DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 105

[Docket No. 91N-384L]

RIN 0905-AD08

Food Labeling: Labeling Statements on Foods for Special Dietary Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to conform them to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). With the passage of the 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act), certain provisions concerning label statements on foods for special dietary use in reducing or maintaining caloric intake or body weight are no longer appropriately included in that regulation but are now more appropriately defined as nutrient content claims applicable to the general population and regulated under 21 CFR part 101. FDA is making changes in 21 CFR 105.66 to reflect this fact. FDA is also announcing its intention to reexamine 21 CFR part 105 and revise that part as necessary to ensure that it provides appropriate coverage for foods for special dietary use.

DATES: Effective May 8,1994, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by February 5, 1993.

ADDRESSEES: Written objections may be sent to the Dockets Management Branch (HFS-155), Food and Drug Administration, rm., 1-23, 12420 Parklawn Dr., Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. 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" (the general principles proposal) that would, among other things, establish general principles for the use of claims describing the nutrient content of a food and define certain specific nutrient content claims that can be used to describe the levels of certain nutrients in a food.

The general principles proposal was issued in response to the 1990 amendments (Pub. L. 101-535) to the act. With respect to nutrient content claims, the 1990 amendments amended the act by adding section 403(r)(1)(A) (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 using terms which are defined in regulations adopted by the agency under section 403(r)(2).

The proposed regulations on nutrient content claims included provisions similar or identical to some provisions in § 105.66, which addresses foods for special dietary use in reducing or maintaining caloric intake or body weight. Therefore, the general principles proposal included several changes in § 105.66 to eliminate redundancy in the regulations and to conform § 105.66 to the 1990 amendments. Specifically, FDA proposed to redesignate requirements terms such as "low calorie" and "reduced calorie," for other comparative calorie claims, and for sugar claims from § 105.66 to new § 101.60, which defines terms used to make nutrient content claims for the calorie content of foods. This redesignation is necessary because terms such as "low calorie" and "reduced calorie" are no longer appropriately regulated under the regulations for foods for special dietary use but are now more appropriately defined under the 1990 amendments as nutrient content claims for foods intended for use by the general population. FDA also proposed to delete from § 105.66 any inappropriate reference to specific nutrient content claims or similar terms and any statement that is inconsistent with the 1990 amendments.

FDA also proposed to delete the exemption (§ 105.66(e)(3)) for formulated meal replacements and other foods that are represented for special dietary use as a whole meal from the requirements in § 105.66(e)(1). These requirements bear on the use of label terms that suggest usefulness as low calorie or reduced calorie foods, such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener." FDA proposed to remove this exemption so that such claims could be expressly permitted under § 105.66, and thus not be prohibited as implied nutrient content claims under the 1990 amendments, until more appropriate regulations can be issued. The agency stated its view that claims that are permitted under § 105.66 meet the requirements of section 403(r) of the act (56 FR 60421 at 60458).

FDA noted in the proposal that a significant portion of § 105.66 remains appropriate for regulating foods that are for special dietary use (56 FR 60421 at 60457). Such foods are those that are specifically represented as, or that purport to be, useful as part of a weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although products low or reduced in calories can be useful in reducing or maintaining body weight). The agency did not propose to remove the remaining portion of § 105.66, which includes requirements for label statements about nonnutritive sweeteners and for the use of the term "diet" and related terms. FDA noted, however, that it plans to reexamine the provisions remaining in § 105.66 and initiate additional rulemaking as appropriate (56 FR 60421 at 60457).

FDA is publishing a final rule based on the general principles proposal and on a related proposal (56 FR 60421 at 60478, November 27,1991) concerning nutrient content claims related to the fat/fatty acid, and cholesterol content of food elsewhere in this issue of the **Federal Register**. This final rule effecting revisions in § 105.66 is being published as a separate document because § 105.66 was issued under the authority of section 403(j) of the act. Thus, revisions to § 105.66 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 the provisions of a final rule and to request a public hearing on that objection. Such an opportunity is not provided as part of the notice and comment procedures apply to that most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments.

The agency received only a few comments in response to the proposed revisions in § 105.66. Some of the comments received by the agency addressed matters concerning other regulations in 21 CFR part 105 (i.e., §§ 105.62 and 105.67) which are outside the scope of this rulemaking and are not being addressed here. However, after review of these comments, FDA believes that other regulations in part 105 may need to be reexamined, and that additional rulemaking may need to be initiated to ensure that these regulations

fully address their subject matter. In its reexamination of § 105.66, FDA will consider among other things, whether that regulation adequately describes foods for use in reducing or maintaining body weight, such as formulated meal replacements, whether it appropriately provides for use of terms such as "diet" on such foods, and whether "artificially sweetened" or "sweetened with a nonnutritive sweetener" should be included as label terms suggesting usefulness as low calorie or reduced calorie foods. These actions will be undertaken at some time in the future and FDA will solicit comments on the relevant issues at that time.

All of the relevant comments on proposed revisions in § 105.66 supported FDA's intent to revise this regulation to conform it to the provisions of the 1990 amendments. However, some of the comments raised concerns about some of the specific actions that FDA proposed. These comments are addressed below.

II. Comments and Agency Response

1. One comment asserted that requiring formulated meal replacements that bear terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" to meet the requirements for low or reduced calorie foods, or to make another comparative calorie claim, would effectively ban the sale of these foods. The comment stated that formulated meal replacements do not meet the definition of "low calorie" or "reduced calorie," and that a "reference" food would have to be identified to make a "reduced calorie" or other comparative calorie claim. The comment pointed out that FDA did not address what the reference food should be for formulated meal replacements. The comment requested that FDA provide in the regulations that a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, and that bears terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," not be required to be a "low calorie" or "reduced calorie" food, or to bear another comparative calorie claim, if its labeling is not false or misleading, and the product is useful as part of a weight loss or weight control program.

As noted above, FDA had proposed to delete the exemption in § 105.66(e)(3) for formulated meal replacements and other foods that are represented to be of special dietary use as a whole meal, from the requirements in § 105.66(e)(1) so that such foods would be expressly authorized to make "diet ," "dietetic," or "artificially sweetened" claims under § 105.66. Thus, these claims on these foods would not be prohibited as unauthorized implied nutrient content claims under the 1990 amendments. However, FDA has reconsidered the circumstances under which claims should be regarded as implied nutrient content claims and as claims for special dietary use. As stated in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, the agency does not consider claims made solely to portray the usefulness of a 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 claim subject to § 101.13. On the other hand, a claim of dietary usefulness made in a context that is relevant to the general population (e.g., where the label states that the food is "low calorie") would be subject to the requirements for nutrient content claims. FDA views a claim such as "use as part of a weight reduction program," made in conjunction with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," on a formulated meal replacement to be a claim that solely portrays the usefulness of the food for a special dietary need, as described in part 105. Thus, such a claim by itself, without any other reference to nutrient aspects of the food relative to the general population, is not a nutrient content claim. Therefore, FDA concludes that there is no need to subject formulated meal replacements to the requirements of § 105.66(e)(1) to preclude claims such as "diet" on such products from being prohibited as implied nutrient content claims.

FDA, thus, has decided not to delete § 105.66(e)(3) and thus will continue to permit formulated meal replacements and other foods that are represented to be of special dietary use as whole meals to use terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on their labels and labeling without having to comply with the requirements of § 105.66(e)(1). Therefore, the concern raised that formulated meal replacements are unable to comply with the requirements of§105.66(e)(1) is moot.

However, FDA advises that the use of terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on the label or in the labeling of any food, including a food for special dietary use, is subject to the acts general prohibition against false or misleading labeling in section 403(a) of the act. Thus, FDA can take action against any false or misleading use of a term such as "diet." For example, if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement to avoid the requirement that foods using the label term "diet" either be low in calories, reduced in calories or bear another comparative calorie claim, FDA would consider the food to be misbranded because it is falsely represented as a formulated meal replacement. Such a food would also be in violation of § 105.66(e)(l) because it is not a formulated meal replacement, FDA is likely to take action against any food that uses terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on its label or in its labeling in this manner.

2. A comment stated that FDA should amend § 105.66(e)(1) in the final rule to clarify that this regulation applies only when the specific terms "diet," "dietetic," "artificially sweetened," and "artificially sweetened with nonnutritive sweetener" appear on the label as self-contained terms, but not when a term such as "diet" is used in a statement that represents the product to be useful as part of a weight loss "diet," The comment stated that the proposal could be misunderstood to mean that FDA is prohibiting the use of all other claims suggesting that a product is useful in a weight loss "diet" if that product does not meet the definition for "low calorie" or "reduced calorie." The comment stated that such an interpretation would be inconsistent with FDA's express intention of permitting such claims as stated in the final rule establishing § 105.66 (43 FR 43248 at 43253, September 22,1978), wherein the agency stated:

> * * * any food may make a claim of special dietary usefulness for weight control on some basis other than its being "low calorie," "reduced calorie," or comparatively useful * * *. The claim must not be misleading and the basis for the claim must be conspicuously and clearly stated in conjunction with the claim. These foods may make appropriate claims, e.g., "for calorie restricted diets" or "useful for weight control.*'

The agency advises that it continues to hold the position that it stated in the final order establishing § 105-66. In that rulemaking, FDA stated that a food that purports to be useful for weight control on some other basis than its being "low calorie," "reduced calorie," or comparatively useful in controlling calorie intake is subject to the provisions of § 105.66(a) and (b) but not § 105.66(e). The agency stated that to

comply with § 105.66(a) and (b), such foods must bear nutrition labeling, labeling about the presence of nonnutritive ingredients, and a conspicuous and nonmisleading statement about the basis of the claim (43 FR 43248 at 43253, September 22, 1978).

Concerning the matter raised by the comment, i.e., the use of statements incorporating the term "diet" on foods for special dietary use intended for weight reduction, the agency concludes that such statements do not invoke the requirements of § 105.66(e), except when made on meal replacements or other foods represented to be of special dietary use as a whole meal, which are subject to § 105.66(e)(3), when they are used in a manner that does not suggest that the food is a "low calorie" or "reduced calorie" food. Such foods are subject to the requirements of § 105.66(a) and (b). However, the revision of the regulation sought by this comment, i.e., a provision in the regulation clarifying the circumstances where § 105.66(e) applies, is beyond the scope of tins rulemaking. FDA stated in the general principles proposal that it only intended to make changes in § 105.66 at this time that are necessary to conform this section to the 1990 amendments. FDA will fully consider any necessary clarification of § 105.66(e)(1) in this regard when it initiates additional rulemaking on this section as stated above.

3. One comment suggested that the "Weight Watchers" line of foods falls within the provisions of § 105.66 because it provides information on the product label that suggests that these products can be useful in an overall weight-control diet plan. In addition, this same comment expressed concern that use of the brand name "Weight Watchers" would be prohibited on those products introduced into the marketplace after October 25, 1989, i.e., the date after which products introduced into the marketplace that make nutrient content claims in their brand names must use terms in the claims that are defined by the agency in a regulation, or that have been approved by the agency in response to a petition (section 403(r)(2)(A)(i), (r)(2)(C), and (r)(4)(A)(ii) of the act).

FDA advises that, in general, it would regard a brand name such as "Weight Watchers," when accompanied by information on the product label that suggests that the product can be useful in an overall weight-control diet plan, without any other reference to nutrient aspects of the food relative to the general population, to be a claim that solely portrays the usefulness of the food for a special dietary need as described in part 105 (see comment 1 of this document). Under these circumstances, such a claim is subject to the provisions of § 105.66 and is not a nutrient content claim. Accordingly, such a claim in a brand name may continue to be used on such products irrespective of whether a specific product under that brand name was introduced into the marketplace before October 25, 1989.

III. Conclusions

After review and consideration of the comments received in response to the November 27, 1991, proposal, FDA concludes that no evidence or information has been presented that would alter the agency's tentative determination that it should amend § 105.66 to conform that regulation to the provisions of the 1990 amendments. Therefore, FDA is amending § 105.66 as proposed with the exception of the revision in the final rule discussed in comment 1 of this document. FDA has also corrected two inadvertent errors that appeared in the proposal in the codified text of paragraph (e)(1). First, the proposed text omitted the words "such as" that had immediately preceded "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" in the existing regulation. It was not the agency's intent to delete these words from the revised text, and thus, they are being restored in the final rule. Secondly, FDA has conformed paragraph (e)(1) with respect to comparative calorie claims to paragraph (d). FDA has also made other minor editorial revisions in the text of the final rule for internal consistency.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the general principles proposal (56 FR 60467). At that time, FDA determined under § 25.24(a)(11) that the actions proposed therein (which include this action) are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

4. Several comments on the general principles proposal suggested that there would be significant adverse environmental effects from the actions proposed therein because they would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts ere attributable to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste.

Neither the 1990 amendments nor FDA's proposed regulations require a food company to make nutrient content claims on its product labels. Food companies have known since November 8,1990, the date of enactment of the 1990 amendments, that possibly by May 8,1993, their labels would not be able to include nutrient content claims unless the claims conformed to FDA's regulations. In the general principles proposal (56 FR 60421) the agency proposed that this final rule would become effective 6 months after its date of publication in the **Federal Register.** However, the agency has determined that this final rule will become effective May 8,1994. FDA believes that this effective date will allow ample time for food companies to use up most of the label and packaging stocks that existed on November 8, 1990, and that contained nutrient content claims. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected, and that an environmental impact statement is not required.

V. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96-354), FDA has reviewed the final rule to redesignate certain requirements in § 105.66 to § 101.60 to determine its impact on small entities, including small businesses. Although the food labeling reform initiative taken as a whole, would result in a major rule, FDA has determined that redesignating certain requirements in § 105.66 to § 101.60 for conformance to the 1990 amendments, will not result in a significant impact on a substantial number of small entities. FDA has not received any new information or comments that would alter this determination. Therefore, FDA certifies in accordance with the Regulatory Flexibility Act, that no significant impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule, and the agency has determined that the rule, if promulgated, will not be a major rule as defined by that order.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 10,1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, end each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is required shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to this regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register.**

List of Subjects in 21 CFR Part 105

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 105 is amended as follows:

PART 105—FOODS FOR SPECIAL DIETARY USE

1. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 706 of the Federal Food, Drug, and Cosmetic Act (2'1 U.S.C. 321, 341, 343, 348, 350,371, 376).

2. Section 105.66 is revised to read as follows:

§ 105.86 Label statements relating to usefulness in reducing or maintaining body weight

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie"* foods. A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie"* foods and other comparative calorie claims. A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such food in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in § 101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for a dietary use other than regulating body weight, e.g., "for low-sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

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

Dated: October 22,1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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