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]

BILLING CODE 4160-01-M

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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

goals and the resulting need to allow modified versions of certain standardized foods to bear descriptive names that are meaningful to the consumer. FDA believes that the action proposed herein will promote honesty and fair dealing in the interest of consumers. This proposal applies only to standards of identity and not to standards of fill or quality.

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

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

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0112.

SUPPLEMENTARY INFORMATION:

I. Introduction

One of the main purposes of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) was to establish the circumstances in which claims could be made that describe the nutrient content of food. In response to the 1990 amendments, elsewhere in this issue of the **Federal Register**, FDA is proposing definitions for such nutrient content claims together with general principles and procedures governing their use. A use of nutrient content claims in which there is a great deal of both industry and consumer interest, but that is not addressed in the nutrient content claims document, is as part of the statement of identity of substitutes for standardized foods.

Foods that are subject to food standards, or that substitute for foods that are subject to food standards, make up a substantial portion of the nation's food supply. There is a strong desire among consumers for substitute foods that have been modified to reduce their fat, saturated fat, cholesterol, or sodium levels below those that are required, or that would occur, under existing food standards. This desire has been voiced in consumer comments in related FDA rulemakings and in statements made at public hearings held by the agency in recent years.

Manufacturers have responded to this consumer desire by placing statements on food labels, including the labels of foods that are subject to standards of identity, that describe the products as "reduced fat" or "light." FDA has been concerned about these actions for two reasons. First, as a general matter, because no uniform set of definitions exists for these nutrient content claims, they are being used in an inconsistent manner, which can result in consumers being confused and misled. Second, FDA is concerned because these nutrient content claims are being used in a manner that is not provided for in the standards of identity. Thus, the use of these nutrient content claims has had the effect of undermining confidence in the labeling of standardized foods, and FDA has taken regulatory action against some of these uses.

FDA's objective, however, is to facilitate, not to hinder, consumer's selection of healthful alternative foods. As Congress recognized in adopting the 1990 amendments (see section II. G. of this document), this objective can be fostered by the use of statements regarding the level of certain nutrients in foods. The agency also recognizes that for foods subject to standards of identity, this objective requires action to provide for the use of accurate, easily understood statements of identity that inform consumers about the nutritional characteristics of substitute products. Finally, FDA believes that such action is necessary to ensure that the substitute products are equivalent to the standardized foods that they replace with respect to nutritional quality and similar to them with respect to essential performance and organoleptic characteristics.

Therefore, FDA tentatively concludes that it is appropriate in addressing the use of nutrient content claims in foods in general, to specifically address the naming of foods that substitute for standardized products using nutrient content claims with standardized terms. That is what the agency intends to do in this document.

II. Background on Food Standards and Food Names

A. The Federal Food, Drug and Cosmetic Act of 1938

Congress provided for the establishment of definitions and standards of identity for particular foods in section 401 of the Federal Food, Drug, and Cosmetic Act (the act) of 1938. Congress' original concept of food standards was that there are certain traditional foods that everyone knows, such as bread, milk, and cheese, and that when consumers buy these foods, they should get the foods that they are expecting. Thus, the definitions and standards of identity fixed the content of the food that could be called by a particular name. For example, any food called "bread" has to comply with the definition and standard for that food. Many of the food standards established by FDA were in the form of restrictive recipes that defined the composition of these foods in great detail. As a result, many food manufacturers argued that food standards suppressed competition and stifled innovation.

FDA has promulgated approximately 300 standards of identity under section 401 of the act. These standards are codified in 21 CFR parts 131 through 169. Under the misbranding provisions of section 403 of the act, if a food resembles a standardized food but does not comply with the standard, that food must be labeled as an "imitation."

B. Formal Rulemaking Keeps Standards Behind Technology

Because of the elaborate, formal rulemaking procedures specified for food standards in section 701(e) of the act, many months or years were often required to adopt a standard or to amend one once it had been adopted. As a result, FDA found it almost impossible to keep food standards up-to-date with advances in food technology and nutrition.

C. Food Additive Provisions and the "Safe and Suitable" Policy

Before enactment of the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960, virtually all ingredients of standardized foods were prescribed individually by name. These amendments, however, included requirements for the premarket approval of new food and color additives and, thus, eliminated questions of safety from the development of food standards.

As a result, FDA felt that it could depart from the strict recipe approach to food standards. In the standard for frozen raw breaded shrimp, which was issued in 1961 (now codified at 21 CFR 161.175), instead of specifying each individual ingredient allowed in the breading, FDA simply provided for "safe and suitable" batter and breading ingredients.

FDA defined "safe and suitable" in 21 CFR 130.3(d) to mean regulated food additives, color additives, generally recognized as safe substances (GRAS), and other functional ingredients used in conformance with provisions of the act at levels no higher than necessary to achieve the intended functional effect. A number of current standards of identity permit the use of "safe and suitable" ingredients.

D. The 1973 "Common or Usual Names" Policy

In the **Federal Register** of March 14, 1973 (38 FR 6964), FDA promulgated regulations governing the establishment of "common or usual names" for nonstandardized foods. FDA advised in the proposed rule of June 22, 1972 (37 FR 12327), that new food standards need not be issued if, for certain foods, appropriate labeling would be sufficient to protect the interest of consumers. In such cases, in lieu of a full food standard, the agency would rely instead on the establishment of the common or usual name of the food.

One of the principal benefits of this regulation (now codified at 21 CFR part 102) was that new products and names for them could be adopted by informal notice-and-comment procedures, rather than by the costly and time-consuming process of formal rulemaking under section 701(e) of the act. The new regulation did not prove to be widely applicable, however, because many foods (e.g., ice cream, cheese) are defined not only by ingredient content but also by technical descriptions of methods of manufacture, processing, or storage, which are much more amenable to presentation in a standard of identity.

E. The 1973 "Imitation" Policy

In a further attempt to provide for advances in food technology and thus to give manufacturers relief from the dilemma of either complying with an outdated standard or having to label their new products as "imitation," FDA sought in 1973 to narrow the scope of food standards by adopting the so-called "imitation" policy. Until 1973, there were no objective criteria for the use of the term "imitation." In the **Federal Register** of August 2, 1973 (38 FR 20702), FDA promulgated 21 CFR 101.3(e), which provides that only nutritionally inferior substitute foods are required to be labeled "imitation."

In its proposed rule of January 19, 1973 (38 FR 2138), FDA noted that vast strides in food technology had been made since the act was enacted in 1938, and that "there are now on the market many new wholesome and nutritious food products, some of which resemble and are substitutes for other, traditional foods. Significantly, it is no longer the case that 'such products are necessarily inferior to the traditional foods for which they may be substituted."

In addressing the nutritional properties of substitute foods in which fat and calories are reduced, FDA stated that since a reduction in fat content or caloric content may well be desirable, such a reduction should not be regarded as nutritional inferiority.

The regulation defined "nutritional inferiority" as any reduction in the content of an essential nutrient that is present at a level of 2 percent or more of the U.S. Recommended Daily Allowance (U.S. RDA), as established in 21 CFR 101.9(c)(7). It also provided that a substitute food would not be deemed to be an imitation if, in addition to not being nutritionally inferior, its label bears a common or usual name that complies with 21 CFR 102.5, or it bears "an appropriately descriptive term that is not false or misleading."

Under this policy, FDA took the position that an appropriately descriptive term included not only a description of the change from the standardized food (for example "reduced fat") but also the fact that the food was a substitute or alternative to a standardized food. FDA felt that it was necessary to include the latter fact to ensure that the consumer was not misled into believing that he or she was buying the traditional food. Thus, a cheddar cheese product in which the fat was reduced (FDA's informal view was that fat had to be reduced by 50 percent for it to be "reduced") had to be called "reduced fat cheddar cheese substitute." Many manufacturers, however, felt that terms such as "substitute" or "alternative" have a derogatory meaning and imply to the consumer that the products are of inferior quality, or that they are less nutritious than the respective standardized foods. The manufacturers felt that consumers would consequently be unwilling to accept and purchase the substitute products.

FDA also took the position that if such a product were labeled without the use of the term "substitute" or "alternative," the product would purport to be the standardized food. Thus, the manufacturer could seek to amend the standards of identity to provide for the modified food. However, if the manufacturers marketed the food without doing so, the product was subject to regulatory action as a misbranded food.

F. The 1989 Advance Notice of Proposed Rulemaking

In the **Federal Register** of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) concerning food labeling. The agency requested public comments on several matters, including "whether to formally define commonly used food nutrient content claims and/or reconsider the use of standards of identity for foods." The notice stated that because of the growing public interest in eating healthy foods, manufacturers had begun to place statements on their labels that described their products in such ways as "low in _____" and "reduced _____." FDA had found, however, that these nutrient content claims were not always used in honest or consistent ways. To bring some order to the marketplace and to ensure that consumers are not misled, FDA stated that it was developing a series of nutrient content claims for use on the labels of foods.

G. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling and food standards law since passage of the act in 1938. The effect of this legislation is to clarify and strengthen FDA's legal authority to require nutrition labeling on foods and to establish the circumstances under which claims may be made about nutrients in foods. Several provisions of the 1990 amendments relate to the proposal discussed below.

Section 3(a) of the 1990 amendments revised the act by, among other things, adding new paragraph 403(r)(1)(A). This provision states that a food is misbranded if it bears a claim in the label or labeling that either expressly or by implication characterizes the level of any nutrient of the type required by nutrition labeling (i.e., amounts of saturated fat, total fat, cholesterol, sodium, complex carbohydrates, total carbohydrates, sugars, total calories derived from any source and derived from total fat, and various vitamins and minerals), unless such claim has been specifically defined (or otherwise exempted) by regulation, as required by section 403(r)(2)(A)(i) of the act.

Section 3(a) of the 1990 amendments also added new section 403(r)(5)(C) to the act, which 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 are not subject to section 403(r)(2)(A)(i). Thus, a nutrient content claim that is part of the 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 even if FDA has not defined the term. This exemption was necessary to protect the status of existing standards having names that make a nutrient content claim (such as "low-fat milk"). The

legislative history of the 1990 amendments (Ref. 1, p. 22) reveals that Congress was aware, however, that the Secretary and, by delegation, FDA have the authority to correct this problem by amending the portions of the standards of identity pertaining to food labels to conform with the regulations issued under new section 403(r) of the act.

Section 3(b)(1)(A)(iii) of the 1990 amendments requires that the Secretary issue regulations to define the following terms (unless the Secretary finds that the use of any such terms would be misleading): "Free," "low," "light"/"lite," "reduced," "less," and "high."

Section 7(1) of the 1990 amendments amended 403(i) of the act by striking out the provision that exempted standardized foods from the requirement for full ingredient labeling. Under the pre-1990 amendment provisions of paragraph 403(i) of the act, only those components of standardized foods classified as "optional" had to be declared by their common or usual name on the label, and then only when specifically required by FDA.

Section 8 of the 1990 amendments removed section 401 of the act from the coverage of section 701(e). Thus, FDA may now use informal notice-and-comment rulemaking, rather than formal rulemaking, in adopting new food standards and in amending or repealing existing standards, except for the existing standards for dairy products and maple syrup.

III. Existing Regulations Employing Nutrient Content Claims

FDA has adopted several regulations prescribing nutrient content claims. For example, the regulation on sodium labeling (current 21 CFR 101.13) defines various levels of sodium on a per serving basis as follows: "Sodium free" (less than 5 milligrams), "very low sodium" (35 milligrams or less), "low sodium" (140 milligrams or less), and "reduced sodium" (75 percent reduction for the food as a whole). The agency has also defined "low calorie" and "reduced calorie" foods relating to usefulness in reducing or maintaining caloric intake or body weight (current 21 CFR 105.66), as well as terms such as "sugar free," "sugarless," and "no sugar" (current 21 CFR 105.66(f)).

A number of standards of identity have been established that incorporate the terms "light," "low," "non," or "reduced" in the names of the standards, including: lowfat dry milk (§ 131.123), nonfat dry milk (§ 131.125), nonfat dry milk fortified with vitamins A and D (§ 131.127), lowfat milk (§ 131.135), acidified lowfat milk (§ 131.136), cultured lowfat milk (§ 131.138), light cream (§ 131.155), light whipping cream (§ 131.157), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), low sodium cheddar cheese (§ 133.116), low sodium colby cheese (§ 133.121), lowfat cottage cheese (§ 133.131), nonfat milk macaroni products (139.121), and low-fat cocoa (§ 163.114).

In addition, FDA has issued many temporary marketing permits (TMP's) under terms of § 130.17 for various low-, reduced- and non-fat alternative foods such as light eggnog, nonfat cottage cheese, and light sour cream. By issuing a TMP, FDA expresses its willingness to refrain from instituting regulatory action against a product on the grounds that it does not conform to the applicable standard while market tests are conducted to measure consumer acceptance of the product, identify mass production problems, assess commercial feasibility, and determine whether the standards of identity should be amended to provide for the new food.

IV. The Current Situation

In the August 1989 ANPRM (54 FR 32610), FDA stated that it was aware that manufacturers were using nutrient content claims such as "low in _____" or "reduced _____" on a wide variety of food labels, and that, in the absence of definitions provided by FDA, the nutrient content claims were being used in an inconsistent manner, so that consumers were likely confused or being misled.

The agency is also aware that these nutrient content claims are being applied to products that substitute for foods for which FDA has published standards of identity, particularly dairy products defined in 21 CFR Part 131 (Milk and cream), Part 133 (Cheese and related cheese products), and Part 135 (Frozen desserts), as well as mayonnaise and salad dressings defined in 21 CFR Part 169 (Food dressings and flavorings). By use of nutrient content claims such as "low fat," "reduced fat," or "no fat," these products are represented as containing levels of fat that are below the minimum levels required by the respective standards of identity for the foods for which the products substitute.

As discussed above, the formal rulemaking procedures specified for food standards in section 701(e) of the act have made it difficult to update the many existing food standards. Consequently, certain food standards do not reflect advances in food technology or current knowledge regarding nutrition and health. The most immediate problem is with fat, which was considered to be an economically and nutritionally valuable component of food when the act was enacted in 1938 and which is the basic characterizing ingredient in many foods for which standards have been adopted over the last 50 years, primarily dairy products.

Today, high dietary levels of cholesterol and fat/fatty acids are implicated as significant risk factors in the development of cardiovascular and other chronic diseases. Both "The Surgeon General's Report on Nutrition and Health" (Ref. 2) and the National Academy of Science's report on "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 3) focus on fat consumption by Americans as the primary diet-related risk factor for cardiovascular disease.

Technological developments have brought about new products having a reasonable degree of consumer acceptance that are low or reduced in fat and cholesterol. The inflexibility of the traditional standards system, however, places these and similar products at a disadvantage when they attempt to enter the market because they cannot legally be called by a name that is easily recognized or desired by consumers. For instance, a product called "sour cream" must contain a minimum of 18 percent milkfat, as required by the standard of identity, § 131.160, even though lower fat products are now available.

FDA is aware that the issues discussed in this document, including suggestions for improvements in the food standards system, have been addressed repeatedly for many years by experts and observers both inside and outside the agency (Refs. 4 through 15). The role of food standards was assessed by a committee of the Food and Nutrition Board of the National Academy of Sciences' Institute of Medicine (IOM) as part of a recent study supported by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. In its report entitled "Nutrition Labeling, Issues and Directions for the 1990's" (Ref. 16), the committee observed that: "In 1990, less skepticism exists about consumers' abilities, aided by informative labeling, to protect themselves against debased or diluted products * * *. Attention is now focused on the consumption of too much fat rather than the possibility that some products will be made using less of an ingredient than was historically considered a valuable constituent. Accordingly, it seems clear to the [IOM] Committee that any system that significantly impedes the marketing of reduced-, low-, and non- or no-fat

substitutes should be examined and, presumably, changed." FDA believes that this is a fair assessment of the current situation.

V. Pending Petitions

The Milk Industry Foundation (MIF), Washington, DC 20006, a trade association representing manufacturers and distributors of dairy products, filed a petition, dated September 12, 1988 (Docket No. 88P-0329), to establish a standard of identity for "light sour cream." MIF believes that establishing a standard of identity for "light sour cream" would promote public health, satisfy consumer demand, and would assure that "light sour cream" has an appropriate reduction in fat content. Since the MIF petition was filed, FDA has received a number of applications from companies desiring to market test "light (or lite) sour cream," and the agency has issued 19 TMP's for the product. FDA received two additional petitions to establish a standard for "light sour cream" from H. P. Hood, Inc. (Docket No. 89P-0105), and Crowley Foods, Inc. (Docket No. 89P-0403), at the time these manufacturers submitted applications to extend their TMP's.

MIF also filed a petition, dated September 16, 1988 (Docket No. 88P-0334), to establish a standard of identity for "light eggnog." MIF stated in its petition that establishing a standard of identity for light eggnog would promote public health, satisfy consumer demand, and would assure that light eggnog products have a significant reduction in fat content. Since the MIF petition was filed, FDA has received a number of applications from companies desiring to market test "light (or lite) eggnog." The agency has issued 33 TMP's for the product. H. P. Hood, Inc., submitted a petition (Docket No. 89P-0329) to establish a standard for "light eggnog" at the time they applied to extend their TMP for this product.

FDA has received a number of letters from firms indicating that they desire to participate in the extended market tests for "light sour cream" and "light eggnog," and FDA has issued letters of approval for participation in the extensions.

The International Ice Cream Association (IICA), Washington, DC 20006, a trade association representing manufacturers and distributors of ice cream and other frozen desserts, and the Public Voice for Food and Health Policy (Public Voice), Washington, DC 20036, a national nonprofit consumer research, education, and advocacy organization, submitted petitions dated February 23 and March 30, 1990, respectively, asking FDA to amend the standard of identity for ice milk to change the name of the food to "reduced fat ice cream" and to establish standards of identity for products designated as "lowfat ice cream" and "nonfat ice cream." The Public Voice petition would, in addition, reduce the maximum milkfat content in the standard of identity for ice milk from 7 percent to 5 percent.

Kraft General Foods, Inc. (KGF), Philadelphia, PA 19103, a manufacturer and distributor of a broad range of food products within the United States, also submitted a petition, on March 14, 1990, to establish a standard of identity for "nonfat ice cream." The Calorie Control Council (CCC), Atlanta, GA 30342, an international association of manufacturers of low-calorie and diet foods and beverages, including manufacturers of a variety of sweeteners and other low-calorie ingredients, submitted a petition, dated March 5, 1990, to add a provision to each of the IICA proposed standards (i.e., "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream") to permit the use of any safe and suitable sweeteners, including saccharin, aspartame, and acesulfame potassium (acesulfame K), in the foods. IICA submitted another petition, dated March 29, 1990, to expand its February 23, 1990, petition to include a provision in the standard of identity for ice cream (§ 135.110) and in each of its proposed standards to permit the use of safe and suitable sweeteners, as provided in the CCC petition.

On January 22, 1991, FDA published an advanced notice of proposed rulemaking (56 FR 2149) concerning the filing of these petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, lowfat, and nonfat ice creams.

FDA is responding to the above petitions in this proposal although FDA will also respond to some portions of the petitions to amend the standards for ice cream and ice milk in a separate proposal to be published at a future date. FDA encourages these petitioners and all interested persons to comment on this proposal and on the other nutrient content claim proposals published elsewhere in this issue of the **Federal Register**.

VI. Rationale and Legal Issues

A. Appropriateness of the Proposed Action

Questions concerning the naming of foods that are substitutes for standardized foods and concerning the use of standardized terms with nutrient content claims to describe products that substitute for standardized foods have confronted the agency for almost 20 years. In response to FDA's proposed rule on the "imitation" policy published in the **Federal Register** of January 19, 1973 (38 FR 2136), one comment recommended that the "imitation" regulation should preclude the use of a standardized name in connection with the name of a nonstandardized product (38 FR 20702, 20703). FDA rejected this suggestion, however, on the grounds that it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling. The agency confirmed this interpretation in the **Federal Register** of January 19, 1979 (44 FR 3964), stating that the existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a nonstandardized food.

In further commenting on the use of standardized names for substitute foods in the **Federal Register** of August 19, 1983 (48 FR 37666), FDA again advised that in some cases, it may be reasonable and appropriate to include the name of a standardized food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. The agency stated that when this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food that it resembles and for which it is intended to substitute. The agency stated that the modification of the traditional or standardized food's name must be descriptive of all differences that are not apparent to the consumer. Thus, the agency concluded, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.

As discussed in section III of this document, a number of standards of identity have been established that incorporate the terms "light," "low," "non," or "reduced" in the names of the standards. Thus, the use of nutrient content claims (similar to those discussed herein) in connection with standardized terms is neither new nor unusual.

However, FDA did not have available a uniform set of defined nutrient content claims that could be referenced in a regulation of that provided for their use in a generic sense in connection with standardized terms, nor did it have a mandate from Congress to provide statements regarding the level of these

nutrients in foods "in a manner that facilitates the public's understanding" (Ref. 1, p. 18). New section 403(r) (1) of the act (added by section 3 of the 1990 amendments) provides for the establishment of FDA-defined nutrient content claims on food labels to accurately and truthfully inform consumers about the nutritional content of products complying with the definitions. FDA believes that this section together with section 401 of the act, which gives the agency authority to promulgate definitions and standards of identity if such action will promote honesty and fair dealing in the interest of consumers, and the amendment of section 701(e), which makes it possible to adopt new standards by notice and comment rulemaking, provide the agency with the authority and the means to adopt the new generic standard in proposed § 130.10.

FDA believes that this proposed action is reasonable and appropriate, and that it is needed to provide the consumer with accurate, descriptive, and fully informative labeling that will not only promote honesty and fair dealing in the interest of consumers but will also facilitate achievement of the national nutritional goals. The agency invites comments with respect to the appropriateness and need for the action proposed in this document.

B. Departure From Traditional Policy

FDA is aware that the regulatory approach in proposed § 130.10 represents a departure from the agency's traditional policy with respect to the naming of substitute foods. FDA notes, however, that its policies have always evolved, even in the absence of significant legislative amendments to the act.

For example, in 1953 FDA held that the nondairy product "Chil-Zert" was misbranded under section 403(c) of the act because it was a substitute for ice cream (which was not standardized at the time) but was not labeled as "imitation," even though the package was conspicuously labeled "Not an Ice Cream" and "Contains No Milk or Milk Fat." By 1973, however, when FDA instituted the "imitation" policy, the agency had decided that a nutritionally equivalent substitute for a standardized food need not be labeled "imitation" provided its label bore a common or usual name, or an appropriately descriptive name, that was not misleading. Moreover, FDA also decided that "since a reduction in fat content or calorie content may well be desirable, such a reduction should not be regarded as nutritional inferiority" (38 FR 2138).

FDA believes that recent developments make further changes in FDA's policies appropriate. Through the 1990 amendments, Congress has given FDA the authority to ensure that consumers are given information about the ingredient and nutrient content of virtually all foods and to establish the circumstances under which claims may be made about the levels of nutrients in foods. Thus, the agency can now rely more on labeling requirements, and less on restrictive recipes, in carrying out its mandate to ensure that consumers get the products they expect, and that the nutritional and health-related properties of foods are properly conveyed to the consumer.

VII. FDA Proposal

A. Generic Standard

FDA recognizes that valuable and helpful information concerning the nutrient content of food could be conveyed to consumers if defined nutrient content claims could be used in a consistent and responsible manner in the names of certain substitute foods. A substitute food as defined in proposed § 101.13(d) in the general proposal on nutrient content claims, published elsewhere in this issue of the **Federal Register**, is one that may be used interchangeably with another food that resembles, i.e., organoleptically, physically, and functionally similar to, that food, and is not nutritionally inferior to that food unless labeled as an "imitation."

The agency is also defining in that proposal the terms "free," "low," "light" or "lite," "reduced," and "high." In addition, FDA is proposing to define the terms "very low" (for sodium only) and "source" and to make provision for the use of comparative statements using the terms "less," "fewer," and "more" because the agency has tentatively concluded that they would be useful in helping consumers choose a healthy diet. FDA is also defining the term "modified" in proposed § 101.13(k) to be used in the statement of identity of a food that bears a comparative claim in conformity with the requirements of 21 CFR part 101.

Given these developments and the other developments discussed in this proposal, FDA believes that it is now appropriate for it to set forth general requirements governing the establishment of standards of identity for certain nutritionally equivalent alternate foods. The proposed general requirements in § 130.10 specify the conditions under which aspects of traditional standards and appropriate nutrient content claims may be used to define new standardized foods.

The establishment of individual new standards may be necessary for certain foods, but, in general, the promulgation of a large number of individual regulations would be time-consuming and unnecessarily wasteful of the agency's resources. Consequently, FDA believes that a generic standard applicable to the vast majority of alternate foods offers the most reasonable and effective approach. Proposed § 130.10 describes the conditions under which a variety of substitute foods may use nutrient content claims and standardized names.

B. Existing Standards Using Nutrient Content Claims Not Affected

Currently there are a number of standards, such as lowfat cottage cheese (§ 133.131) in which a nutrient content claim ("lowfat") is already part of the name of the food. The names of such foods would remain unchanged by the regulation proposed in this document. In recognition of the fact that various nutrient content claims have already been incorporated in the names of a number of standardized foods (see listing of such foods in section III of this document), Congress exempted these foods from compliance with the nutrient content claim-provisions of the 1990 amendments (section 403(r)(5)(CC) of the act). FDA points out, however, that these existing standards are subject to amendment to make them consistent with the nutrient content claim definitions that are being proposed in a document published elsewhere in this issue of the **Federal Register**.

C. Substitute Foods Defined by This Proposal

1. Nutrient Content Claims

FDA is proposing in § 130.10 a generic standard of identity that prescribes the conditions under which substitute foods (as defined in proposed § 101.13(d)) that do not comply with a standard of identity defined in 21 CFR parts 131 through 169 because of a deviation that is described by a nutrient content claim, but that do comply with the standard in most other respects, may be named using a nutrient content claim and the standardized term. In § 130.10(a), FDA is proposing that the use of the nutrient content claim to name the new food must comply with the requirements of § 101.13 and with the requirements of the regulations in 21 CFR part 101 that define the particular nutrient content claim that is used.

Proposed § 101.13, which is published elsewhere in this issue of the **Federal Register**, prescribes the general circumstances in which claims that characterize the level of a nutrient in a food may be made on a food label or in labeling. Proposed § 101.13(b) limits the claims that can be used, expressly or by implication, to characterize the level of a nutrient (nutrient content claim) of the type required to be declared in nutrition labeling pursuant to § 101.9 to those that have been defined by FDA regulation.

Moreover, the substitute food must meet the definition for the nutrient content claim that FDA has adopted. For example, to use a "reduced fat" nutrient content claim as part of the statement of identity for a cheddar cheese product, it will not be enough for the product to have slightly less than the minimum milkfat content required by the standard of identity for cheddar cheese (§ 133.113). Rather the product will have to have a significant fat reduction. Proposed § 101.62(b)(4)(i) requires that a food must be specifically formulated, altered, or processed to reduce its fat content by 50 percent or more, with a minimum reduction of more than 3 grams per label serving size and per reference amount customarily consumed, from the reference food that it resembles and for which it substitutes to bear such a claim. Regular cheddar cheese contains 10 grams fat per 30 gram serving. Therefore, if this proposal is adopted, "reduced fat cheddar cheese" will have to contain 5 grams or less fat per serving to comply with these requirements and with § 130.10.

Proposed § 130.10(a) requires that the food comply with the traditional standard in all respect except as described by the nutrient content claim and as provided in paragraphs (b) and (d) of the regulation. These exceptions are discussed below.

A number of the standards in 21 CFR parts 131 through 169 contain several requirements for the standardized foods. FDA realizes that some alternate foods using nutrient content claims may deviate from the standard in more than one aspect. For example, eggnog, as defined in § 131.170, must contain not less than 6 percent milkfat and one or more of the optional egg yolk containing ingredients specified in § 131.170(c), such that the egg yolk solids content is not less than 1 percent by weight of the finished food. A product such as nonfat eggnog would deviate from the standard in that it would contain less than 6 percent milkfat and less than the required amount of egg yolk solids content. FDA is requesting comment concerning how far a product may deviate from a standard and still qualify for use of the standardized name.

2. Serving Size

Elsewhere in this issue of the **Federal Register**, FDA is publishing a reproposal of its serving size regulations (first proposed July 19, 1990 (55 FR 29517)) as part of its food labeling initiative to implement the provisions of the 1990 amendments. To prevent consumer deception as a result of a manufacturer reducing the serving size and thereby the calorie, fat, or sodium content per serving, FDA is proposing in § 101.12, which is published elsewhere in this issue of the **Federal Register**, that the serving size of a substitute product, such as a "low calorie" version of the food, must be based on the same reference amount customarily consumed as that of the regular counterpart food. Thus, any change in the characteristics of the food will be the result of changes in the food and not of changes in the serving size.

3. Presentation of Information

To avoid consumer confusion, FDA believes that the principal display panel of the label should clearly describe the difference between the traditional standardized product and the modified substitute product bearing the standardized term, and that the product should be labeled in accordance with proposed nutrient content claim regulations in proposed § 101.13 and other regulations in part 101 (proposed elsewhere in this issue of the **Federal Register**).

For example, for a reduced fat product to comply with §§ 101.13 and 101.62, a truthful comparative statement must appear in immediate proximity to the most prominent use of the fat claim, stating the percentage difference in fat between the modified product and the traditional standardized product. Proposed § 101.62 also requires the declaration of quantitative information comparing the actual amount of fat in a serving of a reduced fat product as compared to the amount in the traditional standardized product. Thus, the principal display panel of the label of a product such as "reduced fat sour cream" that contains 50 percent less fat than regular sour cream will have to include the statement "contains 50 percent less fat than regular sour cream. fat content has been reduced from 6 grams to 3 grams per serving" in immediate proximity to the most prominent (as defined in § 101.62(b)(2)(ii)) statement of identity.

D. Nutritional Inferiority

FDA is proposing to specifically require in § 130.10(b) that a substitute food named by use of a nutrient content claim and a standardized term not be nutritionally inferior, as defined in § 101.3(e)(4), to the traditional standardized food. For example, a cheddar cheese product containing 33 percent less milkfat than regular cheddar cheese that is nutritionally inferior to cheddar cheese under § 101.3(e) would be subject to the requirements of section 403(c) of the act and thus properly labeled as "imitation cheddar cheese."

In § 101.3(e)(4)(i), FDA defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in the food in a measurable amount. FDA has defined measurable amount of an essential nutrient in a food in § 101.3(e)(4)(ii) as 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under current § 101.9(c)(7)(iv) per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9. FDA is proposing in the document on Mandatory Nutrition Labeling, published elsewhere in this issue of the **Federal Register**, to establish Reference Daily Intakes (RDI's) for use in declaring nutrient content in nutrition labeling and to replace the current U.S. RDA's with the RDI's. If FDA adopts that proposal, nutritional equivalence will be based on the established RDI.

Dairy products typically contain a significant quantity of fat-soluble vitamins, such as vitamin A, in the milkfat portion. For example, one serving (30 grams) of cheddar cheese provides 8 percent of the U.S. RDA for vitamin A. A 33-percent reduction in the amount of milkfat in "modified cheddar cheese" also reduces the amount of vitamin A and other fat-soluble vitamins per serving. Therefore, FDA believes that vitamin A and other essential nutrients must be added to restore nutrients to products to ensure that the substitute food is not nutritionally inferior to the standardized food. FDA is proposing to provide for that addition in § 130.10(b). Under this proposal, the addition of nutrients will be reflected in the ingredient statement.

E. Performance Characteristics of Food

FDA believes that consumers expect that a product bearing a standardized name will not only resemble the traditional standardized food but will perform like the traditional standardized food. Consumers may assume that the substitute product can be used interchangeably with the traditional standardized food in all applications.

Therefore, in order not to mislead consumers, FDA is proposing in § 130.10(c) to require that a product bearing the standardized name have similar performance characteristics to the standardized food. FDA is proposing that the performance characteristics on which the substitute food is judged include physical properties (e.g., texture, melting point, freezing point), flavor characteristics (e.g., aroma and taste), functional properties (e.g., body, spreadability), and shelf life.

FDA recognizes, however, that it may not be possible or practical to produce substitute products that perform similarly to the traditional standardized food in all respects. As discussed in section IV of this proposal, many existing standards require certain levels of fat because fat was considered to be a valuable component of food when these standards were established. Reduced fat substitute foods, under proposed § 101.62 (b)(4), must have at least 50 percent of the fat removed. The fat is replaced by one or more other ingredients. Many manufacturers "agree that successful fat reduction typically extends beyond the abilities of one single ingredient. It requires a firm understanding of what fat does in a product, and how those functions can be replicated with nonfat ingredients. This understanding covers three primary arenas: Mouthfeel/textural characteristics, flavor characteristics and functionality/ processing concerns" (Ref. 17, p. 28).

Fats exhibit unique physical properties in a food. The fatty acid composition, crystal formation, melting and solidifying properties, and association with aqueous components of the food are important regarding the various textural properties fat imparts. For example, milkfat is important in ice cream because it inhibits the formation of large ice crystals and provides a smooth texture to the food.

Fats are important carriers for flavor because most food flavors, both natural and artificial, whether inherent in a food or added to a food, are fat soluble. Fats are also major contributors to flavor compound precursors and to functional characteristics. For example, a cheddar cheese substitute "made from milk with increased polyunsaturated fatty acid content does not develop normal flavor or body characteristics" (Ref. 18, 337).

FDA believes that shelf life is another important performance characteristic because the moisture content of a food may increase significantly with the reduction of a component such as fat. The increase in moisture becomes a factor in the microbial stability of products. In a food such as "reduced fat ice cream," the increase in moisture also can lead to the formation of large ice crystals because the higher level of free moisture makes the product less freeze-thaw stable (Ref. 17, p. 40).

Therefore, to assure that consumers are not misled as to the characteristics of the modified product, FDA is also proposing in § 130.10(c) to require that if a product bearing a standardized term does not perform in the same way as the traditional standardized food, the label must include a statement informing the consumer of any significant differences. For example, a reduced fat margarine may not perform the same as margarine for use in frying, and if this proposal is adopted, a statement such as "not recommended for frying purposes" must appear on the label. Under 403(f) of the act, FDA believes that the statement must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. FDA believes that the statement must appear in the same area of the label as the statement of identity for the modified product so that the consumer will know where to find such information. Therefore, FDA is proposing in § 130.10(c) to require that this statement appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence which shall be no less than one-half the size of the most prominent nutrient claim on the panel but no smaller than one-sixteenth of an inch.

The agency tentatively concludes that this information is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act. FDA is requesting comments concerning what differences in performance characteristics a modified standardized product may possess and still resemble the standardized food closely enough to be included in that product category.

F. Other Ingredients

1. Ingredients Provided For by Proposed Regulation

FDA believes that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used. Therefore, FDA is proposing in § 130.10(d)(1) that ingredients used in the product be those ingredients provided for by the traditional standard except that, in addition, "safe and suitable" ingredients, as defined in 21 CFR 130.3(d), may be used to improve texture, add flavor, prevent syneresis, or extend shelf life so that the product is not inferior in performance characteristics to the traditional standardized food.

If flavors are added to a modified standardized product, the label must comply with § 101.22. According to § 101.22(i), if the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor, by word, vignette (e.g., depiction of a fruit), or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, under § 101.22(i), the name of the food on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food. In addition, the name of the characterizing flavor shall be accompanied by the word or words "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor. For example, the name of an artificially butter-flavored light margarine would be "light margarine, artificially flavored" if the labeling implies that the product has a buttery taste. Also, natural and artificial flavors must be declared in accordance with applicable sections of 21 CFR part 101 in the ingredient statement in accordance with proposed § 130.10(f).

2. Use of Similar Ingredients

The provision for the use of safe and suitable ingredients proposed in § 130.10(d)(1) is not intended to allow for the replacement or exchange of any required ingredient or component of a required ingredient in the standardized food with functionally similar ingredients from other sources not provided for by the standard. For example, the standard for sour cream (§ 131.160) states that sour cream contains not less than 18 percent

milkfat. FDA believes that replacing the milkfat in sour cream with vegetable oil to make a product labeled as "cholesterol free sour cream" would be misleading because consumers expect sour cream to be a dairy product. Therefore, FDA is proposing in § 130.10(d)(2) that a required ingredient or component of an ingredient that is specifically required by the traditional standard shall not be replaced or exchanged with a similar ingredient from another source unless the traditional standard provides for the use of such ingredient. Thus, a manufacturer who used vegetable oil to replace or substitute for the milkfat in a modified sour cream product would not be able to take advantage of § 130.10.

FDA realizes that many modified versions of standardized foods may contain a greater percentage of moisture than permitted under the traditional standard because of the water contributed by ingredients with a high water content, such as skim milk. For example, colby cheese as defined in § 133.118 may contain not more than 40 percent moisture. Modified colby cheese containing one-third less fat than regular colby cheese may exceed this moisture limit because less whey is drained from the product during processing. FDA is requesting comment from interested persons concerning the appropriateness of the addition of high moisture ingredients and water to foods as ingredients to replace fat and calories in substitute products. FDA is aware of the recent development of fat analogs and is also requesting comments from interested persons concerning the appropriateness of the use of approved fat analogs to replace the fat in substitutes for standardized foods.

3. Ingredients Prohibited by the Standard

The majority of standards of identity prescribe the ingredients that may be included in a standardized food. However, there are some standards of identity defined in 21 CFR Parts 131 through 169 that specifically prohibit the addition of certain ingredients. For example, the standard for milk chocolate, § 163.130, states that milk chocolate may be spiced, flavored, or otherwise seasoned with one or more of the optional ingredients specified in the standard, other than any such ingredient or combination of ingredients that imparts a flavor that imitates the flavor of chocolate, milk, or butter (§ 163.130(a)). FDA believes that ingredients specifically prohibited by the standard should not be used in a substitute food. Therefore, FDA is proposing in § 130.10(d)(3) that an ingredient or component of an ingredient that is prohibited by the standard as defined in 21 CFR Parts 131 through 169 shall not be added to a substitute food.

G. Nomenclature

1. How Foods Are to be Named

FDA is proposing in § 130.10(e) to provide that the name of a substitute food that complies with § 130.10 is the respective standardized term plus an appropriate defined nutrient content claim (e.g., reduced fat sour cream). If a food meets the requirements of § 130.10, it is itself a standardized food. Therefore, even though it does not meet the requirements of the standard underlying the term included in its name, its name need not include the term "substitute" or "alternate." It does not purport to be the traditional standardized food named by that term. It purports to be a food that satisfies the requirement of the standard in § 130.10. Thus, it is appropriately named by use of only the nutrient content claim and the standardized term.

2. Name That Is To Be Used

FDA believes that foods that comply with any standard in 21 CFR parts 131 through 169 must use that standardized name. For example, cream cheese is defined in 21 CFR 133.134 as a product containing at least 33 percent milkfat by weight of the cream cheese, and the maximum moisture content is 60 percent by weight. Neufchatel cheese (§ 133.162) is a product similar to cream cheese except that the milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food, and the maximum moisture content is 65 percent by weight. A modified cream cheese containing 25 percent less fat than cream cheese complies with the standard for neufchatel cheese. The standardized name "neufchatel cheese" must appear on the principal display panel, but the comparative statement "contains 25 percent less fat than cream cheese" may also appear on the label. FDA believes that the use of comparative labeling in accordance with regulations in part 101 provides the consumer with useful information in the selection of a variety of foods.

H. Ingredient Labeling

FDA is proposing in § 130.10(f)(1) that each of the ingredients used in the food shall be declared on the label as required by applicable regulations in 21 CFR parts 101 and 130. Under § 101.4, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

To assist the consumer in differentiating between the traditional standardized food and the modified version of the standardized food, FDA is proposing in § 130.10(f)(2) that all ingredients added under the "safe and suitable" provision, if not provided for by the traditional standard, as well as permitted ingredients added at levels in excess of those allowed by the traditional standard, must be appropriately identified as such with an asterisk in the ingredient statement. The statement "*Ingredients not in regular _____" (fill in name of the traditional standardized food), or "*Ingredients in excess of amount permitted in regular _____" (fill in name of the traditional standardized food), or both as appropriate, shall immediately follow the ingredient statement in the same type size.

FDA believes that the consumer may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. Therefore, the agency is proposing that nutrients added to restore nutrients shall not be identified by an asterisk in the ingredient statement.

FDA is requesting comments on the proposed approach to ingredient labeling and on other methods of identifying ingredients not provided for by the traditional standard of identity.

VIII. Noncharacterizing Changes in Standardized Foods

A. Foods Meeting the Requirements of the Standards

When an ingredient or component of an ingredient not specifically required by the standard is removed or reduced (e.g., reduced-cholesterol liquid eggs) or is added (e.g., bread with added oat bran) to a product, the food does not deviate from the established standard of identity. In the former example, the liquid eggs are standardized in § 160.115. The standard does not specifically state how much cholesterol must be present in the eggs, nor does cholesterol contribute any important characteristics to the eggs. Therefore, cholesterol is not a required component of the eggs.

In the latter example, oat bran may be added to bread as one of the optional ingredients included in the standard of identity for bread (§ 136.110). FDA traditionally has considered optional ingredients as nonmandatory ingredients of standardized foods.

unless the standard of identity specifies that one or more of a group of optional ingredients must be present in a food.

FDA specifically considered the issue of the use of nutrient content claims in conjunction with the names of standardized foods in its tentative final rule relating to cholesterol nutrient content claims (55 FR 29456 through 29466, July 19, 1990). In the tentative final rule, FDA stated that defined cholesterol nutrient content claims could be used in association with the names of standardized and nonstandardized foods (except for those foods that are inherently free of, or low in cholesterol). However, the agency noted that for most standardized foods, a change in cholesterol content does not in and of itself change the character and nature of the food such that the food is no longer the standardized food. Thus, the agency said, for most of these foods, the use of nutrient content claims in conjunction with their standardized names will not create common or usual names that will take the food out of the standard for the purposes of § 101.3(e). FDA said that for these foods, the nutrient content claim merely points out the special property (i.e., the cholesterol content) of the food.

FDA further stated in the cholesterol tentative final rule that the use of the same lettering for the nutrient content claim and for the standardized name may be misleading because it would imply that the food is not the standardized food, but a different food that does not meet the requirements of the standard. The agency said that therefore, when cholesterol content claims are used in conjunction with a standardized name, they should be distinguished from that name by type, color, style of lettering, or type size in order to clearly differentiate the identity of the food from the cholesterol claim. FDA received no comments either for or against this policy in response to the tentative final rule.

FDA recognizes that valuable and helpful information concerning the nutrient content of food could be conveyed to consumers if defined nutrient content claims could be used in a consistent and responsible manner in the names of standardized foods. The agency also recognizes that, for the first time, defined nutrient content claims will be available as required by the 1990 amendments.

Because the substitute foods discussed in this proposal may be labeled using nutrient content claims and standardized terms in the statement of identity under proposed § 130.10, the foregoing factors have led FDA to decide to change the position that it set out in the tentative final rule for cholesterol and to tentatively conclude that foods that qualify for the use of a defined nutrient content claim but that still comply with a traditional standard of identity should also be labeled using nutrient content claims and standardized terms in the statement of identity. FDA has been led to this view by two additional factors. First, FDA believes that using inconsistent methods of labeling foods would be confusing to the consumer. Second, FDA believes that this approach provides an additional way to highlight those foods in which the cholesterol level is substantially less than in a food that substitutes for the food (see section 403 (r)(2)(A)(ii)(I) and (r)(2)(A)(iii)(I) of the act and the discussion of those sections in the companion documents on descriptors). Therefore, FDA tentatively concludes that the use of the same lettering for defined nutrient content claims and for the standardized name would not be misleading to consumers.

Thus, under these circumstances, FDA believes that the use of defined nutrient content claims and standardized terms in the statement of identity of a food is appropriate even though the food still complies with the standard of identity. The ingredient statement would reflect any modification of any ingredient used in the food. All claims used must comply with the applicable regulations in 21 CFR part 101 (proposed in separate documents published elsewhere in this issue of the **Federal Register**).

B. Substitute Foods Not Meeting the Requirements of the Standards Because of the Restoration of Nutrients

FDA is advising that substitute foods that do not comply with a traditional standard because nutrients may have been removed coincidental with the removal of a component not required by the standard, and those nutrients are added back to the food to restore nutrients to the levels present in the traditional food, may use a nutrient content claim and the standardized term in association with the statement of identity of the product if the claim complies with the requirements of proposed § 101.13 and with the requirements of the regulations defining the nutrient content claim in 21 CFR part 101. FDA believes that naming foods in this manner will provide for the use of accurate, easily understood statements of identity that inform consumers about the nutrient content of the substitute product. FDA believes that this policy makes sense in light of current national nutritional goals.

FDA believes that the restoration of these nutrients to the food should not be highlighted on the principal display panel or in the statement of identity of the product. In FDA's fortification policy (§ 104.20), the agency stated that it is inappropriate to make any claim or statement on a label or in labeling, other than in a listing of the nutrient ingredients as part of the ingredient statement, that any vitamin, mineral, or protein has been added to a food that replaces a traditional food to avoid nutritional inferiority in accordance with § 101.3(e)(2).

For example, a product such as liquid eggs that has been processed to reduce the cholesterol content may be nutritionally inferior to traditional liquid eggs because some processes to remove cholesterol from a product may inadvertently remove significant quantities of nutrients such as vitamin A. The standard for liquid eggs (§ 160.115) does not provide for the addition of nutrients to the food to restore these nutrients. Without the addition of nutrients to the food, this product would be an imitation food and thus subject to the requirements of section 403(c) of the act in accordance with 21 CFR 101.3(e). FDA believes that a policy that would require such a result would make little sense in light of current dietary guidance. Therefore, FDA tentatively concludes that if nutrients that were inadvertently removed from the liquid eggs during the process to remove cholesterol have been added back to the food, the product may be called "reduced cholesterol liquid eggs" if it complies with nutrient content claim regulations in part 101. All nutrients added to the product would have to be listed in the ingredient statement.

IX. Request for Comment

The agency is requesting comments on the proposed regulation in general, and in particular with respect to the provision concerning the requirement that the performance characteristics of the new product must remain similar to those of the standardized food. FDA encourages the submission of technical data and other information pertaining to the identification and measurement of key performance characteristics for different types of substitute foods, as well as comments about performance properties that are of greatest importance to consumers.

X. Environmental Impact

FDA 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.

XI. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to part 101 requirements as required by Executive Orders 12291, 12612, and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking, and Executive Order 12612 requires federal agencies to ensure that federal solutions, rather than state or local solutions, are necessary. Finally, the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

Because no marginal costs are expected to be incurred to comply with this proposed regulation, the agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because this regulation is intended to regulate food for interstate trade and individual State regulations may hinder interstate trade, FDA finds that there is no substantial Federalism issue which would require an analysis under Executive Order 12612.

FDA is proposing a change that will provide for consistent use of nutrient content claims for foods that substitute for standardized foods found in 21 CFP parts 131 through 169. This action will codify terms that manufacturers are currently using with TMP's. By establishing a generic standard of identity for modified standardized foods, FDA will avoid having to issue new TMP's or, ultimately, establish individual new food standards. Thus, rather than raise costs to industry and consumers, this action will lower future costs of marketing standardized foods. Rather than addressing a market failure, this action remedies an existing public regulation problem. The benefits of this action include both a reduction of the administrative costs of TMP's and elimination of consumer confusion for terms used to describe standardized and nonstandardized foods.

Options considered include no action, which would cause the agency to continually issue TMP's for each new modified standardized food and, ultimately, to issue separate food standards for each modified food. The other option, which is not appropriate or practicable at this time, would be to eliminate many food standards. Formal rulemaking procedures specified in section 701(e) of the act still apply for amending or repealing food standards for dairy standards and maple syrup under the 1990 amendments. These procedures often require many months or years.

Under existing Federal laws, removal of Federal food standards would allow each state to establish their own standards, which could inhibit interstate trade. Congress, in section 6 of the 1990 amendments, specifically provided for preemption of State laws for foods that are subject to a standard of identity established under section 401 of the act, unless specific exemptions are granted by FDA. Congress' action should help the food industry to conduct its business in an efficient and cost-effective manner, although the agency remains open to consider individual situations.

As firms will not be required to change existing labels, FDA finds that there are no marginal costs of this regulation. This action is also expected to facilitate international trade by providing expanded markets for new products such as low cholesterol and low fat foods that are appropriately named.

XII. Comments

Interested persons may, on or before February 25, 1992, submit to the Docket Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. 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. House of Representatives Report 101–538 on the Nutrition Labeling and Education Act of 1990 (H.R. 3562), June 13, 1990.

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

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

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List of Subjects in 21 CFR Part 130

Food additives, Food grades and standards.

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 130 be amended as follows:

PART 130—FOOD STANDARDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

§ 130.10 Requirements for substitute foods named by use of a nutrient content claim and a standardized term.

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter but that do not comply with the standard of identity because of a deviation that is described by a nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b) and (d) of this section.

(b) *Nutrient addition.* Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in § 101.3(e) (4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g. if appropriate, "not recommended for cooking"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type which shall be no less than onehalf the size of the type used in such claim but no smaller than one-sixteenth of an inch.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients to improve texture, add flavor, prevent syneresis, or extend shelf life may be used so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169.

(2) An ingredient or component of an ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(2) Ingredients not provided for, and ingredients used in excess of those provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Dated: November 4, 1991.

[FR Doc. 91-27170 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 101

[Docket No. 91N-0344]

RIN 0905-AD08

Food Labeling: Use of Nutrient Content Claims For Butter

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to adopt a regulation that will permit the use of nutrient content claims ("descriptors") that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). FDA believes that the proposed regulation will provide the consumer with a selection of modified butter products that are informatively labeled and will promote honesty and fair dealing in the interest of consumers.

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

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

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0112.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Situation With Respect to Butter—The Act of March 4, 1923—Sections 201a and 401 of the Federal Food, Drug, and Cosmetic Act

The Act of August 2, 1886 (24 Stat. 209), defined "butter" as:

* * * the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter.

The Act of March 4, 1923 (21 U.S.C. 321a) amended the Act of August 2, 1886, by adding the requirement that butter must contain not less than 80 percent by weight of milkfat. FDA has not established any further standards of identity concerning butter because section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) specifically states that "no definition and standard of identity and no standard of quality shall be established for * * * butter."

B. Pending Petitions

Johanna Farms, Inc., Flemington, NJ 08822, submitted a citizen petition, dated April 9, 1990 (Docket No. 90P-0141), requesting that FDA establish, by regulation, a common or usual name for