million. Therefore, in accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and has determined that the final rule, if promulgated, will not be a major rule as defined by that Order.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal

would have on small entities including small businesses and has determined that, in accordance with section 605(b) of the Regulatory Flexibility Act, that there will be no significant economic impact on a substantial number of small entities.

### VI. Environmental Impact

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

### VII. Comment Period

Interested persons may, on or before January 27, 1992, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

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

## PART 101—FOOD LABELING

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

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

2. Section 101.25 is amended by revising the section heading, and paragraphs (b), (c), (d), and (h) and by removing and reserving paragraphs (a) and (g) and (h) to read as follows:

**§ 101.25 Labeling of food in relation to fat, fatty acid, and cholesterol content.**

(a) [Reserved]

(b) A food label or labeling may include a statement of the cholesterol content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in accordance with the provisions of § 101.9; and

(2) The cholesterol content, stated to the nearest 5-milligram increment per serving, is declared in nutrition labeling in accordance with the provisions of § 101.9(c)(6)(ii).

(c) A food label or labeling may include information on the fatty acid content of the food: *Provided*, That it meets the following conditions:

(1) The food is labeled in accordance with the provisions of § 101.9; and

(2) The amount of fatty acids, calculated as the triglycerides and stated in grams per serving to the nearest gram, is declared in nutrition labeling in accordance with the provisions of § 101.9(c)(6)(ii). Fatty acids shall be declared in the following two categories, stated with the following headings, in the following order, and displayed with equal prominence:

(i) *Cis, cis*-methylene-interrupted polyunsaturated fatty acids, stated as "Polyunsaturated", and

(ii) The sum of lauric, myristic, palmitic, and stearic acids, stated as "Saturated".

(d) *Descriptors.* (1) The terms "cholesterol free," "free of cholesterol," or "no cholesterol" or phrases that mean the same thing may be used to describe a food provided that:

(i) The food contains less than 2 milligrams of cholesterol per serving;

(ii) The food contains 2 grams or less of saturated fat per serving;

(iii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim; and

(iv) If the food inherently contains less than 2 milligrams of cholesterol per serving without the benefit of special processing or reformulation to lower cholesterol content, it shall be labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "applesauce, a cholesterol free food").

(2) The terms "low cholesterol" or "low in cholesterol" may be used to describe a food provided that:

(i) The food contains 20 milligrams or less of cholesterol per serving and per 100 grams;

(ii) The food contains 2 grams or less of saturated fat per serving;

(iii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim; and

(iv) If the food inherently contains 20 milligrams or less of cholesterol per serving and per 100 grams without the benefit of special processing or reformulation to lower cholesterol content, it shall be labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "lowfat cottage cheese, a low cholesterol food").

(3) The term "____ percent fat free" may be used to describe a food provided that:

(i) The food contains 3 grams or less fat per serving and per 100 grams, and

(ii) The label or labeling discloses the amount of total fat per serving of the food expressed to the nearest gram. When the total fat content is less than 0.5 grams per serving, the amount may be declared as "0." Such disclosure shall appear in immediate proximity to such claim.

* * * * *

(g) [Reserved]

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

Dated: November 4, 1991.

**David A. Kessler,**

*Commissioner of Food and Drugs.*

**Louis W. Sullivan,**

*Secretary of Health and Human Services.*

[FR Doc. 91-27156 Filed 11-26-91; 8:45 am]

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**21 CFR Part 130**

**[Docket No. 91N-0317 et al.]**

**RIN 0905-AD08**

## Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the General Provisions for food standards to prescribe a general definition and standard of identity for substitute foods named by use of a nutrient content claim defined in 21 CFR part 101 (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (for example "reduced-fat sour cream"). FDA is proposing this action in recognition of current national nutrition