DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Pascua Yaqui Tribe of Arizona and State of Arizona Gaming Compact of 1993, which was enacted on June 24, 1993.

DATES: This action is effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: July 30, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–19928 Filed 8–17–93; 8:45 am]

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federal register

Wednesday
August 18, 1993

Part XIII

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Tonto Apache Tribe and the State of Arizona Gaming Compact of 1993, which was enacted on July 6, 1993.

DATES: This action is effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: August 11, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–19929 Filed 8–17–93; 8:45 am]

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Wednesday
August 18, 1993

Part XIV

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Yavapai-Apache Nation and State of Arizona Gaming Compact of 1993, which was enacted on June 24, 1993.

DATES: This action is effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: August 11, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–19930 Filed 8–17–93; 8:45 am]

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Wednesday
August 18, 1993

Part XV

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Agreement Between the Yavapai Prescott Indian Tribe and the State of Arizona concerning Class III Gaming, which was enacted on June 24, 1993.

DATES: This action is effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: August 11, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–19931 Filed 8–17–93; 8:45 am]

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Wednesday
August 18, 1993

Part XVI

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through her delegated authority, has approved the Gila River Indian Community and State of Arizona Gaming Compact of 1993, which was enacted on July 6, 1993.

DATES: This action is effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Hilda Manuel, Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: August 11, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–19932 Filed 8–17–93; 8:45 am]

BILLING CODE 4310–02–M

federal register

Wednesday
August 18, 1993

Part XVII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 5, et al.
Food Labeling for Human Consumption; Rules, Proposed Rule and Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 101

[Docket Nos. 91N–0384, 84N–0153, and 91N–0317 et. al.]

RIN 0905–AD08 and 0905–AB68

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Foods; Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is modifying its regulations on nutrient content claims and nutrient content claims used with a standardized term. In January of 1993, the agency published a document entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments." The document gave interested persons an opportunity to comment on technical issues not raised in earlier comments pertaining to nutrient content claims. This document addresses the comments that the agency received in response to that document that identified technical matters or specific provisions that resulted in unintended technical consequences and that were not raised in earlier comments.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Constance B. Henry, Center for Food Safety and Applied Nutrition (HFS–156), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1993, FDA published a final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (58 FR 2302) (hereinafter referred to as "nutrient content claims final rule"). That final rule, among other things, defined nutrient content claims (also known as "descriptors") and provided for their use on food labels; defined specific nutrient content claims that included the terms "free," "low," "good source," "high," "reduced," "less (or fewer)," "more," and "light" or "lite;" established values for these terms for various nutrients; and established procedures for the submission and review of petitions regarding the use of nutrient content claims.

In that same issue of the **Federal Register**, FDA also published a final rule entitled "Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (58 FR 2431) (hereinafter referred to as "the general standard"). This final rule provided a general definition and standard of identity for foods named using a nutrient content claim, such as "fat free" or "light," in conjunction with a traditional standardized name (for example "reduced fat sour cream").

II. Technical Issue Comments

A. Nutrient Content Claims, General Principles

In the **Federal Register** of January 6, 1993, FDA also issued a final rule entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments" (58 FR 2066) (hereinafter referred to as the "implementation final rule"). The implementation final rule, among other things, provided 30 days for the submission of comments on technical issues. FDA advised that it was not interested in receiving comments that it had already received and considered. FDA urged interested persons to limit their comments to technical matters such as inconsistencies or unintended consequences of specific provisions not raised in earlier comments. In order to ensure consideration of any comments, interested persons were to certify that their comments were so limited. FDA further advised that if the comments identified any technical provisions of the final rules that FDA agrees should be changed, FDA would take action to modify those provisions. FDA stated that this approach would enable it to quickly address any unintended effects of the final rules, yet not delay the finality that is imperative for both industry and consumers.

Following publication of the nutrient content claims final rule, FDA received approximately 50 letters containing one or more comments from industry, consumers, and other interested persons. Of these submissions, 25 included technical issue comments as described in the implementation final rule. The other submissions raised matters that merely require clarification or that are beyond the scope of technical concerns and would require further rulemaking. FDA is responding below to the specific technical issues that the comments raised. Those issues that are beyond the scope of this document or that are otherwise not relevant to this rulemaking are not discussed below. These matters should be the subject of separate rulemaking or petitions to the agency (e.g., a definition for a new term). In addition, FDA has included in this document technical changes that it is making after reconsideration of the regulations on its own initiative or in response to informal questions. Because the changes FDA is making in these final rules are technical in nature and are based on a full prior opportunity for comments, the agency finds that further opportunity for public comment on them is unnecessary.

Minimum Type Size

1. In several sections in the nutrient content claims final rule, the agency prescribed minimum type size requirements for a variety of required declarations (e.g., § 101.13(g) (21 CFR 101.13(g)) for referral statements). However, the agency did not specify minimum type size requirements for certain other required information (e.g., § 101.13(j)(2)(iv) accompanying information), even though a one-sixteenth inch minimum was discussed in the preamble for these provisions. The agency was relying on the general provisions in § 101.2(c) (21 CFR 101.2(c)) which specifies the minimum acceptable type size for required labeling information. However, § 101.13 and the other regulations for nutrient content claims in subpart D of part 101 (21 CFR part 101) are not listed in § 101.2(b), which identifies the sections to which § 101.2(c) is applicable. The agency has received numerous inquiries about the fact that there is no codified minimum type size for some of the labeling information required under the nutrient content claims regulation.

FDA has determined that there remains a need to specify the minimum type size for this type of information. Therefore, the agency is modifying § 101.2(b) to include §§ 101.13, 101.54, 101.56, 101.60, 101.61, 101.62, and 101.65 among those sections for which a minimum type size for required label information is specified. For consistency, the agency is also modifying § 101.2(f) to include §§ 101.13, 101.54, 101.56, 101.60, 101.61, 101.62 and 101.65. Finally, because § 101.25 was removed by the nutrient content claims final rule,

reference to this section is being deleted from § 101.2(b) and (f). In effect, label information required by the nutrient content claims regulations, but whose type size is not otherwise specified, will be required to be in letters and/or numbers no less than one-sixteenth of an inch in height unless otherwise specified by § 101.2(c).

Type Size and Style

2. In § 101.13(f) of the nutrient content claims final rule, the agency required that a nutrient content claim be in type size and style no larger than two times that of the statement of identity.

Some comments stated that the words "and style" must have been a typographical error. They said that because type style is not related to type size these words did not make sense in the sentence and should be dropped.

While the agency agrees that the words "and style" are used in an awkward manner in § 101.13(f), the agency believes that the concept that is the basis of the requirement remains important. There is a great variety of print styles available for use in labeling. Some of these styles, like Helvetica 95 Black, are very bold and prominent. Others, like Helvetica 25 Ultra Light, are thin and much less prominent. The purpose of the phrase "and style" as used in § 101.13(f) was to ensure that a claim not have undue label prominence compared to the statement of identity by virtue of the style of type used. However, because this phrasing has presented some confusion, the agency is modifying the provision to require that a claim not have an unduly prominent style when compared to the statement of identity. Accordingly, FDA has revised § 101.13(f) to state that a nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

The agency advises that in implementing § 101.13(f), after taking into account the relative difference in the size of the claim compared to the size of the statement of identity, claims that are noticeably more prominent because of a difference in style will not be considered in compliance with this requirement.

Referral Statements on the Information Panel

3. Section 403(r)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act), which was added by the Nutrition Labeling Education Act of 1990 (the 1990 amendments), requires that all products making a nutrient content claim bear the referral statement "See ———— for nutrition information," with the blank filled in with the identity of the panel on which nutrition labeling is located. Section 101.13(g)(2) states that if the nutrient content claim appears on more than one panel, the referral statement may be omitted from the panel that bears the nutrition information.

A question has been raised as to whether the referral statement is required on the information panel if the claim does not appear on any other panel, or whether it may also be omitted if the claim appears only on the information panel.

The preamble to the nutrient content claims final rule (58 FR 2302 at 2306, comment 6) states that under § 101.13(g)(2) the referral statement is not required when a claim appears on the information panel. As reflected by this response, the agency intended that the referral statement not be required on the panel that bears nutrition information. However, because the wording of § 101.13(g)(2) is apparently unclear, the agency is modifying § 101.13(g) to specifically state that the referral statement is not required on the panel that bears nutrition information. Although this modification creates an apparent redundancy in the regulation, FDA is willing to accept redundancy in this instance in the interest of clarity.

Substitute Referral Statement on Small Packages Bearing Claims

4. In the final rule on nutrition labeling, the agency provided in § 101.9(a) (21 CFR 101.9(a)) that if a nutrient content claim was made on a product label, the product would have to bear nutrition labeling without regard to whether it was exempt from mandatory nutrition labeling for some other reason (e.g., the small business exemption). In addition, as noted above, section 403(r)(2)(B) of the act requires that all products that make nutrient content claims bear in immediate proximity to the claim the referral statement "See ———— for nutrition information," with the blank filled in with the identity of the panel on which nutrition labeling is located. Finally, the mandatory nutrition labeling regulation provides in § 101.9(j)(13)(i) that foods in small packages that have a total surface area available to bear labeling of less than 12 square inches (sq in) and that make no nutrient content claims and provide no other nutrition information, may provide an address or telephone number that a consumer can use to obtain the required nutrition information.

As discussed in the document for nutrition labeling, published elsewhere in this issue of the **Federal Register**, the agency has learned through inquiries informal questions that some products, many intended for individual use with meals in restaurants, have extremely small areas available to bear labeling information (less than 3 sq in), and thus do not have sufficient space available to bear the normal nutrition labeling information required when a nutrient content claim is made. In the nutrition labeling technical corrections document published elsewhere in this issue of the **Federal Register**, the agency has modified § 101.9(j)(13)(i)(B) to permit individual serving-size packages of food for use in restaurants and similar situations to use the minimum type size allowed under § 101.2(c)(5) of one thirty-second inch for nutrition labeling, provided that the packages comply with the requirements of that regulation, including that they have a total area available to bear labeling of 3 sq in or less. If a package still cannot comply with this requirement, manufacturers are advised to write the agency requesting alternative means of compliance in accordance with § 101.9(g)(9).

The agency recognizes that in many of these situations, there will not be sufficient space available for the specified referral or disclosure statement. For some packages, there will be a single panel of available label space. In such circumstances, no referral statement is necessary because, as explained in the previous comment, the claim is on the same panel as the nutrition information. However, in those circumstances in which the claim is on a panel other than the one containing the nutrition information, the agency believes that it is reasonable to permit the referral statement to be one thirty-second inch in height as permitted in § 101.2(c)(5). Therefore, the agency is modifying § 101.13(g)(1) to permit products that comply with § 101.2(c)(5) to have a referral statement in the minimum type size of one thirty-second inch.

Because other type size requirements in § 101.13 and in regulations in subpart D refer to § 101.13(g) for their size requirement, this modification will have the effect of changing the minimum type size to one thirty-second inch for all declaration provisions referring to § 101.13(g). For consistency, the agency is also modifying § 101.13(d)(2), which requires a disclaimer statement for substitute foods and requires the same relative type size but does not reference § 101.13(g) and § 101.13(i)(2), which requires a disclaimer statement on certain percent and amount claims, to permit the information to appear in type

of one thirty-second inch in appropriate circumstances. The agency is also modifying 101.13(g) for clarity and consistency with § 101.13(d)(2).

In those rare circumstances where the product is not able to comply with this modified requirement, any request for alternative means of compliance in accordance with § 101.9(g)(9) should include a suggestion for a referral statement to be used to identify the location of nutrition labeling.

Accompanying Information on Small Packages

5. In § 101.13(j)(2) and in the relevant sections in the various nutrient content claims regulations in subpart D of part 101, the agency required that for foods bearing relative claims, the label or labeling must state the identity of the reference food and the percentage (or fraction) by which the amount of the nutrient that is the subject of the claim in the labeled food differs from the amount of the nutrient in the reference food. This information must be adjacent to the most prominent claim. The agency also required that quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that of the reference food be provided adjacent to the most prominent claim or on the information panel.

FDA received inquiries in response to the implementation final rule about how to present this information on small packages. The agency advises that because the minimum type size requirement for this statement is established by § 101.2 (see comment 1 above), all exemptions provided in § 101.2(c) for small package sizes would apply to the required accompanying information. Consequently, for example, accompanying information could be provided in type size as small as one thirty-second inch on packages having less than 12 sq in of available label space that met the requirements for an exemption in § 101.2(c)(2) or (c)(3).

However, some manufacturers of extremely small packages (less than 3 sq in) inquired about how to provide the required accompanying information when there was insufficient label space to do so even taking into account the exemptions in § 101.2(c).

The agency determined in the nutrient content claims final rule that the percentage that the nutrient has been reduced and the identity of the reference food (e.g., 25 percent fewer calories than regular cheesecake) are essential to consumer understanding of the claim. This information can often be structured in such a way that it is part of the claim or takes up little more space than the claim itself. Thus, it would not be appropriate to excuse packages with a small amount of label space that make comparative claims from the requirement to place this information adjacent to the most prominent claim.

However, because of the limited amount of space available to provide the required information, and the fact that an alternate means of presentation of that information is possible, the agency finds that it is appropriate to provide more flexibility for declaration of the quantitative information comparing the amount of subject nutrient in the labeled food with that in the reference food on packages with an extremely small amount of available space (that is, those with less than 3 sq in). The agency believes that in this limited circumstance, it is more important that the required information be presented rather than that it be presented in the manner that is most appropriate to prevent consumer confusion, i.e., as part of the same presentation of information, therefore, for these products. The statement of the amount of the subject nutrient that is part of the nutrition information can satisfy the requirement for the portion of the accompanying information that specifies the amount of the nutrient for the labeled product. A statement of the amount of nutrient for the reference product would still be required.

However, as is the case with referral statements on extremely small labels (less than 3 sq in of available label space), if the manufacturer still believes that there is insufficient label space to comply with this requirement, the agency believes that it is appropriate for the manufacturer to request flexibility under § 101.9(g)(9) and suggest appropriate steps that may be taken to comply with these requirements.

Alternate Spellings

6. In the nutrient content claims final rule (58 FR 2302 at 2321 (comment 60)), the agency stated that "although [it had] not specifically provided for variations in the spelling of various descriptive terms or their synonyms, except for 'light' ('lite'), the agency believes that reasonable variations in the spelling of these terms would be acceptable provided that these variations are not misleading to consumers." The agency added that it would consider on a case-by-base basis variations in spelling whose use is questionable.

Comments requested that the agency formally codify this policy so that there would be no confusion as to the permissibility of nonmisleading spelling variations.

The agency agrees that codifying the policy will facilitate compliance by providing in the codified language, rather than in just the preamble, explicit permission to use alternate spellings of descriptive terms. This provision will eliminate any confusion as to permitted label statements. Therefore, FDA is adding new § 101.13(b)(4), which states, that the use of reasonable variations in the spelling of the various descriptive terms and their synonyms, e.g., "hi," and "lo," is permitted provided that these variations are not misleading.

Definition of Meal-Type Products

7. In the nutrient content claims final rule, the agency defined a "meal product" and a "main dish product" for the purpose of making a nutrient content claim using the meal/main dish claims criteria. These criteria are different from those for individual foods. The definition for a "main dish product", among other things, requires that the food weigh at least 6 ounces (oz) per labeled serving and contain not less than 40 grams (g) for each of at least two different foods from two of the following four food groups: (1) Bread, cereal, rice and pasta group; (2) fruits and vegetable group, (3) milk, yogurt, and cheese group, and (4) meat, poultry, fish, dry beans, eggs, and nuts group. The definition also requires that these foods should not include sauces, condiments, relishes, pickles, olives, jams, jellies, syrups, breading, or garnishes. The agency stated, however, that the amount of a food in a sauce, e.g., tomatoes in a tomato sauce, could count toward the 40 g criterion. For meals, the agency required that the food weigh at least 10 oz per labeled serving and contain not less than 40 g from each of at least 3 different foods from 2 or more of the described food groups and again excluded certain foods from the 40 g criterion.

Several comments maintained that many main dish products would not be able to meet the specified definition. They stated, for example, that the major ingredient for many products was a large portion of pasta, often with sauce. The comments requested that for main dish products, the 40 g requirement be eliminated, or that the requirement be 40 g from one food group and not less than 10 g from two or more additional food groups with a total contribution from all food groups of at least 80 g (6 oz is about 170 g). They requested that the requirements for meals be similarly modified.

The comments further claimed that the requirement that FDA adopted would force manufacturers to add to their products excessive amounts of

certain ingredients such as cheese, in amounts in excess of the reference amount customarily consumed (RACC) for the individual food. These comments cited, as an example, that for the cheese in a meal-type product to meet the 40 g criterion, and thereby to qualify as one portion of food from a food group, the meal type product would have to contain more cheese than the 30 g that constitutes the RACC for an individual serving of cheese. This amount, the comments said, is significantly higher than one half the RACC of an average individual food that the agency stated was the basis for the 40 g criterion for a portion of food to qualify as a component of a meal-type product.

The agency does not intend to preclude meal-type products that are consistent with dietary recommendations that diets include a variety of foods from meeting the definitions for meals and main dishes and from qualifying to use the definitions for nutrient content claims for meal-type products. However, the definitions for main dishes suggested by the comments are far too broad. For example, the definition suggested by the comments would allow a product that is little more than a single ingredient with a small amount (10 g) each of two other foods to be mixed together and be considered a main dish for purposes of making claims. Such a food would not necessarily be the major component of a meal, as required by the definition of main dish products. The agency believes that such foods are more properly considered to be mixed dishes, which may still make a claim if they qualify for it using the RACC for mixed dishes and the criteria for individual foods (see § 101.12(b), Table 2, (21 CFR 101.12(b), Table 2).

However, the agency acknowledges that in the preamble and the codified language, it stated that to qualify for the definition of a meal, each 40 g would have to come from different foods. These statements have the unintended effect of prohibiting manufacturers from using a combination of foods from one of the four food groups to meet the 40 g criterion. For example, they would prohibit combinations such as shrimp and scallops, peas and carrots, or even swiss cheese and cheddar cheese from being considered a food from a food group unless a single ingredient contributed 40 g of food to the product. The agency did not intend to so limit the definition.

The agency intended to permit manufacturers to combine different foods from the same food group to meet the 40 g criterion. This position will allow a wider variety of products to qualify as meal-type products than would the position the agency inadvertently took in the final rule, but will still encourage manufacturers to make products that contain a variety of foods with different nutrient profiles. By allowing combinations of foods from the same food group to qualify for the 40 g criterion, certain nutrient dense ingredients could be combined with less nutrient dense foods from the same food group, or a variety of foods in the same food group could be used. For example, carrots and peas together could be used to meet the 40 g criterion for the fruit and vegetable food group and a combination of cheese and milk could be used to meet the 40 g criterion for the dairy food group. Similarly, for meals, it would be appropriate to combine two or more foods (e.g., two or three fruits or vegetables totaling at least 40 g) to meet the requirement of a 40 g portion of food from a food group. Consequently the agency is modifying § 101.13(l)(1)(ii) and (m)(1)(ii) to reflect these criteria.

However, because the dietary guidelines suggest that people should eat a variety of foods from the various food groups, as the agency stated in the final rule, a product that purports to constitute a meal, and therefore a major portion of the day's food intake, should have significant portions of at least three different foods having different nutrient profiles. Hence, the agency believes that each portion of food in a food group that constitutes one of the required 40 g portions should be composed of different foods or combinations of foods than the other 40 g portions. Foods that are made from similar ingredients (e.g., two foods each made from flour, eggs, and water) or that have similar nutrient profiles, e.g., a variety of pastas, would not provide variety and nutrient diversity and therefore would not be appropriate to constitute two of the three required portions of a meal. Therefore, 80 g of a variety of pasta would generally not qualify as two 40 g portions of different foods in a meal. However, a variety of pastas could be combined to meet the requirements for one 40 g portion.

Rounding

8. The agency has received many inquiries as to whether a product must meet the definition of a claim based on the rounded or the unrounded values.

In the nutrient content claims final rule, the agency stated in § 101.13(o) that compliance with requirements for nutrient content claims would be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9. The agency also stated in § 101.13(j)(1)(ii)(B) that for purposes of relative claims other than "light," when comparing a single manufacturer's product to the labeled product, the nutrient value for the single manufacturer's product shall be the value declared in the nutrition labeling of the product, i.e., the rounded value. However, the agency did not further specify whether the values used to determine compliance with a claim were to be the rounded or unrounded values.

The agency acknowledges that the requirement for relative claims that stipulates that the nutrient value for a single manufacturer's product must be the value declared in the nutrition labeling on the product may result in the unintended consequence of causing inconsistencies between the various required label values, specifically, the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the food has been modified. These inconsistencies will have the additional unintended consequence of causing consumer confusion. For example, a product that is reduced in fat by 25 percent compared to a reference product may contain 5.5 g fat (rounded to 6 g of fat in the nutrition label) when the reference product contains 7.4 g of fat (rounded to 7 g of fat). If the labeled values were used to declare the nutrient values in the accompanying information, the product would appear to have a reduction of only about 15 percent. Consequently, if rounded labeled values are used in the accompanying information, it would appear that the product was not reduced in fat to the extent declared, and consumer skepticism and confusion would result. There might also be consumer confusion if the actual values that were used to make the comparison, and that were shown in the accompanying information, differed from the values in the nutrition information.

Conversely, if all claims were based on rounded values rather than actual values, a relative claim could comply with the definitions but still be misleading if the percentage reduction specified was 25 percent or greater but the actual reduction was not. For example, if a food containing 5.4 g of fat (rounded to 5 g of fat) was compared to a food containing 6.5 g of fat (rounded to 7 g) it would appear, using the rounded values, that there was greater than a 25 percent reduction in the amount of fat in the labeled product. However, using the actual values, the

labeled food would have been reduced by only slightly more than 15 percent. FDA stated in the nutrient content claims final rule that nutrient reductions less than 25 percent were not meaningful and were therefore misleading. There would still be other circumstances which might be confusing. For example, if a food was reduced in the level of a nutrient by at least 25 percent and therefore qualified to make a reduced claim, the specified percentage reduction might differ from the declaration of amounts of nutrient in the compared foods depending on whether rounded or unrounded values were used to specify the percentage reduction.

Therefore, particularly for relative claims, there are advantages and disadvantages in requiring either the rounded or the unrounded nutrient values to be used in determining whether a food qualifies to make a nutrient content claim and to be declared on the label. The agency believes, however, that it is more important to prevent consumer confusion by having consistency on the food label than to be prescriptive as to the method by which nutrient values for relative claims are determined and used. It is essential, though, as discussed in the nutrient content claims final rule, that the actual nutrient reductions must be nutritionally meaningful. Therefore, to help eliminate consumer confusion, the agency is modifying § 101.13(j)(1)(ii)(B) to permit comparisons to a single manufacturer's product using either the values declared in the nutrition labeling or the actual nutrient values, provided that the label is internally consistent, that is, that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the food has been modified are consistent and will not cause confusion when compared, and that the actual modification is at least equal to the percentage specified in the definition of the claim.

Further, for absolute claims, because there is no need to specify the actual amount of the nutrient in the food relative to the claim and, as discussed in the mandatory nutrition labeling final rule, because there is no nutritional difference between rounded and unrounded values of a nutrient in a food, the agency does not see a need to specify which value should be used in determining whether or not a food qualifies to make a nutrient content claim.

Exemption for Grandfathered "Diet" Soft drinks.

9. Section 403(r)(2)(D) of the act, which was added by the 1990 amendments, states that section 403(r)(2) of the act does not apply to a claim that uses the term "diet" if the claim is contained in the label or labeling of a soft drink, was in use on such soft drink before October 25, 1989, and the use of the term was in conformity with § 105.66 at the time of enactment of the 1990 amendments. This provision has the effect of exempting such claims from the referral and disclosure statement requirements and the special disclosure statements (those required by section 403(r)(2)(A) of the act).

One comment asked that the exemption be included in the regulation to ensure that it is applied uniformly.

To clarify the existing exemption and to facilitate compliance, the agency is modifying § 101.13(q)(2) to state that claims for such grandfathered soft drinks are exempt from section 403(r)(2) of the act, including the referral (§ 101.13(g)) and disclosure (§ 101.13(h)) statement requirements. This modification fully responds to the comment's concern.

Applicability of General Requirements of Nutrient Content Claims to Claims About Salt and Sugar

10. Sections 101.60 and 101.61 establish the requirements for nutrient content claims about calories and sugar and sodium and salt, respectively. However, the introductory paragraphs to these sections state only that the general requirements in these introductory paragraphs are applicable to claims about calories and sodium. The agency intended that the general requirements apply to all claims and specifically that general requirements for claims defined in §§ 101.60 and 101.61 apply to all claims defined therein. Therefore, to avoid any possible confusion as to the applicability of these general requirements, the agency is adding explicit mention of sugar and of salt in the general requirements paragraphs in §§ 101.60(a) and 101.61(a), respectively.

Criteria for "Free" Claims

11. In the November 27, 1991, document on nutrient content claims (56 FR 60421) (hereinafter referred to as the nutrient content claims proposal), the agency proposed that claims, including claims that a food was "free" of a nutrient, be based on the amount of nutrient in a labeled serving of the product and in a RACC. In the nutrient content claims final rule, the agency determined, based on comments, that using the amount of nutrient per labeled serving as a criterion for various claims, in addition to the amount of nutrient per RACC, was too restrictive. Consequently, in the final rule, the agency retained the requirement that most claims, including those for products "free" of a nutrient, be based on the amount of a nutrient per RACC and deleted the criterion of amount of the nutrient per labeled serving. The agency further required that if the value of the nutrient in a labeled serving of the food did not meet the maximum or minimum amount of nutrient per RACC that qualifies a food for the claim, the claim must be followed by declaration of the criteria for the claim e.g., "sodium free, less than 5 mg sodium per 240 milliliters (8 fl oz)" (see § 101.13(p)(1)).

In addition, in the final nutrition labeling regulation (58 FR 2079), FDA prescribed how the nutrient values are to be expressed in nutrition labeling. The nutrition labeling regulation prescribed levels for nutrients that are nutritionally trivial, i.e., those nutrients that are present in a food at insignificant amounts and that consequently are declared as zero on the nutrition label (e.g., less than 5 calories and less than 0.5 g total fat). Because these values are nutritionally trivial, they are also the defining values for "free" claims.

Comments pointed out that there are situations, primarily on single serving products whose labeled serving exceeds the RACC, in which a product bearing a "free" claim will have a value in nutrition labeling other than zero for that nutrient. This situation, the comments said, would be confusing to consumers. For example, if an 8 fl. oz. (240 milliliters (mL)) bottle of soda contained 4 calories, the value for those calories could be rounded to zero in the nutrition labeling, and the product would meet the definition for "calorie free" (less than 5 calories per 240 mL). However, if the same soda were sold in a single serving 12 fl. oz. container, a labeled serving of the product would contain 6 calories. While this product would meet the current requirements for a "calorie free" claim based on the RACC, it would have to declare 5 calories in the nutrition label. The comment said that declaration of a numeric value other than zero in nutrition labeling for a nutrient for which a "free" claim is made would have the unintended effect of permitting seemingly conflicting labeling information that would be confusing to consumers. The comments suggested that "free" claims, therefore, should be based on the amount of nutrient per labeled serving rather than per RACC.

The agency agrees that because of the unique nature of the word "free," i.e., that there is none of the nutrient in the food, the perception and expectations created in consumers' minds by the use of the word, in the situations cited in the comments, would be in conflict with a nutrient value other than zero in the nutrition information. Such declarations could be confusing to consumers, and this consequence is unintended. "Free" claims are different than claims such as "low," which do not create an expectation in consumers' minds that the food bearing the claim will possess a specfic amount of the nutrient in question.

Consequently, FDA has reconsidered this aspect of the final rule. Based on the considerations discussed above as well as those of justice and the public interest, FDA has decided that to present misleading and confusing labeling when "free" is used, it will include in the final rule the requirement for "free" claims that it proposed in the November 27, 1991, document that the determination of whether a product is free of a nutrient be based on the value of the nutrient per RACC and per labeled serving. Moreover, this change in the requirements for "free" claims on individual foods eliminates an inconsistency with the requirements for "free" claims for meal-type products. Meal-type products must meet the required nutrient values on a per labeled serving basis, regardless of the size of the serving. Consequently, the agency is including this reuqirement for "free" claims in §§ 101.60(b)(1)(i), 101.60(c)(1)(i), 101.61(b)(1)(i),101.62(b)(1)(i), 101.62(c)(1)(i), 101.62(d)(1)(i)(A), and 101.62(d)(1)(ii)(A).

Per 50-g Criterion for Rehydrated Products

12. The determination as to whether a product can make a claim is based on the amount of nutrient in the product "as packaged." In the nutrient content claims final rule, the agency also established a requirement that products having a small RACC (30 g or less or 2 tablespoons or less) that bear certain claims, such as "low," must meet the nutrient values for the claim (e.g., 3 g of fat or less) per 50 g of product as well as per RACC. However, the agency provided that for dehydrated products that typically must be rehydrated with water before consumption, the 50 g criterion refers to the "as prepared" form. In the nutrient content claims final rule, FDA stated that this provision would make the basis of the claim for these products consistent with the nutrient values in nutrition labeling which are based on the amount of product customarily consumed. The agency stated that such a requirement for foods that are reconstituted with water is appropriate because water generally adds a negligible amount of additional nutrients to the "as packaged" form of the product, although it does increase the weight of the dehydrated food.

One comment requested that this exception to the per 50 g criterion be extended to products that are reconstituted with diluents other than water that contain a negligible amount of nutrients such as vinegar. The comment suggested that this modification would be consistent with the intent of the final regulation and would assure that dehydrated foods are not forced to meet a more rigid standard than equivalent amounts of the regular product because the per 50 g criterion was being applied to a more nutrient dense form of the food. The comment maintained that to not allow reconstitution of products with such diluents when determining compliance with the per 50 g criterion would have the unintended effect of prohibiting claims on certain dehydrated products when the regular version of the product would qualify for the claim. The comments maintained that when such products are reconstituted in whole or part with certain diluents other than water, they have similar nutrient profiles compared to regular versions of the same foods because, on a per serving basis, the diluent makes an insignificant contribution to the nutrient content of the food.

In response to this comment, the agency has reconsidered this aspect of the final rule. Although the agency still believes that it is appropriate to base all claims on the amount of nutrient in the "as packaged" form, the agency agrees that where a RACC of the diluent used to reconstitute a product contributes insignificant amounts of nutrients, the difference in nutrient profiles between the "as packaged" and the "as prepared" versions of the food bearing the claim would be insignificant when equivalent portions of the food are compared.

Therefore, the agency is modifying the regulations to provide that foods that must be reconstituted with a diluent that has an insignificant amount of all nutrients per RACC may make claims based on the reconstituted ("as prepared") version of the product. Insignificant amounts of nutrients (as defined in § 101.9(f)(1)) are the amounts that can be declared as zero in nutrition labeling, or, in the case of total carbohydrate, dietary fiber and protein, as less than 1 g. The agency has modified § 101.13(h) and the various affected provisions in part 101 subpart D (e.g., §§ 101.60(b)(2)(i)(B) and 101.62(d)(2)(i)) to reflect this change.

Light in Sodium

13. In the final rule, the agency provided for use of the terms "light" and "light in sodium" when the amount of sodium in a food has been reduced by at least 50 percent. The agency stated in § 101.56(c)(1)(i) that the term "light" or "lite" without further qualification could be used on a product for which the reference food contains 40 calories or less and 3 g of fat or less per RACC if the sodium content is reduced by 50 percent or more. The agency also provided in § 101.56(c)(2)(i) that the term "light in sodium" as a single term could be used on a product for which the reference food contains more than 40 calories or more than 3 g fat per RACC if it is reduced in sodium by 50 percent or more.

Inquiries to the agency have raised the question whether the manner in which the regulation was worded would preclude products whose sodium content has been reduced by 50 percent but whose reference food contains 40 calories or less and 3 g of fat or less, from using the term "light in sodium."

The agency did not intend to prohibit products that qualify for an unqualified "light" claim to express, in more explicit terms, the actual nature of the nutrient modification made to the food, such as "light in sodium," "light in fat," or "light in calories." Therefore, the agency sees no problem with "low calorie," "low fat" foods that qualify for the term "light" because of a 50 percent reduction in sodium content using the term "light in sodium." Likewise, it would not consider that foods that qualify to use the unmodified term "light" because of their calorie or fat content are prohibited from using the more explicit descriptions, "light in fat" or "light in calories."

The agency does not believe that it is necessary to provide a change in the codified language that would specifically state this position. However, if FDA finds that labeling using the terms "light in sodium," "light in fat" or "light in calories," carries a problem, the agency would consider additional rulemaking in the future.

Fortification

In § 101.54(e) of the nutrient content claims final rule, the agency defined "more" as a relative claim used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food that contains at least 10 percent

more of the Daily Value (DV) per reference amount than an appropriate reference food. In addition, the agency stated that for "more" claims in which the claim is based on a nutrient that has been added to the food, the fortification must be in accordance with the policy on fortification of foods in § 104.20 (21 CFR 104.20). Finally, the agency determined that the terms "fortified," "enriched," and "added" have the same nutritional meaning as the term "more." The agency concluded that, except for standardized foods in which one of the terms was defined, all foods bearing these terms would have to comply with the same quantitative definition as the term "more." However, the agency differentiated appropriate reference foods for the various terms.

14. A number of comments raised concerns about the final rule for "more," stating that FDA had not adequately considered the consequences of these provisions. They stated that because the fortification policy does not include current nutrition information and is not all inclusive, certain rationally fortified foods would be prohibited from making "more" claims, as well as the "fortified" and "enriched" claims. For example, the fortification policy does not address the issue of fortification with fiber. Many comments stated that the fortification policy was intended to be a policy and not a regulation, that FDA had acknowledged that the policy was incomplete, and that at the time of the original publication of the fortification policy it was anticipated that additional bases for rational fortification could be included from time to time. Comments maintained that the agency has unintentionally endangered consumer awareness and consumption of fortified products, such as breakfast cereals, and; has outlined a final rule that will be confusing to consumers and that will inadvertently limit the rational fortification of foods.

One comment requested that the reference to § 104.20 be deleted from the regulation. Other comments suggested that in order to allow for nutrient content claims on fortified foods for beneficial nutrients that are not covered by the fortification policy, the agency should revise § 101.54 to state that fortification of the food must be in accordance with the policy on fortification of foods in § 104.20 or be otherwise rational.

The agency has considered these comments. It was not the agency's intention to preclude rational addition of a nutrient to a food simply because it was not explicitly addressed in the fortification policy in § 104.20. However, the agency is concerned that to delete any reference to the fortification policy could result in claims on foods with irrational or inappropriate fortifications. The agency recognizes that there are additions of nutrients to foods other than those specifically mentioned in § 104.20 that are rational. The agency notes that the fortification policy as specified in § 104.20, was developed at a time when less technology was available for food formulation and when food consumption behaviors and recommendations may have varied from those considered appropriate today. For example, the fortification policy does not address the issue of fortification of foods with fiber, and yet there may be a number of applications of fiber fortification that can be considered rational and appropriate. The same considerations may apply to fortification of foods with food components such as carotenes or the addition of vitamins and minerals for which RDI's are established, to breakfast cereals.

However, to make such changes would require amending § 101.54(e)(1)(ii) and § 101.54(e)(2)(ii) for individual foods and meal-type products, respectively, to specify that rational fortifications other than those described in § 104.20 may qualify for "more" claims. The agency believes that such changes are outside the scope of this proceeding and require additional rulemaking. The agency is, therefore, not making these changes at this time. FDA intends to initiate rulemaking to permit rational fortifications other than those described in § 104.20 to qualify for "more" claims.

15. Many comments were also concerned that the terms "enriched," "fortified," and "added" had been determined by FDA to be synonymous with "more." The comments suggested that the terms "enriched" and "fortified" had never been associated with the term "more," and that equating these terms with "more" is not discussed in the fortification policy. Further, they stated that the historical meaning for "fortified" has generally been that vitamins or minerals have been added during processing—not that the food is better than another food. They said that to prohibit rationally fortified products from using these terms is inconsistent with the valuable role that these foods play in the diet.

Other comments suggested that not all foods heretofore identified as fortified have an added 10 percent of the DV of the subject nutrients. Comments stated that in many instances, including various standards of identity, a level of fortification other than 10 percent of the DV of an added nutrient is specified as the level required for the food to bear the term "fortified." The comments stated that if foods that have rational additions of nutrients do not qualify for the "more" claim, and are, therefore, not able to specify that those nutrients have been "added" to the food or that the food is "fortified," consumers may not be able to distinguish traditionally fortified foods from nonfortified foods. The comments said that as a result, fewer foods, such as cereals and other grain products, will contain rational, beneficial fortifications. This effect, they concluded, would not be in the interest of public health, especially for children and the elderly.

Many comments suggested that the terms "enriched," "fortified," and "added" be permitted on foods containing a total of 10 percent of the relevant DV of the nutrient per reference amount (some of which is added) instead of only being permitted on foods that contain an additional 10 percent of the DV of the nutrient. This step would make the amount of nutrient in foods bearing these claims the same as that for "good source" claims. Other comments suggested that "enriched," "fortified," and "added" be deleted from the final rule.

The agency continues to be convinced that the terms "enriched," "fortified," and "added" are nutrient content claims that must be defined in order to be used. As stated in the nutrient content claims final rule (58 FR 2302 at 2364), the agency believes that the term "added" is related to the term "more" as the term "reduced" is related to the term "less." Both "added" and "reduced" describe differences in the level of a nutrient between two similar foods that result from a manipulation in the level of that nutrient in the food bearing the term. Just as the 1990 amendments required that "reduced" be defined because it is a nutrient content claim, the agency believes that the term "added" must also be defined, or it cannot be used. In addition, as reflected in the agency's fortification policy (§ 104.20(h)(3)) the terms "enriched" and "fortified" are synonymous with "added."

However, the agency recognizes that there are a variety of historical uses of the terms "fortified" and "enriched" to which FDA has not objected even though the food did not bear an additional 10 percent of the DV of a nutrient compared to an appropriate reference food. The terms have come to mean that some level of nutrient was added to a food beyond the level of the nutrient that the particular product would have had were it not fortified or

enriched. Therefore, the agency continues to believe that the terms "added," "enriched," and "fortified" signal a difference in a food either compared to a similar food or compared to itself without the addition of the nutrient. However, unlike "reduced," the unfortified food is often not marketed because of the recognized nutritional benefits that the fortified product has over the unfortified version of the food. Therefore, the agency considers that even though the unfortified version of a food is not marketed, it is the appropriate reference food.

In addition, as discussed in the nutrient content claims proposal (56 FR 60421 at 60453), the agency continues to believe that, consistent with the longstanding provision in § 101.9(c)(7)(v), "No claim may be made that a food is nutritionally superior to another food unless it contains at least 10 percent more of the [Reference Daily Intake (RDI) or Daily Reference Value (DRV)] of the claimed nutrient per serving (portion)." This provision was carried through in the July 19, 1990 mandatory nutrition labeling proposal (55 FR 29487), and the agency retained the concept in the definition for "more," i.e., that a food must contain at least 10 percent more of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium before a comparative claim using the term "more" may be used. The agency went on to explain that at least a 10 percent difference relative to the RDI or DRV is necessary before consumers can be assured that there is truly a difference in the foods being compared. It further said that this finding is consistent with the agency's proposed definition of "[good] source" which the agency ultimately adopted (58 FR 2302 at 2361) and which requires that a nutrient must be present in a food at a level of at least 10 percent of the RDI or DRV before the food can be designated as a "[good] source" of the nutrient.

Therefore, the agency continues to believe that "enriched," "fortified," and "added" appropriately have the same quantitative definitions as the term "more," and that for a food to bear the terms, there must be a 10 percent difference in the amount of nutrient in the labeled food and the reference food. Consequently, the agency is not changing the definition for "more" or its related terms, "enriched," "fortified," and "added."

However, the agency recognizes that the terms "enriched," "fortified," and "added" have historically been used to signal that a nutrient has been added to a food. The agency tentatively considers that it would be appropriate to except from this 10 percent added requirement, the limited circumstances in which the use of the terms "'fortified," "enriched," and "added" have traditionally been used to signal that, through the rational addition of a nutrient, a food contains a significant amount of the specified nutrient, as well as those limited circumstances in which fortifications have been sanctioned by recognized, authoritative scientific bodies or nutrition based organizations e.g., the National Academy of Sciences, or the Women, Infants and Children Program (WIC) of the U.S. Department of Agriculture (USDA). However, to permit a food to be labeled with the terms "added," "fortified," or "enriched" in such circumstances would require additional rulemaking. Such exceptions to the 10 percent added requirement raise significant questions that are beyond the scope of this proceeding. Consequently, the agency is not making these changes at this time. As soon as practicable, FDA intends to initiate rulemaking to permit such fortifications.

The agency notes that section 403(r)(5)(C) of the act exempts claims (e.g., "fortified" and "enriched") that are required by a standard of identity from compliance with the definitions established in part 101, subpart D.

16. Comments requested that the referral statement requirement be eliminated when the terms "fortified," "enriched," and "added" are part of the statement of identity. Other comments requested that the accompanying information not be required because it could be cumbersome and confusing, especially when a wide variety of nutrients are added to a food.

The agency cannot excuse a food that bears a claim, even in the statement of identity, from carrying the referral statement because that statement is required by the statute (section 403(r)(2)(B) of the act). However, identification of the reference food and the information on the difference between the labeled food and the reference food are not specifically required by the statute. In the proposal (56 FR 60421 at 60445), the agency stated that it was necessary to identify the reference food because the amount of a nutrient in a food product, e.g., potato chips, may vary widely. To not provide this information would be to not provide a fact that was material to the understanding of the claim. FDA advises that because the terms "fortified," "enriched," and "added" imply that specific nutrients are added to a specific food, i.e., the unfortified version of the food itself, and because these foods often do not exist in their unfortified form, explicit identification of the reference food does not appear to be necessary because it would not significantly contribute to the understanding of the claim. However, the agency also recognizes that as written, the regulations require identification of the reference. Thus, FDA intends to address this issue in the rulemaking it will initiate on the use of "fortified."

Saturated Fat Free Claims; Second Criterion

17. In the nutrient content claims final rule, the agency added a second criterion for saturated fat free claims, i.e., that the level of *trans* fatty acid not exceed 1 percent of the total fat. This criterion was added because there is increasing scientific evidence that suggests that *trans* fatty acid acts in a similar manner to saturated fat with respect to raising serum cholesterol and, therefore, should be controlled. The agency stated that it would be misleading for products that were labeled "saturated fat free" to contain measurable amounts of *trans* fatty acid because consumers would expect such products to be "free" of components that significantly raise serum cholesterol. The agency stated that 1 percent was the appropriate threshold because analytical methods for measuring *trans* fatty acid below that level are not reliable.

The comments stated that in foods where the total fat content is under 30 g per serving, the 1 percent criterion is 0.3 g. Furthermore, if a cracker or cookie having a serving size of 30 g contained 5 percent fat (1.5 g) it would only be allowed to have 0.015 g of *trans* fatty acids compared to 0.5 g of saturated fat. The comments claimed that these amounts (0.015 g or 0.3 g) cannot be adequately analyzed. The comments suggested that FDA should either eliminate the *trans* fatty acid criterion from the definition of saturated fat free, or that the agency should change it to less than 0.5 g *trans* fatty acid per RACC, an amount that is analyzable and that is consistent with the definition of "free" for fat and saturated fat.

The agency has considered these comments. It did not intend to include a criterion that would, in some cases, not be analyzable. The agency still believes that because there is evidence to suggest that *trans* fatty acid acts in the same manner as saturated fat with respect to serum cholesterol, the level of *trans* fatty acid in those products bearing a "saturated fat free" claim should be limited. However, the agency is persuaded by the comments that the 0.5 g *trans* fatty acid per RACC is an

appropriate second criterion for a saturated fat free claim because this value is analyzable, and it is the same as the value (i.e., a level of 0.5 g) as defined for "saturated fat free" and "fat free." As discussed in the nutrient content claims final rule (58 2302 at 2320), this level is near the reliable limit of detection for a nutrient in a food. In addition, to be consistent with the requirement that free claims be based on a per RACC and per labled serving basis, the agency is persuaded that the *trans* fatty acids should also be less than 0.5g per RACC and per labeled serving for these foods.

Therefore, the agency is modifying § 101.62(c)(1)(i) to require that for products bearing a "saturated fat free" claim, the food contain less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acid per reference amount customarily consumed or, in the case of a meal product or main dish product, that the product contain less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acid per labeled serving.

Lean

18. In the nutrient content claims final rule, FDA adopted the definition of "lean" of the Food Safety and Inspection Service's (FSIS), USDA. FSIS provided that the term "lean" may be used on the label and in labeling for a product that contains less than 10 g of fat, less than 4 g of saturated fat, and less than 95 milligrams of cholesterol per 100 g and per RACC for individual foods and per 100 g and per labeled serving size for meal-type products.

Comments supporting use of the terms "lean" on the labels of meat products and meal-type products persuaded FDA to include a provision in the nutrient content claims final rule consistent with that of FSIS to provide for use of the term "lean" to describe certain comparable foods regulated by FDA under the act. These foods include fishery products and certain types of meat products (e.g., bison, rabbit, and game meats) not regulated by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or in situations in which these products are not subject to USDA regulation.

At the same time, in the mandatory nutrition labeling final rule, FDA defined "saturated fat" (§ 101.9(c)(2)(i)) as the sum of all fatty acids containing no double bonds. This definition was somewhat different from the one that it had previously used, which included only lauric, myristic, palmitic, and stearic acids within the coverage of this term. As a result of the new definition, the number of saturated fatty acids increased, and the declared amount of saturated fatty acid for many foods will be increased.

One comment pointed out that, when FDA adopted the FSIS definitions of "lean," neither agency took into consideration the fact that at the same time the definition of saturated fat was also being changed. The comment contended that the change in definition of saturated fat had the unintended technical consequence that foods, particularly products that contain dairy-based ingredients, that would have qualified to bear the claim "lean" under the old definition may no longer qualify because of the change in the definition.

The agency acknowledges that it did not discuss the effects of adopting a changed definition for "saturated fat" on foods that would be eligible to bear "lean" on labels or in labeling in either the mandatory nutrition labeling final rule or in the nutrient content claims final rule.

FDA agrees that the modification to the saturated fat definition may possibly affect a product's ability to qualify for a "lean" claim which is an unintended effect. The agency has concluded that to avoid changing the universe of products that FSIS envisioned would qualify to bear the term "lean," it should have modified the "lean" definition to reflect the change in the saturated fat definition. To offset this unintended effect, FDA will join with FSIS and increase the saturated fat criterion for the "lean" definition from less than 4 g to 4.5 g or less.

FDA adopted the definition for "lean" and "extra lean" for products that it regulates in the nutrient content claims final rule. In the preamble to that regulation, the agency noted that the data used by FSIS to develop the definitions included nutrient contents of meat, poultry, and fish. Having decided to adopt FSIS' revision to the saturated fat criterion for "lean," FDA has reconsidered both definitions and is now less certain than previously that the definition for "lean," and possibly also "extra lean," developed from data on flesh foods is appropriate for food products that do not contain flesh foods as ingredients. The agency intends to reevaluate its decision and will consider additional rulemaking to reexamine how the terms "lean" and "extra lean" should apply to nonflesh foods.

Environmental Impact Statement

19. Under § 101.69(h), all petitions for nutrient content claims must include either a claim for a categorical exclusion under § 25.24 (21 CFR 25.24) or an environmental assessment under § 25.31 (21 CFR 25.31). However, this requirement was not specifically articulated in each of the individual petition format paragraphs. To be consistent with the petition formats for health claims in § 101.70(f) and food additives in § 171.1(c), and to help ensure that this required information is not omitted from food labeling petitions, the agency is specifically articulating this requirement in §§ 101.69(m)(1), (n)(1), and (o)(1).

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

In the **Federal Register** of January 6, 1993 (58 FR 2431), FDA adopted a new general definition and standard of identity in § 130.10 (21 CFR 130.10) for food named by the use of a nutrient content claim defined in part 101 (such as "fat free," "low calorie," or "light") in conjunction with a traditional standardized name (for example "reduced fat sour cream"). The purpose of the new standard was to assist consumers in maintaining healthy dietary practices by providing for modified versions of certain standardized foods that bear descriptive names that are meaningful to consumers.

The new standard requires, among other things, that the modified versions of the standardized foods: (1) Not be nutritionally inferior, (2) possess performance characteristics that are similar to those of the standardized food, (3) contain a significant amount of any mandatory ingredient required to be in the food simulated, and (4) be made from the same types of ingredients as permitted in the standard for the traditional food, except that ingredients may be used to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness. However, any ingredients that are specifically prohibited by the standard for the traditional food may not be used in the modified version of that food. Section 130.10 provides for the use of water and fat analogs to replace fat and calories but specifically prohibits the replacement of required ingredients of standardized foods with ingredients from a different source. For example, vegetable oil may not replace milkfat in the manufacture of a modified version of sour cream.

20. The agency has received several inquiries regarding § 130.10(d)(3) which states that "an ingredient or a 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" (58 FR 2431 at 2447). Comments claimed that this provision is inconsistent with the policy in § 130.10(b) that requires that nutrients be added to the new food to restore nutrient levels, so that the new food is not nutritionally inferior. One comment suggested that FDA amend § 130.10(d)(3) by adding an exception to allow for compliance with § 130.10(b). The comments contended that without such an exception, no nutritionally improved versions of important products such as peanut butter would be permitted, except when labeled as imitations.

The agency acknowledges that it is arguable that a conflict exists between §§ 130.10(b) and (d)(3). Any conflict that exists was unintended, and is a consequence of the agency's need to develop a general definition and standard of identity for modified foods that would require that such foods resemble the traditional food in as many ways as possible and yet enable these new foods to achieve a nutritional goal. One of the provisions deemed necessary in the general standard was to prohibit the use of substances in the manufacture of the modified food that are prohibited in the traditional standardized food. Unfortunately, it prevents the addition of vitamins in modified peanut butter products. Thus, such food may not be made under the general standard (§ 130.10).

In the case of peanut butter, the standard of identity in § 164.150 states that artificial flavorings, artificial sweeteners, chemical preservatives, vitamins, and color additives are not suitable ingredients for use in the food. According to testimony at the hearings and the resulting findings of fact (33 FR 10506 at 10509; July 24, 1968) when the standard of identity for peanut butter was adopted, addition of vitamins was thought to be unnecessary when peanut butter was consumed as part of a balanced diet.

FDA notes that peanut butter is the only case where a conflict exists with a prohibition of added nutrients and the need to add nutrients to make a modified version of food that is not nutritionally inferior to the traditional standardized food. FDA does not believe that it would be appropriate to make a technical modification of § 130.10 to allow the addition of nutrients to peanut butter as requested by the comments. Amendment of the standard of identity for peanut butter to delete the specific reference to the addition of vitamins in § 164.150(c) could accomplish the same result. This approach would allow the general standard to remain a generic standard applicable to any standardized food. Accordingly, FDA intends to initiate a rulemaking as soon as possible to remove the specific prohibition in the peanut butter standard regarding added vitamins.

In the interim, the agency notes that the common or usual name regulation for peanut spreads in 21 CFR 102.23 permits the manufacture and distribution of modified peanut butter products containing fewer calories and less fat under the name "peanut spread." The peanut spread common or usual name regulation also provides for the addition of nutrients, so that these products will not be nutritionally inferior to peanut butter and thus will not be required to be labeled with the term "imitation."

21. In § 130.10(d)(2) of the general standard, FDA required that "an ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) 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 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream)."

One comment stated that § 130.10(d)(2) should be revised or deleted because this provision and the provision in § 130.1(d)(4) that requires that a significant amount of a mandatory ingredient be present in the modified food have the effect of making the entire regulation unworkable and unusable for a large portion of standardized foods. The comment stated that to make a reduced calorie version of a traditional standardized food, it may be necessary to replace the mandatory sugar ingredient with a noncaloric sweetening ingredient or the mandatory fat with a nonfat ingredient. The comment contended that unless such substitutions are permitted, the new version is impossible to make.

FDA does not believe that a modification of § 130.10(d)(2) is warranted and is not making the requested change. FDA believes that the comment overstated the problem. Water and fat analogs may be used to replace part of the fat required to be in the traditional standardized food, in accordance with § 101.30(d)(5), as long as their use is not prohibited by the standard. Thus, if the standard of identity for the traditional food requires that it contain vegetable oil, the modified reduced fat version of the food must include a significant amount of this ingredient under § 101.30(d)(4), as noted by the comment. This amount must be at least sufficient to achieve its technical effect in the food, e.g., contributing substantially to the food's rheological properties. However, the amount of oil can be significantly reduced over that traditionally used, and the rheological properties of the food achieved by the use of the other ingredient. The agency also recognized, that in making reduced fat versions of traditional standardized foods, manufacturers would need to add other ingredients such as water and fat analogs to counter the loss in creaminess or lubricity provided by the fat component, and it provided for such ingredients in § 101.30(d)(5) of the standard. In addition, as noted in the final rule, removal of the milkfat from ice cream would be acceptable under § 130.10 as long as the product retained its dairy character through the use of nonfat dairy ingredients. However, vegetable oil could not be used to replace the milkfat of traditional dairy products in the manufacture of "reduced cholesterol" or "no cholesterol" dairy products under § 130.10. Consumers consider ice cream to be made from milk products, and they may be misled if vegetable oil is used as a replacement for milkfat in making the modified version of this food.

With respect to the use of nonnutritive sweeteners such as saccharin in modified versions of standardized foods, the agency does not consider these products to be the traditional foods. FDA has established standards of identity for some products made to contain artificial sweeteners, e.g., artificially sweetened canned fruit cocktail in 21 CFR 145.136). Nonstandardized products may be made as special dietary foods under § 105.66 (21 CFR 105.66) and labeled accordingly. Alternatively, manufacturers may petition to amend the standards of identity for the traditional foods to allow for the use of nonnutritive sweeteners as well as nutritive carbohydrate sweeteners, where appropriate.

22. Section 130.10(d)(4) of the general definition and standard of identity requires that an ingredient that is specifically required by the standard of identity as defined in parts 131 through 169 of this chapter shall be present in the modified product in a significant amount. A significant amount of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

Some comments on § 130.10(d)(4) suggested that FDA should remove this paragraph, and others suggested that it should be amended because it adversely

affects manufacturers' ability to produce modified versions (e.g., nonfat, no cholesterol, or sodium free) of standardized foods. To allow manufacturers to make such nonfat or no cholesterol versions of products such as mayonnaise, one comment suggested that § 130.10(d)(4) be modified to read as follows:

An ingredient that is specifically required by the standard as defined in parts 130 through 169 of this chapter, shall be present in the product in a significant amount unless the defined nutrient content claim used as part of the name of the food is generally understood by consumers to be inconsistent with the presence of a significant amount of the ingredient (e.g., "fat free" is inconsistent with the use of vegetable oil or cream). A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

FDA does not agree that removal or modification of § 130.10(d)(4) is necessary. FDA notes that this provision was included in § 130.10 to help to ensure that the modified product made under this standard would not deviate so far from the traditional standardized food as to be misleading to consumers. In addition to requiring that the new food possess similar performance characteristics as the traditional food, i.e., physical properties, flavor characteristics, functional properties, and shelf life, FDA required that ingredients mandated to be present in a food by a standard of identity must also be present in the modified food, and that no ingredients prohibited from use in the standardized food be used.

As stated in the final rule (58 FR 2431 at 2433), the agency believes that consumers expect that a product such as "light mayonnaise" would contain a significant amount of vegetable oil and egg yolk because these ingredients are required to be present in regular mayonnaise. These ingredients are also designated in recipes in cookbooks for making mayonnaise. FDA continues to believe that this provision is necessary to promote honesty and fair dealing in the interest of consumers because it will ensure that a § 130.10 food will bear an appropriate relationship to the traditional standardized food.

FDA acknowledges that some manufacturers may wish to make "nonfat" or "no cholesterol" versions of foods for which standards of identity require that the food contain a certain level of vegetable oil or animal fat, and that they will be prohibited from doing so under § 130.10. However, the agency points out that such foods may be marketed with appropriate labeling. For example, products made to simulate mayonnaise that contain no fat may be labeled with terms such as "mayonnaise dressing," "imitation mayonnaise," or other such name that is not misleading. In the case of products simulating margarine products, but containing no fat or oil ingredient, the term "spread" may be used. In each instance, if the standardized term is used in conjunction with a term such as dressing or spread, the agency would expect that the characteristics of the resulting food would be similar to those of the standardized food so as not to be misleading to consumers.

The agency is also taking this opportunity to modify the provisions for nutrient content claim petitions to correct an editorial error that appeared in the final rule of January 6, 1993. Section 101.69(c) provides that an original petition for a nutrient content claim should be submitted to the agency along with one copy of the petition or a computer readable disk containing the petition. The format provisions for the various types of nutrient content petitions, however, refer to the petition as being in quadruplicate. The amendments below remove "in quadruplicate" from each of the format sections.

III. Economic Impact

FDA has examined the economic implications of this final rule to provide for certain technical amendments to labeling of food, according to the standard in Executive Order 12291 and as required by the Regulatory Flexibility Act (Pub. L. 96–354). The amendments are intended to clarify certain provisions of the regulation and do not add new requirements. Therefore, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. In addition, in accordance with the Regulatory Flexibility Act, FDA has determined that this final rule would not have a significant adverse impact on a substantial number of small businesses.

IV. 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 impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The changes in this document are technical in nature and do not affect the overall intent of the regulation.

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, 21 CFR part 101 is 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 101.2 is amended by revising paragraphs (b) and (f) to read as follows:

§ 101.2 Information panel of package form food.

* * * * *

(b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, subpart D of part 101, and part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

* * * * *

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.13, 101.17, subpart D of part 101, and part 105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to part 10 of this chapter.

3. Section 101.13, effective May 8, 1994, is amended by adding new paragraph (b)(4); by revising paragraphs (d)(2) and (f), the introductory text of paragraph (g), paragraph (g)(1), the parenthetical phrase in paragraph (h)(1); and paragraphs (i)(2), (j)(1)(ii)(B), (l)(1)(ii) introductory text, (m)(1)(ii) introductory text, and (q)(2) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(4) Reasonable variations in the spelling of the terms defined in part 101 and their synonyms are permitted

provided these variations are not misleading (e.g., "hi" or "lo").

* * * * *

(d) * * *

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less than one thirty-second of an inch.

* * * * *

(f) A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

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

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by § 101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with § 101.2(c)(5), in which case the referral statement may be in type of not less than one thirty-second of an inch.

* * * * *

(h) * * *

(1) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form) * * *

* * * * *

(i) * * *

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not "low" in or a "good source" of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch unless the package complies with § 101.2(c)(5), in which case the disclaimer may be in type of not less less than one thirty-second of an inch, or

* * * * *

(j) * * *

(1) * * *

(ii) * * *

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section, or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting label is internally consistent to (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information and the declaration of the percentage of nutrient by which the food has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

* * * * *

(l) * * *

(1) * * *

(ii) Containing not less than three 40-g portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section.

* * * * *

(m) * * *

(1) * * *

(ii) Containing not less than 40 g of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

* * * * *

(q) * * *

(2) A soft drink that used the term "diet" as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Such claims are exempt from the requirements of section 403(r)(2) of the act (e.g., the referral statement also required by § 101.13(g) and the disclosure statement also required by § 101.13(h)). Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current § 105.66 of this chapter and the requirements of § 101.13.

* * * * *

4. Section 101.60 is amended by revising the introductory text of paragraph (a), paragraph (b)(1)(i), and the parenthetical phrase in paragraph (b)(2)(i)(B) and paragraph (c)(1)(i) to read as follows:

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

(a) *General requirements.* A claim about the calorie or sugar content of a food may only be made on the label or in the labeling of a food if:

* * * * *

(b) * * *

(1) * * *

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

* * * * *

(2) * * *

(i) * * *

(B) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form) * * *

* * * * *

(c) * * *

(1) * * *

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii), per reference amount customarily consumed and per labeled serving or, in the case of a meal product or main dish

product, less than 0.5 g of sugars per labeled serving; and

* * * * *

5. Section 101.61 is amended by revising the introductory text of paragraph (a), paragraph (b)(1)(i) and the parenthetical phrase in paragraphs (b)(2)(i)(B) and (b)(4)(i)(B) to read as follows:

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

(a) *General requirements.* A claim about the level of sodium or salt in a food may only be made on the label or in the labeling of the food if:

(b) * * *

(1) * * *

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving or, in the case of a meal product or a main dish product, less than 5 mg of sodium per labeled serving; and

* * * * *

(2) * * *

(i) * * *

(B) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the "as prepared" form) * * *

* * * * *

(4) * * *

(i) * * *

(B) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50-g criterion refers to the "as prepared" form) * * *

* * * * *

6. Section 101.62 is amended by revising paragraph (b)(1)(i), the parenthetical phrase in paragraph (b)(2)(i)(B), paragraph (c)(1)(i), the parenthetical phrase in the introductory text of paragraph (d)(1)(i), paragraph (d)(1)(i)(A), the parenthetical phrase in the introductory text of paragraph (d)(1)(ii), paragraph (d)(1)(ii)(A) and the parenthetical phrase in the introductory text of paragraph (d)(2)(ii), paragraph (d)(2)(ii)(A), the introductory text of paragraph (d)(2)(iv), (d)(2)(iv)(A), the introductory texts of paragraphs (d)(4)(i) and (d)(4)(ii), and paragraphs (e)(1) and (e)(2) to read as follows:

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

* * * * *

(b) * * *

(1) * * *

(i) The food contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving or, in the case of a meal product or main dish product, less than 0.5 g of fat per labeled serving; and

* * * * *

(2) * * *

(i) * * *

(B) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

* * * * *

(c) * * *

(1) * * *

(i) The food contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acid per reference amount customarily consumed and per labeled serving, or in the case of a meal product or main dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acid per labeled serving; and

* * * * *

(d) * * *

(1) * * *

(i) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed and per labeling serving or, in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving; and

* * * * *

(ii) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed and per labeling serving or, in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving; and

* * * * *

(2) * * *

(ii) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

(A) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

* * * * *

(iv) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

(A) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

* * * * *

(4) * * *

(i) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

(ii) * * * (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 101.9(f), per reference amount customarily consumed of all nutrients, the per 50-g criterion refers to the 'as prepared' form) * * *

* * * * *

(e) *"Lean" and "extra Lean" claims.* (1) The term "lean" may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m) provided that the food contains less than 10 g total fat, 4.5 g or less saturated

fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

* * * * *

7. Section 101.69 is amended in paragraphs (m)(1), (n)(1), and (o)(1) by removing ", in quadruplicate," from the second paragraph in the letter, and by adding a new paragraph "E." to paragraph (m)(1), and a new paragraph "C." to paragraphs (n)(1) and (o)(1) before the phrase "Yours very truly," to read as follows:

§ 101.69 Petitions for nutrient content claims.

* * * * *

(m) * * *

(1) * * *

E. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

* * * * *

(n) * * *

(1) * * *

C. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

* * * * *

(o) * * *

(1) * * *

C. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Dated: August 10, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–19610 Filed 8–12–93; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Parts 5, 101, 105, and 130

[Docket Nos. 90N–0134 et al.]

RIN 0905–AD08 and 0905–AB68

Food Labeling: Establishment of Date of Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is modifying the date of applicability of the mandatory nutrition labeling and nutrient content claims provisions of the Federal Food, Drug, and Cosmetic Act (the act), which were added by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). Although the date, May 8, 1994, remains the same, under this modification it will apply to all food products labeled on or after May 8, 1994, rather than to all food products initially introduced into interstate commerce on or after that date. This action is in accordance with section 10(a)(3)(B) of the 1990 amendments, which allows the Secretary of Health and Human Services (the Secretary) (and by delegation, FDA) to delay, for up to 1 year, the date on which FDA will enforce any section if undue economic hardship would result.

DATES: FDA will apply section 403(q) and 403(r)(2) of the act and the regulations that implement this section of the act (21 CFR 101.9 implements section 403(q) except 403(q)(4) of the act; 21 CFR 101.13, subpart D of 21 CFR part 101, and 21 CFR 130.10 implement section 403(r)(2)) on May 8, 1994, for all products labeled on or after that date.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–151), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(q) (nutrition labeling) and 403(r)(2) (nutrient content claims) of the act are effective May 8, 1993. However, under section 10(a)(3)(B) of the 1990 amendments, the Secretary may delay the application of that section of the act for up to 1 year if it is found that compliance with it by that date would cause an undue economic hardship. On January 6, 1993, in a final rule entitled "Food Labeling: Establishment of a Date of Application" (58 FR 2070) (hereinafter referred to as "the date of application final rule"), FDA made this finding and announced that it would delay application of those sections until May 8, 1994, at which time all foods introduced into interstate commerce would have to comply.

Although the 1990 amendments require that regulations implementing section 403(q) and 403(r)(2) of the act be promulgated 24 months after the date of their passage (see sections 2(b)(2) and 3(b)(2) of the 1990 amendments), they are silent as to when they are to be effective. For consistency of implementation, FDA made the regulations implementing these sections of the act effective on their date of applicability, that is, May 8, 1994.

The agency advised that compliance could begin immediately with these regulations, which include: (1) Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Labeling (Docket Nos. 90N–0135, 91N–0162, 78P–0091, 87P–0194/CP, and 90P–0052) (58 FR 2079); (2) Food Labeling: Reference Daily Intakes and Daily Reference Values (Docket No. 90N–0134) (58 FR 2206); (3) Food Labeling; Serving Sizes (Docket No. 90N–0165) (58 FR 2229); (4) Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food (Docket Nos. 91N–0384 and 84N–0153) (58 FR 2302); (5) Food Labeling: Use of Nutrient Content Claims for Butter (Docket No. 91N–0344) (58 FR 2448); (6) Food Labeling: Label Statements on Foods for Special Dietary Use (Docket No. 91N–384L) (58 FR 2427); and (7) Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term (Docket No. 91N–0317 et al.) (58 FR 2431). The agency stated, however, that "[A]ll products initially introduced into interstate commerce on or after May 8, 1994, shall comply" with the requirements of these final rules.

II. Technical Issue Comments

In the **Federal Register** of January 6, 1993 (58 FR 2066), FDA also issued a final rule entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments" (hereinafter referred to as "the implementation final rule"). The implementation final rule, among other things, provided 30 days, until February 5, 1993, for the submission of comments on technical matters or unintended technical consequences of specific provisions of the regulations. FDA advised that it was not interested in receiving comments that it had already considered, and thus it required that interested persons certify that their comments focused solely on the type of technical matters outlined by the agency. FDA further advised that if the comments identified any technical provisions of the final rules that the agency ultimately agreed should be changed, the agency would take action to modify those provisions. FDA stated that this approach would enable it to quickly address any unintended effects of the final rules, yet not delay the finality that is imperative for both industry and consumers.

Following publication of the date of application final rule, FDA received 12

letters from industry and industry associations that argued that even though the agency intended to delay the date that it would apply the final rules on nutrition labeling and nutrient content claims for a full year, the approach that the agency took in the date of applicability final rule would not have that effect. By linking the delay in application to the date that product was introduced into interstate commerce rather than the date the food is labeled, the comments argued, the agency would force firms to begin to apply the new labels well in advance of the date that FDA said that it expected compliance to begin.

The comments said that processed fruits, vegetables, fish, and other foods that are of a seasonal nature would be most directly affected by the agency's action with respect to the applicability date. The comments pointed out that these products are often labeled months before they are introduced into interstate commerce. For example, the comments pointed out that under the date of application final rule, seasonal products packed in the summer of 1993 would have to be labeled in accordance with the new rules because some of these products were intended to be introduced into interstate commerce after May 8, 1994. The comments argued that such a result would completely undercut the agency's purposes in delaying the applicability date of the final rule. One comment from a manufacturer of seasonal products noted that if this approach were adopted by FDA, at least 50 percent of its 1993 pack would bear the old label and those products not distributed by May 8, 1994, would either have to be destroyed or relabeled.

Other comments pointed out that the economic impact analysis was understated as to the cost the new labeling requirements would have on the food industry because the cost data submitted by industry had been based on the presumption that products labeled up through May 7, 1994, could continue to be sold.

Several comments argued that the language "All products initially introduced into interstate commerce on or after May 8, 1994, shall comply" is not consistent with the 1990 amendments or with the intent of Congress. These comments interpreted section 10(a)(2) of the 1990 amendments, which states that section 403(q) and 403(r) of the act shall not apply to food that was labeled before the effective date of the amendments made by sections 2 and 3 of the 1990 amendments, to mean that section 403(q) and 403(r)(2) of the act shall not apply to food labeled before the effective date of the implementing regulations, regardless of the effective date chosen by FDA. Moreover, some of the comments stated that the term "initially introduced into interstate commerce" is confusing (i.e., whether it applies to a product that has actually crossed a State line or has simply been identified for interstate shipment). These comments also expressed concern about the difficulty in determining when introduction into interstate commerce actually occurs and the use of the term for enforcement purposes. Depending on the interpretation, the comments noted that large manufacturers had an advantage over small firms because they could gain exemption for a product from the new labeling requirements by moving it before the effective date to an interstate warehouse for subsequent distribution, something that many smaller firms do not have the capacity to do. Thus, the comments argued that the term creates an "unlevel playing field" for the various food manufacturers.

All of the comments stated that applying the effective date to products labeled on or after May 8, 1994, would provide a more even-handed approach to the implementation of the new labeling requirements and also provide for more efficient enforcement.

The agency has carefully considered the issue raised by these comments. FDA does not agree that section 10(a)(2) of the 1990 amendments means that section 403(q) and 403(r)(2) of the act do not apply to food labeled before the effective date of the implementing regulations. While section 10(a)(2) of the 1990 amendments does state that section 403(q) and 403(r)(2) of the act are not to apply to food labeled before the effective dates of the amendments made by sections 2 and 3 of the 1990 amendments, section 10(a)(1)(A) and 10(a)(1)(B) of the 1990 amendments specify those dates. They state that the amendments made by sections 2 and 3 shall take effect 6 months after the date of promulgation of all final regulations required to implement section 403(q) and 403(r) of the act or, if such regulations are not promulgated, 6 months after the date proposed regulations are to be considered as such final regulations; that is, 6 months after November 8, 1992.

Therefore, the date on which the amendments made by sections 2 and 3 of the 1990 amendments took effect is May 8, 1993. The 1990 amendments do not provide for extending the effective date of these amendments. Section 10(a)(3)(B) states, however, that the Secretary may delay the application of section 403(q) and 403(r)(2) for no more than 1 year. Neither the 1990 amendments nor their legislative history state how the agency should implement such a delay. Moreover, as stated above, the 1990 amendments are silent as to the date that the regulations implementing section 403(q) and 403(r)(2) of the act are to be effective.

Traditionally, FDA has implemented the effective date of a statutory provision of a regulation, unless otherwise directed by law, by relating it to the initial introduction of a product into interstate commerce (e.g., see "Uniform Compliance Date for Food Labeling Regulations; Notice to Manufacturers, Packers, and Distributors" (55 FR 276, January 4, 1990)) because the authority of the act extends to products shipped in interstate commerce. The agency took this traditional approach in the date of application final rule.

After review of the various comments, however, FDA has reconsidered whether to employ this approach in applying section 403(q) and 403(r)(2), using the principles set out in § 10.33 (21 CFR 10.33) as guidance. Based on the comments, FDA recognizes that applying section 403(q) and 403(r)(2) of the act to all foods introduced into interstate commerce after May 8, 1994, will not provide the full effect that FDA intended in delaying the application of these sections.

First, making compliance turn on the date that food enters interstate commerce will mean that large firms will have a greater opportunity to take advantage of the delay than small firms because small firms generally have more limited distribution systems. The delay in application of section 403(q) and 403(r)(2) of the act was intended, however, to provide relief, in large measure, to small firms. Thus, the "date introduced into interstate commerce" formulation of the date of application does not advance the purposes of the delay.

Basing the date of application on the date of labeling will result in a more equitable application of the regulations because it will mean that the date of application will turn simply on the date that the food is labeled and not on access to a distribution system. Thus small firms will have a greater opportunity to participate in the delay under such a formulation than under that provided in the date of application final rule.

Making the date of application turn on the date of labeling will also be easier to enforce than if it turned on the date of introduction into interstate commerce. A particular lot of a food

product may be introduced into interstate commerce on a series of dates over a period of time. Thus, a lot that bears proper labeling at the time that distribution begins may at some point in its life become misbranded, unless it is relabeled. Such a result would in no way help to ease the undue economic hardship that the delay in applicability was intended to address.

Finally, the agency recognizes that a change in the applicability date (and thus the date that the regulations are to be effective) will mean that all packers, including seasonal packers, will have the benefit of the full 1-year delay in the application of section 403(q) and 403(r)(2) of the act that the agency has determined appropriate under section 10(a)(3)(B) of the 1990 amendments (58 FR 2070 at 2075).

The agency acknowledges that a change in the definition of how the applicability date will be administered will result in some delay in the time that all products appearing on the grocery shelf will be labeled in complete conformance with the new regulations. However, FDA believes that the effects of this delay will have minimal impact in terms of either consumer confusion or public health consequences. The agency points out that products have already begun to appear in the marketplace with labels conforming to the new nutrition labeling requirements. The agency also points out that under either the "introduced into interstate commerce" or "labeled before" effective date formulation, there will be a period of time in which products labeled according to the two different regulatory requirements will be in the marketplace. These products will, primarily, be those with long shelf lives that are either introduced into interstate commerce or labeled just before the effective date. Therefore, under any possible scenario, there will be a transition period during which products labeled in conformance with the two different regulatory requirements will be in the marketplace simultaneously.

Consumers will have some time to become accustomed to this situation, and FDA food label education materials explain to consumers that two different labels will be on the market at the same time and provide instructions in how to distinguish the new label. Therefore, the additional incremental delay in new label appearance being introduced by this document should not result in any significant increase in potential consumer confusion. The agency also points out that the primary beneficiaries from this delay, that is, processed fruits, vegetables, fish, and other foods that are of a seasonal nature, will begin applying the new labels as the packing season of the summer of 1994 progresses and the new labels will appear in the market only a few months after the May 8, 1994, effective date.

Therefore, based on the public interest and consideration of justice, FDA has reconsidered the applicability date for section 403(q) and 403(r)(2) of the act and the effective date of the regulations implementing those provisions (§ 10.33(d)). Based on the factors discussed above, FDA has decided that it will apply that section of the act, and that the regulations implementing it will be effective, to all products that are labeled after May 8, 1994 (§ 10.33(d)). The term "labeled" means the date that the label is affixed to the product or product container.

III. Economic Impact

The agency agrees that the regulatory impact analysis (RIA) that it published in the **Federal Register** of January 6, 1993, did not consider the cost to industry caused by applying the effective date based on the date of introduction into interstate commerce (58 FR 2927, January 6, 1997). In reviewing the information submitted in response to the proposals and the RIA of November 27, 1991 (56 FR 60366 *et seq.*), the agency recognizes that the data and information submitted did not anticipate the manner in which the agency would apply the effective date for the regulations implementing section 403(q) and 403(r)(2) of the act. Although the technical issue comments contained only minor amounts of information and data concerning the costs of the application of the effective date, FDA has assessed the potential costs of the action being implemented in this final rule.

In the date of application final rule, the agency concluded, based on its review of available data and comments, that the costs of the overall food labeling reform initiative will be reduced by nearly one-half (a cost savings of approximately $700 million) by extending the date for compliance with the food labeling requirements to May 8, 1994. Further, the agency concluded that action will significantly alleviate the economic hardship that would otherwise result if section 403(q) and 403(r)(2) of the act were made applicable, as proposed, on May 8, 1993.

Technical issue comments to the date of application final rule expressed concern that the application of the May 8, 1994, effective date to products initially introduced into interstate commerce on or after May 8, 1994, was inconsistent with congressional intent, unfair to small business, and created a hardship for firms manufacturing foods of a seasonal nature. Only limited information was presented as to the economic costs that would occur because of the application of the effective date to the date of introduction into interstate commerce. Based on its review of this information and the technical issue comments, the agency finds that changing the application of the effective date so that it applies to the date of labeling of food products will result in the full reduction of costs that FDA projected. Based on the information presented in the technical issue comments, FDA believes that a major result of the modification of the application of the effective date will be to provide industry with greater flexibility in the scheduling of their steps to implement the requirements of FDA's labeling regulations. Although no information was presented that would enable the agency to assess the impact that modifying the application of the effective date would have on potential benefits from the food labeling reform initiative, the agency believes that the effect will be minimal.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in its final rules establishing requirements under the provisions of the 1990 amendments. As announced in the final rules for nutrition labeling (58 FR 2066 *et seq.*, January 6, 1993), the agency determined that, under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither and environmental assessment nor an environmental impact statement was required. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental assessment or environmental impact statement is not required.

Dated: August 3, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–18888 Filed 8–12–93; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 101

[Docket Nos. 85N-0061, 91N-0098, 91N-0099, and 91N-0100]

RIN 0905-AB67, 0905-AD08

Food Labeling; Health Claims: General Requirements; Fiber-Containing Fruits, Vegetables, and Grain Products and Cancer and Coronary Heart Disease; Fruits and Vegetables and Cancer; and Folic Acid and Neural Tube Defects; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations concerning the use of health claims in food. On January 6, 1993, the agency published a document entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments." The document gave interested persons an opportunity to comment on technical issues not raised in earlier comments pertaining to food labeling regulations on health claims. This document responds to technical comments that the agency received in response to that document and corrects inconsistencies and unintended technical consequences of those regulations.

EFFECTIVE DATE: These technical amendments are effective August 18, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1993 (58 FR 2478), FDA published a final rule to adopt general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of foods in conventional food form, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in such food. This action was taken in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535) that bear on health claims for conventional foods. At the same time, the agency announced its decisions about health claims on 10 disease-nutrient relationships specified in the 1990 amendments.

In the **Federal Register** of April 1, 1993, FDA published corrections of typographical and editorial errors in its final rules implementing the 1990 amendments, including the regulations on general requirements for health claims for food (58 FR 17097), on folic acid and neural tube defects (58 FR 17099), and on dietary fiber and cardiovascular disease (58 FR 17100). The correction notices did not address comments on technical matters or technical unintended consequences of the final rules.

II. Technical Issue Comments

In the **Federal Register** of January 6, 1993 (58 FR 2066), FDA also issued a final rule entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments" (hereinafter referred to as "the implementation final rule"). The implementation final rule provided 30 days for interested persons to comment on technical issues arising in any of the final rules implementing the 1990 amendments. FDA advised that it was not interested in receiving comments that it had already received and considered. FDA urged interested persons to limit their comments to technical matters and to technical unintended consequences of specific provisions not raised in earlier comments. In order to ensure consideration of any comments, FDA directed interested persons to certify that their comments were so limited. FDA further advised that if the comments identified any technical provision of the final rules that FDA agrees should be changed, FDA would take action to modify that provision. FDA stated that this approach would enable it to quickly address any unintended effects of the final rules, yet not delay the finality that is imperative for both industry and consumers.

After publication of the general requirements for health claims final rule and the 10 health claim final rules, FDA received approximately 150 submissions on these rules from industry, consumers, and other interested persons each containing one or more comments. FDA has determined that 22 of the 150 comments qualify in whole or part as comments on technical issues as described in the implementation final rule and is responding below to the specific technical issues that the comments raised. Those issues that do not qualify as technical issue comments, or are otherwise not relevant to this rulemaking, are not discussed below. Because the changes FDA is making in these final rules are technical in nature and are based on a full prior opportunity for comment, the agency finds that further opportunity of public comment on them is unnecessary.

III. Technical Corrections

A. Section 101.14

In the final document on health claims general requirements (58 FR 2478), § 101.14(e)(6) (21 CFR 101.14(e)(6)) prohibits health claims on the label or labeling of a food in conventional food form unless the food contains 10 percent or more of the Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

1. One comment stated that, in the preamble to the nutrient content claims final rule (58 FR 2302 at 2326), the agency indicated that the claim "useful only in not promoting tooth decay" is an unauthorized health claim, thus suggesting that a health claim petition should be submitted for such a statement. The comment noted, however, that virtually none of the sugar-free products on the market would qualify for a health claim based on the requirements of § 101.14(e)(6).

FDA acknowledges that certain food products that have been specially formulated relative to a specific disease condition such as dental caries may be determined to be appropriate foods to bear a health claim but be foods of limited nutritional value. Although not stated in the preamble to the final regulation on general requirements for health claims, it was the agency's intention that such situations be dealt with in the regulations authorizing specific health claims. That is, an exception to the general principle expressed in § 101.14(e)(6) could be granted by regulation, but limited to a specific health claim. Therefore, to clarify this, FDA is adding to § 101.14(e)(6) the phrase "* * * or where provided for in regulations in part 101, subpart E."

2. Comments received on § 101.14(e)(6) indicated concern about the phrase "prior to any nutrient addition." Some comments stated that FDA made it clear in the proposal that it was focusing on foods such as candies, soft drinks, and snack foods (56 FR 60537 at 60556 and 60557, November 27, 1991), and that the final regulation, because of its apparent comprehensiveness, is inconsistent with the intent expressed in the preamble. Several comments stated that this paragraph is very restrictive and will

prohibit health claims on certain breads and other products that are consistent with dietary guidelines for Americans. One comment requested clarification of the paragraph, asking which foods it applies to and the basis for precluding fortification of a food making a health claim to achieve a nutritional benefit which is incidental to the health claims benefit. The comment noted that the paragraph applies more broadly than explained in the preamble and may preclude health claims on much larger categories of foods than candies, soft drinks, and snacks. According to the comment, an unintended consequence of this rule may be the elimination from the diet of nutritionally important foods recommended by the U.S. Dietary Guidelines. The comment recommended that enriched, restored, and fortified foods should be excluded from the reach of this regulation. One comment stated that health claims should be based on appropriate fortification; otherwise, there is no incentive for industry to add important nutrients, such as calcium, to improve the nutritional quality of products or restore nutrients lost in processing. Many comments suggested that FDA needs a more flexible fortification policy. In particular, some comments noted that there is no scientific reason to distinguish between naturally present nutrients and those added pursuant to a policy of rational fortification. Some comments agreed with FDA that it is appropriate that foods bearing health claims should be those consistent with current dietary guidelines.

FDA considers the changes requested by the comments to be beyond the scope of this rulemaking. Interested persons who believe that § 101.14(e)(6) is scientifically inappropriate may petition the agency to revoke or amend the regulation.

The agency recognizes that the issues surrounding fortification—including what might be considered rational fortification with nutrients not addressed in FDA's fortification policy (21 CFR 104.20)—are complex. However, some of the comments misinterpret § 101.14(e)(6). With that regulation, FDA sought to prevent the fortification of food of little or no nutritional value for the sole purpose of qualifying that food for a health claim (58 FR 2478 at 2522). In the preamble to the final rule (58 FR 2522), FDA "stresse[d] that the exclusion of fortification pertains only to fortification to specifically meet the requirements of this provision and not to fortification of the food itself." A food that has traditionally been formulated in accordance with the fortification policy (or one that meets a standard of identity that includes fortification), and that, in that form, contains 10 percent or more of the RDI or DRV for vitamin A, vitamin, C, iron, calcium, protein, or fiber per reference amount customarily consumed, would not be precluded by § 101.14(e)(6) from being fortifed to qualify for a health claim.

The agency disagrees that an unintended consequence of this rule may be the elimination from the diet of nutritionally important foods recommended by the U.S. Dietary Guidelines. As stated in the preamble to the final rule, "Based on a review of the regulatory food composition data base, the agency notes that most foods consistent with dietary guidelines meet [the criterion in § 101.14(e)(6)]." (58 FR 2522).

B. Sections 101.76, 101.77, and 101.78

Section 101.76(c)(ii)(C) (21 CFR 101.76(c)(ii)(C)) specifies that a fiber-containing grain product, fruit, or vegetable bearing a health claim related to cancer and diets high in such foods must meet, without fortification, the nutrient content requirements of § 101.54 (21 CFR 101.54) for a "good source" of dietary fiber. Also, § 101.77(c)(ii)(C) (21 CFR 101.77(c)(ii)(C)) requires that such products contain, without fortification, at least 0.6 grams (g) of soluble fiber per reference amount customarily consumed when making a health claim relating diets high in such foods to a reduced risk of coronary heart disease. Additionally § 101.78(c)(ii)(C) (21 CFR 101.78(c)(ii)(C)) specifies that fruit and vegetable products bearing a health claim relating diets high in such foods to reduced risk of cancer must meet, without fortification, the nutrient content requirements of § 101.54 for a "good source" of at least one of the following: dietary fiber, vitamin A, or vitamin C.

3. Comments submitted to §§ 101.76 and 101.77 requested clarification of the term "without fortification" as used in these final regulations. One of the comments also requested confirmation that the use of fiber-containing ingredients in bakery products that already contain fiber does not constitute "fortification." Another comment stated that, in the agency's discussion of dietary fiber in its final rule on mandatory nutrition labeling, FDA equated "fortification" with "supplementation," a definition that connotes an addition to a fiber source so that the resulting level of fiber in that source exceeds the indigenous level (58 FR 2079 at 2096). The comment asked FDA to clarify that the combination of multiple grains in a food, each of which contains an indigenous level of fiber, is not "fortification" as the agency used the term in its final rule.

In developing the criteria for the health claims related to cancer and fiber-containing grain products, fruits, and vegetables, and to coronary heart disease and fiber-containing fruits, vegetables, and grain products, a prime consideration for the agency was that the scientific evidence supports health claims for foods and dietary patterns rather than for specific nutrients. Further, there is strong reason both for allowing claims only for foods high in fiber and for prohibiting claims if they give the impression that dietary fiber, as a single nutrient, is responsible for the benefit. This is based on the conclusion that, even where the scientific evidence is strongest, it is not possible to separate the effects of fiber from those of other components of the diet.

Thus, consistent with the scientific evidence, the agency limited these claims to those grain products, fruits, and vegetables containing a "good" source of dietary fiber per reference amount in the case of cancer-related health claims (58 FR 2537 at 2545 and 2622 at 2636) and to those fruits, vegetables, and grain products containing at least 0.6 g of soluble fiber per reference amount for claims related to coronary heart disease (58 FR 2552). The agency then addressed the issue of fiber as an ingredient as opposed to naturally occurring fiber. Both §§ 101.76 and 101.77 stipulate that foods must qualify for the claim based on their natural level of fiber. The agency indicated that the purpose of this requirement was to preclude the use of claims on foods that required fortification in order to meet the qualifying criteria (58 FR 2537 at 2545 and 2552 at 2574). The agency explained that this requirement is consistent with the scientific basis for the claim; that is, that grains, fruits, and vegetables in their native form correlate with the health effects. FDA further explained that, because there are not sufficient data that specifically identify dietary fiber, or particular components of fiber, as causal and because this nutrient is being used as a marker for the substance or substances in grain products, fruits, and vegetables, that provide the observed protective effect, it is the native composition of the foods that identifies their usefulness. The agency also noted that, at the same time, this requirement does not prohibit fortification of qualifying foods with dietary fiber, once the qualifying level has been met naturally.

Therefore, FDA stipulated in the final rule that foods must meet the qualifying criteria for fiber content without fortification. The agency recognizes that this provision, which excludes fortified foods, may have prohibited claims on foods that could be determined to appropriately bear a health claim related to the specific health conditions. However, the provision is derived from the scientific evidence and from the standard established for determining the basis for health claims. It was the agency's clear intention to provide for this restriction in the final rule. To reevaluate the issue is beyond the scope of the technical corrections addressed in this document.

IV. Minor Clarifications to the Preambles to the Regulations

4. One comment stated that, under section VI.C. "Inappropriate Levels of Other Substances" in the preamble to the general requirements final regulation (58 FR 2478 at 2520), FDA incorrectly indicated that it did not receive any comments on the proposed regulation to prohibit claims for any food where a substance, other than one for which a disqualifying nutrient level is established, is present at an inappropriate level as determined in the specific provision authorizing the claim in part 101, subpart E. The comment noted that it had submitted a comment opposing this provision. The earlier comment stated that Congress gave the agency great flexibility to make exceptions to the disqualifying level requirements where an otherwise prohibited health claim would assist consumers in maintaining sound dietary practices. Further, the comment stated that the proposed approach would reintroduce an undesirable degree of inflexibility by barring health claims for foods that have levels of other substances not identified by Congress as creating special risks. The comment concluded that, if the agency adopts such an approach, it should be willing to grant exceptions to disqualification with respect to foods having inappropriate levels of these other substances.

FDA notes that the above comment was received and was inadvertently overlooked. The agency has now reviewed the comment, but concludes that it does not require a change in the final regulation. The agency has explained that § 101.14(e)(4) is intended to prevent health claims from appearing on foods that contain substances other than the substance that is the subject of the claim if any of those other substances, although not harmful in their own right, could interfere with the claimed effect on the risk of disease (56 FR 60555 through 60556, November 27, 1991; 58 FR 2520, January 6, 1993). It is not the agency's intent to apply § 101.14(e)(4) rigidly.

5. One comment stated that section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)) is "limited to disease prevention (health) claims that relate to a 'nutrient.'" The comment made three points: (1) In § 101.14, FDA is exceeding the statutory scope of that specific provision to the extent that FDA interprets this section to refer to disease prevention claims that relate to food in general; (2) the agency is blurring the distinction between disease prevention claims for specific nutrients and dietary guidance for food in general; and (3) not all dietary guidance that relates food categories to disease prevention requires a specific regulation.

FDA disagrees with the comment's interpretation of section 403(r) of the act as applying to disease prevention claims. "Disease prevention" claims are not within the scope of the final health claim regulations. A product that is intended to prevent disease is a drug under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)).

FDA defined the term "health claim" in § 101.14(a)(1) as, in part, any claim on the label or in labeling of a food that characterizes the relationship of any substance to a disease or health-related condition. For the sake of clarity, the agency uses the term "dietary guidance" to refer to claims that do not contain both basic elements of a health claim (i.e., a substance and its relationship to a disease or health-related condition) (58 FR 2478 at 2487). The agency believes it adequately addressed the remaining issues raised in this comment in the preamble to the final rule see, e.g., 58 FR 2479 through 2480, and 2487.

6. One comment noted that, in section IV.B.4 of the preamble to the folic acid and neural tube defects final rule (58 FR 2606 at 2617), the agency stated that products containing 800 micrograms (µg) of folic acid were drugs. The comment stated that 800 µg of folic acid is the U.S. RDA for pregnant and lactating women.

The agency agrees that products containing 800 µg of folic acid are not necessarily drugs. Section 172.345 states that folic acid may be safely added to food specified for pregnant or lactating women for its vitamin property provided that the maximum daily ingestion will not exceed 8 milligrams. The agency intends to address the issue of folic acid further in future rulemaking.

V. Economic Impact

FDA has examined the economic implications of this final rule to provide for certain technical amendments to the health claims regulations for food, according to the standard in Executive Order 12291 and as required by the Regulatory Flexibility Act (Pub. L. 96-354). The amendments are intended to clarify certain provisions of the regulation and do not add new requirements. Therefore, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. In addition, in accordance with the Regulatory Flexibility Act, FDA has determined that this final rule would not have a significant adverse impact on a substantial number of small businesses.

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 impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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, 21 CFR part 101 is 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 101.14 is amended by revising paragraph (e)(6) to read as follows:

§ 101.14 Health claims: general requirements.

* * * * *

(e) * * *

(6) Except for dietary supplements not in conventional food form or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

* * * * *

Dated: August 6, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–19447 Filed 8–12–93; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 101

[Docket No. 90N–0165

RIN 0905–AD08

Food Labeling; Serving Size; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is making technical revisions to the regulations that established the general rules for declaring serving sizes as part of the nutrition label. In January 1993, the agency published a document entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments" that gave interested persons 30 days to comment on technical issues not raised in earlier comments pertaining to nutrition labeling. This document addresses the comments received and corrects unintended technical consequences of the final rule.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5662.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1993 (58 FR 2229), FDA issued a final rule entitled "Food Labeling; Serving Sizes" (hereinafter referred to as "the serving size final rule"). The final rule amended the agency's nutrition labeling regulations to: (1) Define "serving size" as the amount of food customarily consumed per eating occasion, (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 139 food product categories, (3) provide procedures for using the reference amounts to determine serving sizes for use on product labels, (4) require the use of both common household and metric measures to declare serving sizes, (5) define "single-serving containers," (6) require that the use of claims be based on the reference amount, (7) permit the declaration of serving size in U.S. measures, and (8) permit the optional declaration of nutrient content per 100 grams (g) or 100 milliliters (mL).

II. Technical Issue Comments

In the same issue of the **Federal Register**, FDA issued a final rule entitled "Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments" (58 FR 2066) (hereinafter referred to as "the implementation final rule"). The implementation final rule, among other things, provided 30 days for the submission of comments on technical issues. FDA advised that it was not interested in receiving comments that it had already received and considered. FDA urged interested persons to limit their comments to technical matters and to technical unintended consequences of specific provisions that they had not raised in earlier comments. To ensure consideration of any comments, FDA directed interested persons to certify that their comments were so limited. FDA further advised that if the comments identified any technical provisions of the final rules that the agency agrees should be amended, FDA would take action to do so. FDA stated that this approach would enable it to quickly address any unintended effects of the final rules, yet not delay the finality of these rules.

Following publication of the serving size final rule, FDA received 15 letters containing 1 or more comments, from industry, consumers, and other interested parties, and over 1,000 telephone calls and other communications on this document. Approximately 10 percent of these communications submitted technical issue comments or raised technical issues as described in the implementation final rule. FDA is responding below to the specific technical issues that the comments raised. Those issues that do not qualify as technical issue comments or are otherwise not relevant to this rule making are not discussed below. Issues that are not merely technical in nature should be the subject of petitions to the agency for further rulemaking. Because the changes FDA is making in these final rules are technical in nature and are based on a full prior opportunity for comment, the agency finds that further opportunity for public comment on them is unnecessary.

III. Technical Corrections

1. One technical comment requested that § 101.9(b)(2)(i) (21 CFR 101.9(b)(2)(i) be further divided into paragraphs to make it easier to interpret. FDA acknowledges that the inclusion of a variety of specifications in one paragraph may be confusing and has therefore subdivided § 101.9(b)(2)(i). The agency has also reordered some of the information and made minor editorial changes in it to improve its comprehensibility. For example, in new § 101.9(b)(2)(i)(B), FDA has made it explicit that for products that are in discrete units that contain between 50 and 67 percent of the reference amount, the manufacturer may declare the serving size as either 1 or 2 units.

2. Several comments asked how to treat products made up of distinct and separate foods packaged together in the same container and intended to be consumed together.

In the mandatory nutrition labeling final rule ("Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label" (58 FR 2079 at 2184)), FDA specified in § 101.9(h)(1) that when separately packaged ingredients are intended to be eaten at the same time, the nutrition information may be specified per serving for each component or, alternatively, as a composite value. This approach was inadvertently omitted in the serving size regulation, and thus no provision for these types of serving size declarations is available. Thus, FDA recognizes that it needs to address how to declare serving sizes for these products when the manufacturer chooses to list the nutrition information separately for each component.

Products that consist of two or more ingredients packaged together and presented as a single product include "complete" products, such as chow mein components in multiple cans and pizza mix with a prepared crust, and mixes and kits with separate packets that require the addition of water or other ingredients, such as macaroni and cheese mix (pasta and cheese packets), stir-fry kits (sauce, vegetables, rice, and noodles packets), cake mix kits (mix, filling, frosting, nuts, and fruit packets), and salad kits (dressing, croutons, grated cheese, and bacon bits packets). Also included among these types of products are products that are distinct and separate foods packaged together in the same container and intended to be consumed together (e.g., pancakes with syrup, chips and dip).

First, for a number of these products, the serving size can be expressed as the amount of the main ingredient plus proportioned minor ingredients based on the "reference amount for the combined product" (see § 101.12(f)). For example, the "reference amount for the combined product" calculated for a