paragraph (d) of this section and shall state:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement.* The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize.* The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

Dated: September 11, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24730 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 95N–0245, 95N–0282, and 95N–0347]

RIN 0905–AD96

Food Labeling; Nutrient Content Claims: Definition for ''High Potency'' and Definition of ''Antioxidant'' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: Define the term ''high potency'' as a nutrient content claim; define nutrient content claims using the term ''antioxidant'' (e.g., ''good source of antioxidants,'' ''high in antioxidants,'' ''more antioxidants''); and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements. FDA is taking these actions to provide for the use of additional nutrient content claims on labels or in labeling in accordance with provisions of the Nutrition Labeling and Education Act of 1990.

EFFECTIVE DATE: March 23, 1999.

FOR FURTHER INFORMATION CONTACT: Camille E. Brewer, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

I. Background

On June 18, 1993 (58 FR 33731), FDA published a proposal entitled ''Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances'' (hereinafter referred to as the 1993 nutrient content claims proposal). In that proposal FDA requested comment on several terms, including ''high potency'' that are often encountered on labels or in labeling of dietary supplements and that seem to imply that the dietary supplement will contribute to good health (58 FR 33731 at 33748). The agency requested comment on whether there were established meanings for these terms, and, if so, whether they characterized the level of the nutrients in the food and thus should be considered to be nutrient content claims. In 1994, in its final rule in the nutrient content claims proceeding (hereinafter referred to as the 1994 nutrient content claims final rule), based on the comments that it received, FDA determined that ''high potency'' is a claim that characterizes the level of a nutrient or nutrients and, therefore, meets the definition of a nutrient content claim in § 101.13(b) (21 CFR 101.13(b)) (59 FR 378 at 391, January 4, 1994).

One comment to the 1993 nutrient content claims proposal stated that FDA failed to address whether certain claims regarding antioxidants were within the scope of the proposed regulation. In the 1994 nutrient content claims final rule, the agency stated that while such claims were not explicitly discussed in the 1993 nutrient content claims proposal, they also are nutrient content claims (59 FR 378 at 389).

However, given the time constraints under which FDA prepared the 1994 nutrient content claims final rule, the agency was not able to adopt a definition either for ''high potency'' or for nutrient content claims for antioxidants. FDA announced its intention to review the suggestions for a definition of ''high potency'' and ''antioxidant'' claims and, based on information received in the comments, to propose an appropriate definition for these terms (59 FR 378 at 391). In the **Federal Register** of December 28, 1995 (60 FR 67184), the agency published a proposed rule entitled ''Nutrient Content Claims: Definition for 'High Potency' Claim for Dietary Supplements and Definition of 'Antioxidant' for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods'' (hereinafter referred to as the high potency/antioxidant proposal).

The agency received approximately 70 comments in response to the high potency/antioxidant proposal. A number of comments supported the proposal, while others disagreed with various aspects of the proposal. A few comments addressed issues that are outside the scope of this rulemaking. A summary of the comments, the agency's responses to the comments, and a discussion of the agency's conclusions follow.

II. High Potency

In the high potency/antioxidant proposal, FDA proposed that the term ''high potency'' may be used on the labels or in the labeling of dietary supplements to describe a nutrient that is present at 100 percent or more of the Reference Daily Intake (RDI) for vitamins and minerals, or of the Daily Reference Value (DRV) for protein and dietary fiber, per reference amount customarily consumed. To describe multinutrient products as ''high potency,'' FDA proposed that at least two-thirds of the nutrients in a product must be present at 100 percent of the RDI for vitamins and minerals or of the DRV for protein and dietary fiber per reference amount customarily consumed.

A. ''High Potency'' as a Nutrient Content Claim

1. The majority of the comments agreed that ''high potency'' is a nutrient content claim. These comments stated that the agency's definition has a basis in the labeling practices of the dietary supplement industry, and that consumers are already familiar with this definition. Some comments stated that the term ''high potency'' is commonly understood to describe the level of a nutrient or nutrients in a product, particularly on dietary supplements of vitamins and minerals.

On the other hand, a few comments stated that ''high potency'' is not a

nutrient content claim. One comment suggested that the agency should limit the scope of its nutrient content claim regulation of the term ''high potency'' to uses involving dietary supplements containing nutrients with RDI's or DRV's. The comment noted, however, that the term ''potency'' has other meanings used in conjunction with products containing dietary ingredients for which no RDI's or DRV's have been established, and that use of the term on such products should continue to be allowed, subject to the general misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the act).

Other comments stated that the agency should withdraw the proposal because ''potency'' has an alternative meaning that FDA did not consider. One comment stated that for botanicals, equivalent amounts of the same dietary ingredient from different plants may differ in the magnitude of the biological responses they produce. The comment stated that, if the term ''potency'' is incorrectly used to describe the level of a dietary ingredient, the proper definition would not be available for correct use in a manner that would provide truthful and accurate information for consumers. The comment also maintained that the use of the term ''potency'' for botanicals should be reserved for those cases where biological assays exist. The comment stated that there would be no way of verifying the claim for a dietary ingredient in the absence of a biological assay for that dietary ingredient.

One comment requested that the agency prohibit ''high potency'' claims for protein and fiber because the ingestion of 100 percent of the Daily Value (DV) for these nutrients in single servings may lead to deleterious health effects.

As noted in several of the comments, the term ''high potency'' is commonly used to describe the level of a nutrient or nutrients, particularly for dietary supplements of vitamins and minerals and, therefore, meets the definition in § 101.13(b) of a nutrient content claim. Thus, FDA rejects the suggestion that it withdraw the proposal to define ''high potency.'' FDA acknowledges that there are other meanings for the term ''high potency.'' However, these meanings are not appropriate for consideration in this proceeding because they do not describe the level of a nutrient. For example, for pharmaceuticals, ''potency'' is a means of comparing the relative activities of drugs in a series (Ref. 1). The comment that discussed the potency of botanicals seemed to be ascribing to ''potency'' a meaning that is closer to the pharmaceutical use of the term than to its use as a nutrient content claim. This rulemaking is about foods, not pharmaceuticals.

Before terms like ''potency'' can be used to describe the level of dietary ingredients other than vitamins and minerals, standards would have to be developed that provide a basis for characterizing the level of these substances. Claims regarding the potency of constituents other than vitamins or minerals would be misleading or false if made without the benefit of standards that establish the validity of such claims. The agency encourages the dietary supplement industry to participate in developing such standards.

Moreover, the Commission on Dietary Supplement Labels (the Commission) is conducting a study on, and will provide the agency with a report containing recommendations for the regulation of label claims and statements for dietary supplements. Issues relating to the ''potency'' of botanicals and other dietary ingredients may be addressed in the Commission's final report. Therefore, the agency believes that consideration of the issue of alternate uses for the term ''potency'' should be delayed at least until issuance of a final report from the Commission.

For dietary supplements of vitamins and minerals, comments supported the agency's tentative view that the term ''high potency'' unambiguously suggests that the nutrients are present at a certain level. However, such support was not as obvious for ''high potency'' claims on products containing protein or fiber. The agency acknowledges the concern raised by one of the comments about the long-term health effects of the ingestion of 100 percent of the DV for protein or fiber in single servings. In recognition of this concern, and because manufacturers who wish to highlight the level of protein or fiber in a product may use other defined terms (e.g., ''good source,'' ''high,'' ''more'') or amount or percent statements as described in § 101.13(i) (e.g., ''30% of the DV for protein''), the agency concludes that it is appropriate to limit the scope of this definition to nutrients with RDI's (i.e., vitamins and minerals). Manufacturers also may use other descriptive terms for protein and fiber (e.g., terms that describe the quality of protein or the solubility of fiber), as long as such claims are truthful and not misleading. Accordingly, FDA is modifying proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) and (f)(2) to reflect that the definition of ''high potency'' is limited to vitamins or minerals. This definition of ''high potency'' precludes the use of this nutrient content claim for protein and fiber.

B. Application to Conventional Foods

2. Several comments from the conventional food industry opposed the provision that limited use of the term ''high potency'' to the labels and labeling of dietary supplements. These comments argued that the proposal would establish an elite nutrient content claim offering attractive marketing opportunities available only to dietary supplements. The comments maintained that this policy would send the misleading message that nutrients obtained from dietary supplements are an especially efficacious way of achieving a balanced diet. The comments also stated that, given current consumer awareness of nutrition, the term ''high potency'' may be appropriate for conventional foods.

The comments pointed out that there are several conventional foods that achieve 100 percent of the DV of a single nutrient without fortification (e.g., vitamin C in orange juice, vitamin A in carrots) as well as a number of foods that achieve 100 percent DV for the majority of nutrients through fortification. The comments stated that the options for describing 100 percent of the RDI or DRV are limited (e.g., ''100 percent DV of Vitamin C,'' ''100 percent DV of 'X' vitamins and minerals''). One comment suggested that FDA define synonyms for ''high potency'' that would be more appropriate for conventional foods (e.g., ''ultra high,'' ''naturally ultra high''). The comment suggested that FDA establish an ''extra high'' claim for which any food providing at least 30 percent of the DV of a nutrient would qualify. The comment stated that such a claim would enable such foods as fluid milk to be labeled as ''extra high'' in calcium. Another comment suggested that ''superior source of'' or ''outstanding source of'' may be appropriate synonyms for ''high potency'' for conventional foods (e.g., see 56 FR 60366, November 27, 1991; 58 FR 33715, June 18, 1993; 59 FR 354, January 4, 1994; and 59 FR 395, January 4, 1994).

FDA does not wish to foster the notion that dietary supplements are a superior (or an inferior) source of nutrients or to promote disparate marketing opportunities for dietary supplements and conventional foods. With regard to labels and labeling, the agency is committed to supporting as much parity between conventional foods and dietary supplements as is possible consistent with the act (e.g., see 56 FR 60366, November 27, 1991; 58 FR

33715, June 18, 1993; and 59 FR 354, January 4, 1994).

The agency is persuaded that the term ''high potency'' can be meaningful and helpful to consumers in constructing healthy daily diets. If FDA were to adopt the same definition of ''high potency'' for conventional foods as for dietary supplements, given the acceptance and understanding of this term from its use on supplements, there is little likelihood that consumers would be confused about the meaning of the claim were it to appear on conventional foods. The agency concludes that the term will likely be useful in highlighting for consumers those products (either dietary supplements or conventional foods) that contain 100 percent or more of the DV for specific nutrients in one serving. Therefore, FDA is not adopting proposed § 101.13(b)(6), which would have limited the use of ''high potency'' to dietary supplements. FDA also is revising proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) and (f)(2) to remove the restriction that the term ''high potency'' be used only on dietary supplements.

The possibility of foods achieving 100 percent of the DV for certain nutrients through fortification was raised in one of the comments. FDA has considered the appropriateness of fortifying a food to meet the requirements for bearing the nutrient content claims in consideration of the terms ''more'' (56 FR 60421, November 27, 1991 and 58 FR 2302, January 6, 1993) and ''healthy'' (59 FR 24232, May 10, 1994). The agency stated that, although random fortification could lead to deceptive and misleading claims, fortification of foods in accordance with the policy set out in § 104.20 (21 CFR 104.20) would ensure that the fortification was rational, and that the resultant claims would not be misleading.

FDA has previously stated that fortifying a food of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading for several reasons. First, there is great potential to confuse consumers if foods like sugars, soft drinks, and sweet desserts are fortified to qualify for a claim, when, at the same time, dietary guidance as contained in the U.S. Department of Agriculture's (USDA's) and U.S. Department of Health and Human Services' (DHHS') 1995 *Dietary Guideline for Americans*, for example, states that these foods provide calories and little else nutritionally (Ref. 2). Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines and may encourage overfortification of the food supply (e.g., vitamin or mineral addition to soft drinks). Consistent with the provisions for ''more'' and ''healthy'' claims, the agency concludes that adherence to the principles stated in its fortification policy in § 104.20 will ensure that a food is not indiscriminately fortified for the sole purpose of making a ''high potency'' claim. Accordingly, the agency is adding new § 101.54(f)(3) which states that, where compliance with the definition of ''high potency'' is based on a nutrient that has been added to the food (other than a dietary supplement), fortification shall be in accordance with the policy on fortification of foods in § 104.20.

The agency points out that it is in the process of reviewing its policy on fortification for the purpose of making health claims. Currently, no expressed or implied health claims may be made on the label or in labeling for a food unless the food 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 before any nutrient addition (see § 101.14(e)(6) (21 CFR 101.14(e)(6)). In response to petitions from the National Food Processors Association and the American Bakers Associations, FDA proposed modifications to § 101.14(e)(6) to allow fruit and vegetable products comprised solely of fruits and vegetables, enriched grain products that conform to a standard of identity, and certain other products that do not contain 10 percent of one of the six listed nutrients, to bear health claims if they meet all other requirements for the claim. FDA is reviewing comments on this proposal (60 FR 66206, December 21, 1995).

With regard to synonyms for nutrient content claims, the agency has stated (58 FR 2302 at 2320):

> Because a goal of the 1990 amendments is to make nutrition information on the label or labeling of foods available in a form that consumers can use to follow dietary guidelines (H. Rept. 101–538, supra, 10), and the act envisions that synonyms for defined terms can be an appropriate means to communicate such information, the agency will evaluate synonyms according to the standard in the 1990 amendments, i.e., that the term is commonly understood to have the same meaning as a defined term. In doing so, FDA intends to be open to considering terms that meet this standard. However, FDA does not intend to permit any synonym that it believes would be unclear in meaning to consumers with respect to characterizing the level of a nutrient in a food.

The agency has no evidence that terms such as ''superior source of'' or ''outstanding source of'' are commonly understood to have the same meaning as ''high potency.'' Likewise, FDA is not aware of any basis on which it could find that terms such as ''very,'' ''ultra,'' or ''extra'' would be understood by consumers to be synonymous with ''high potency.'' Furthermore, terms such as ''ultra'' do not signify the quantity present and therefore may not provide meaningful information to the consumer. Therefore, FDA is not authorizing these terms for use as synonyms to the ''high potency'' nutrient content claim. Interested parties may petition the agency to authorize synonyms or new nutrient content claims under the procedures described in § 101.69 (21 CFR 101.69).

The agency also points out that, on October 25, 1994, the National Food Processors Association (NFPA) petitioned FDA to initiate rulemaking for the adoption of amendments to the regulations governing nutrient content claims and health claims. Among other things, the petition requested that the agency allow manufacturers to tie or ''anchor'' an undefined term (e.g., ''loads of'') to a defined nutrient content claim (e.g., ''high'') as a synonym for that defined term, without FDA preclearance of the undefined term, when the terms are understood by consumers to have the same meaning, when such claims are made in accordance with the requirements for the defined term, and when the defined term also appears in the product's labeling. The proposal responding to the NFPA petition published on December 21, 1995 (60 FR 66206). FDA is currently evaluating comments to that proposal.

C. 100 Percent Criterion

3. Many comments supported the proposal to define ''high potency'' as 100 percent of the DV.

One comment from a trade association for dietary supplement manufacturers objected to the basis for selecting 100 percent of the DV as the requirement for high potency. The association argued that 100 percent is not sufficient to meet the needs of practically all healthy persons, at least for some nutrients, and that this amount is not necessarily the amount that some consumers require to meet what they consider optimal targets for nutrient intake.

One comment stated that consumers will understand ''full potency'' to equal 100 percent of the DV, but that the term ''high potency'' conveys the impression that the nutrient content is above 100 percent. The comment stated that to avoid confusion and protect consumers from misleading information, FDA should not adopt a definition for ''high potency'' until it has conducted a

survey of consumers of dietary supplements concerning public understanding of the meaning of the terms ''high potency'' and ''full potency.'' The comment recommended that FDA adopt not one but two nutrient content claims, one for ''full potency'' and another for ''high potency.'' Other comments stated that ''full potency'' is not an appropriate synonym for ''high potency'' but offered no explanation.

A couple of comments suggested that the proposed regulations be revised to define ''high potency'' for the B vitamins as well as vitamins C and E as above 100 percent of their respective DV's to be consistent with current marketing practices that typically package these nutrients in amounts well above 100 percent of the DV for each nutrient.

The agency rejects the comment that objected to the basis for the definition of ''high potency.'' The RDI's are based on the National Academy of Sciences' Recommended Dietary Allowances (NAS RDA's) and are the cornerstone for several nutrient content claims. Since the inception of the nutrition labeling program (37 FR 6493, March 30, 1972), FDA has relied on the judgment of the NAS' Food and Nutrition Board concerning the essentiality of particular nutrients in human nutrition and for recommendations regarding the required levels of those nutrients to meet the needs of practically all healthy persons. The NAS' RDA's remain the most widely accepted and respected source of information on human nutrient requirements.

The NAS is in the process of revising the basis for the RDA's and may consider optimal nutrition and the prevention of chronic disease in developing a future edition of the RDA's (Ref. 3). FDA expects that label reference values and nutrient content claims will evolve in tandem with the RDA's. In the interim, the agency concludes that the RDA's, and the principles on which they are based, form a firm foundation on which to establish certain label reference values and their derivatives, the nutrient content claims.

FDA did not propose a definition for ''full potency.'' In the high potency/antioxidant proposal, FDA requested comment on whether the term ''full potency'' is generally viewed by consumers as a synonym to ''high potency'' (60 FR 67184 at 67189). The agency is not persuaded by the comment that suggested that consumers interpret ''full potency'' to mean 100 percent of the DV and ''high potency'' to mean more than 100 percent because the comment did not supply any support for its assertions. In fact, FDA did not receive comments supporting ''full potency'' as a synonym for ''high potency.'' Therefore, the agency is not defining ''full potency'' as a synonym for ''high potency.''

FDA does not consider that it is necessary to adopt a separate definition for ''full potency'' because of the lack of evidence that this term describes the level of a nutrient, and that it should be considered a nutrient content claim. Further, the agency is not persuaded that consumer research is necessary to define ''high potency'' at 100 percent of the RDI given that most of the comments supported this definition.

The agency sees no reason to alter the definition of ''high potency'' to require higher levels of certain nutrients because the definition of ''high potency'' does not preclude manufacturers of the B vitamins, vitamin C, or vitamin E from marketing these vitamins at levels above 100 percent of the RDI. The comment did not include an alternate recommendation for a definition, nor did it include any data in support of its assertion regarding the current levels of the B vitamins or vitamins C and E marketed in dietary supplements.

D. Multinutrient Products

4. The majority of comments supported the criterion that two-thirds of the nutrients present in a multinutrient product must be present at 100 percent of the DV to bear a ''high potency'' claim.

One comment stated that FDA's tally of the nutrients likely to be present at levels less than 100 percent of the DV is incomplete, and, therefore, the requirement that 2/3 of the nutrients be present at 100 percent of the RDI may be more rigid than was actually intended. The comment stated that biotin is an extremely expensive ingredient and is seldom included at 100 percent of the RDI. The comment maintained that some trace minerals are commonly present at less than 100 percent of the RDI, and that the definition of ''high potency'' should not require uniformly high levels of these nutrients. The comment stated that some products intended for men or for the elderly now provide less than the RDI levels of iron which represents a desirable trend. The comment stated that requiring that one-half of the nutrients be present at 100 percent of the RDI is more appropriate than requiring that two-thirds be present at 100 percent to bear the ''high potency'' claim.

One comment suggested that the term ''high potency'' be used on the label or in the labeling of a dietary supplement to describe the product if all of the nutrients with RDI's or DRV's in the product are at 100 percent or more, with the exception of: (a) The 11 nutrients deemed impractical or imprudent in the high potency/antioxidant proposal to include at 100 percent of RDI or DRV levels; and (b) the essential nutrient iron, because daily supplementation at 100 percent of the RDI level is not deemed prudent for all people.

One comment recommended that FDA permit multinutrient products that contain one or more nutrients to use the term ''high potency'' along with a specific nutrient referenced in the nutrient content claim. As an example, the comment suggested that if the multinutrient product contains 100 percent of the RDI for vitamin C, the product should be allowed to bear the claim ''high potency vitamin C.'' The comment also suggested that if the multinutrient product contains 50 percent or more nutrients that are above RDI levels, the product should be allowed to declare ''high potency'' with an asterisk. The comment stated that the asterisk would correspond with a same panel reference that lists the nutrients with RDI's or DRV's at 100 percent of their label reference values. Alternatively, the comment suggested that a company could use a phrase such as ''See Supplement Facts Panel for a complete listing, 7 of 12 nutrients in this product exceed RDI/DRV levels'' to draw attention to the number of nutrients present at 100 percent of the RDI or DRV.

The agency points out that the number of nutrients eligible to bear a ''high potency'' nutrient content claim has changed from what was proposed because the claim is now limited to the vitamin or mineral content of the food product. However, two-thirds is a reasonable proportion of nutrients that should be present for a multinutrient product to bear the ''high potency'' claim. To be able to characterize a dietary supplement or conventional food as ''high potency,'' that claim ought to reflect the nature of the food. For a product to bear this claim, it is reasonable to expect that significantly more than half of the RDI nutrients in the food meet the ''high potency'' standard. The two-thirds requirement appropriately captures this expectation. Hence, FDA rejects the suggestion that only 50 percent of the nutrients in a multinutrient product be present at the requisite level to qualify for a ''high potency'' claim.

FDA concludes that the provision that two-thirds of the nutrients be present at 100 percent of the RDI for a

multinutrient product to bear the term ''high potency''is sufficiently flexible to account for the presence at less than 100 percent of the DV for iron, biotin, and those trace minerals that are typically not found at 100 percent of the DV. Because this final rule revises the proposed definition of ''high potency'' to include conventional foods, FDA has revised § 101.54(f)(2) to refer to all multinutrient products, not just dietary supplements.

There is nothing in the high potency/antioxidant proposal that precludes use of such terms as ''high potency vitamin C'' or the use of asterisks that refer to a listing of nutrients that are present at 100 or more percent of the RDI, either for a single or a multinutrient product. To emphasize the fact that the vitamins or minerals present at 100 percent or more of the DV can be described by the term ''high potency,'' FDA is revising proposed § 101.54(f)(1) (redesignated as paragraph (f)(1)(i)) to state that the term ''high potency'' can be used to describe individual vitamins or minerals that are present at 100 percent or more of the RDI. However, if the term ''high potency'' is used on the label of a multinutrient product to refer to the entire product, the two-thirds criterion must be met. There is nothing in § 101.54(f) that precludes other descriptive statements (e.g., ''7 of 12 nutrients in this product exceed RDI/DRV levels'') as long as they are truthful and not misleading.

FDA recognizes that there are ''combination'' products that contain, in addition to vitamins and minerals, dietary ingredients for which no label reference value has been established (e.g., botanicals). (See comment 1 of this document.) FDA advises that the label or labeling of such products must clearly identify which dietary ingredients are being described by the term ''high potency'' (e.g., ''botanical 'X' with high potency vitamin D''), so that FDA can evaluate the appropriateness of the claim under the definition for high potency in § 101.54. Where there is any ambiguity regarding the use of the term ''high potency,'' the agency will evaluate the claim on a case-by-case basis in the context of the entire label and labeling to determine whether the claim is being used to describe the level of a nutrient or to describe the product. Accordingly, FDA is adding new § 101.54(f)(1)(ii) to state that products that contain vitamins or minerals as well as other nutrients or dietary ingredients shall clearly identify which ingredients are described by the term ''high potency.''

5. A couple of comments stated that it is possible that some substances that are technically vitamins and minerals are present in multingredient products at less than 2 percent of the DV (and hence are excluded from nutrition labeling) but perform technological functions in the finished supplement. The comments suggested that these ingredients should not be part of the denominator in determining whether a product meets the two-thirds criterion for a ''high potency'' claim. The comment recommended that proposed § 101.54(f)(2) be revised to clarify that vitamins or minerals present at less than 2 percent of the DV are excluded from being counted with the one-third of the nutrients that may be present to qualify for the claim.

FDA agrees that nutrients present in insignificant amounts should be excluded from being counted in the denominator for determining the ratio of nutrients present at 100 percent of the RDI as long as they are used for technological purposes only and are declared only in the ingredient statement. These same criteria are used in § 101.9(c)(8)(ii)(B) (21 CFR 101.9(c)(8)(ii)(B)) to define vitamins and minerals that may be omitted from nutrition labeling. For vitamins and minerals in conventional foods and dietary supplements, the agency defines any amount less than 2 percent of the RDI as insignificant (see § 101.9(c)(8)(iii)). Accordingly, the agency is revising proposed § 101.54(f)(2) to state that the term ''high potency'' may be used on the label or in the labeling of a food product to describe the product if it contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in § 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

III. Antioxidants

In the high potency/antioxidant proposal, FDA proposed that the term ''antioxidant'' be defined as a collective term inclusive of vitamin C, vitamin E, and beta-carotene when used as part of a nutrient content claim (e.g., ''good source of antioxidants''). The agency proposed that the levels of these nutrients must be sufficient to qualify for a nutrient content claim that characterizes the level of antioxidants in a food without further specifying the antioxidant nutrient. For example, to qualify for a ''high in antioxidants'' claim, FDA proposed that the product must contain 20 percent or more of the RDI for vitamin C and for vitamin E per reference amount customarily consumed, and that 20 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed. The agency proposed that if the food does not contain all three antioxidants at the requisite level, the claim must specify which antioxidants in the food meet the required level (e.g., ''high in antioxidant vitamins C and E''). FDA proposed that nutrient content claims for antioxidants be authorized for both conventional foods and dietary supplements. Finally, the agency proposed that a collective term (e.g., ''complete antioxidant complex,'' ''antioxidant complex'') may be used on the labels or in labeling provided that vitamin C and vitamin E are present at 10 percent or more of the RDI per reference amount customarily consumed, and that 10 percent or more of the RDI for vitamin A is present as beta-carotene per reference amount customarily consumed.

A. Underlying Concepts

6. A few comments requested that the agency withdraw the proposal. One comment stated that the proposal did not discuss the characteristics of botanicals or other nonnutrients that act as antioxidants in the human body. Another comment suggested that the agency broaden its definition to encompass all vitamins, minerals, and plant compounds involved in antioxidant processes. This comment suggested that FDA rely on the 20 percent criterion (i.e., 20 percent or more of the DV, the definition for ''high'' claims) for those nutrients with RDI's but permit the use of the content claim using the term ''antioxidants'' with an asterisk for all other such substances when present in any cognizable amount in food. For example, the comment suggested that the asterisk correspond with the same panel reference to the following statement: ''This product contains————, an antioxidant. An RDI reference amount has not been established for this nutrient.'' One comment stated that only RDI nutrients should be permitted to claim ''high in antioxidants'' or ''good source of antioxidants'' but argued that terms such as ''contains'' or ''provides antioxidants'' should be available for use with other proven antioxidants.

The agency rejects the suggestion that the antioxidant proposal be withdrawn. The purpose of this rulemaking is to define a term used in nutrient content claims that characterize the level in foods of certain antioxidant nutrients. Without such a definition, claims on the label or in labeling of food that describe the level of ''antioxidants'' would, under section 403(r)(1)(A) of the act (21

U.S.C. 343(r)(1)(A)), misbrand the products on which they appear.

Under section 403(r)(1)(A) of the act, a claim that characterizes the level of any nutrient which is of the type required by section 403(q)(1) or (q)(2) to be listed in nutrition labeling may not be made unless the claim is made in accordance with a regulation that FDA adopts under section 403(r)(2) to define the claim. This rulemaking is intended to define the circumstances in which claims can be made that characterize the level of ''antioxidant'' substances in food. Unless FDA completes this rulemaking, labels of dietary supplements, as well as of other foods, cannot contain statements that characterize the levels of ''antioxidants.''

The agency is not persuaded that the term ''antioxidants,'' when used in defined nutrient content claims, should be broadened to include all substances involved in antioxidant processes. The purpose of this rulemaking is not to delineate all known antioxidants. The comments that stated that there are other dietary ingredients that act as antioxidants reflect a misinterpretation of FDA's intent. FDA is not restricting all label and labeling statements about antioxidants to statements about only a limited number of nutrients. Rather, the agency is defining the circumstances in which claims that characterize the level of nutrients that have antioxidant activity, such as ''high in antioxidants'' can be made in compliance with the requirements of the act. As stated above, manufacturers cannot make label statements that characterize the level of a nutrient unless FDA has defined such statements by regulation (see section 403(r)(1)(A) of the act), and FDA cannot define such statements unless it has a reference point, that is an RDI or DRV, against which to measure the nutrient levels. Many of the plant compounds referred to in the comments as antioxidants (e.g., lycopene, lutein, polyphenols) do not have RDI's, and thus it is not possible to characterize the level of these substances because there is no standard against which to do so. Consequently, they cannot be the subject of nutrient content claims at this time. However, FDA did not intend in this rulemaking to decide whether these substances have, or do not have, antioxidant activity.

The agency is not limiting truthful and nonmisleading statements about the properties or the effects of antioxidants. Manufacturers may, for example, craft a statement, subject to section 403(a) of the act, that describes how a nutrient or dietary ingredient that does not have an RDI participates in antioxidant processes. Likewise, claims that describe the effect of a nutrient or dietary ingredient on the structure or function of the body may be made as long as such claims are not false or misleading and, if appropriate, are made in accordance with section 403(r)(6) of the act (see comment 8 of this document). However, irrespective of how many antioxidant substances there are, claims characterizing levels of nutrients or dietary ingredients are not permitted unless authorized by a regulation.

To address the misinterpretation of the agency's intentions, that is evident in the comments, and to clarify the scope of this rulemaking, FDA is changing the paragraph heading in § 101.54(g) from ''Antioxidant claims'' to ''Nutrient Content Claims Using the Term 'Antioxidant'.'' In addition, to emphasize that this regulation concerns the level of certain nutrients, FDA is inserting new text in § 101.54(g) that states that nutrient content claims that characterize the level of one or more antioxidant nutrients present in a food may be used on the label or in the labeling of that food when the nutrients meet the conditions that are established in this regulation. Among the conditions set out in § 101.54(g)(1) is the requirement that an RDI must have been established for each nutrient that is to be subject of a claim.

Regarding the comment that argued that terms such as ''contains'' or ''provides'' antioxidants be available for use with antioxidants without established RDI's, the agency points out that ''contains'' and ''provides'' are synonyms for the defined nutrient content claim ''good source'' (see § 101.54(c)) and, thus, under section 403(r)(1)(A) of the act, can only be used with nutrients for which RDI's have been established. Consequently, a claim such as ''contains lycopene'' would be an unauthorized nutrient content claim because lycopene does not have an RDI. Nonetheless, a statement such as '''x' mg of lycopene per serving'' is permitted under § 101.13(i)(3), which allows for the use of amount or percentage statements that do not implicitly characterize the level of the nutrient in a food (e.g., claims that do not imply whether the amount is high or low based on an established RDI or DRV value), so long as the statement is not misleading in any way. (See Ref. 4, p. 36, C23). For dietary supplements, certain other statements (i.e., simple and comparative percentage claims) can be made under new § 101.13(q)(3)(ii) (see the document entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements'' (hereinafter referred to as ''the nutrient content claims document'') published elsewhere in this issue of the **Federal Register** for further discussion of this issue). Further, as discussed fully under comment 8 of this document, other statements about antioxidant properties of food substances may appear on the labels of foods, provided that they are made in accordance with the statutory requirements.

7. One comment stated that the proposal lacked a scientific definition of the term ''antioxidant'' and suggested that the agency repropose and include a definition for this term. Other comments stated that the distinction between direct and indirect antioxidants made by the agency in the proposal was not useful. These comments argued that consumers are unlikely to distinguish between direct and indirect antioxidants, and that research shows that minerals such as copper, magnesium, zinc, and selenium have known antioxidant effects. The comments asserted that these nutrients should be grouped with vitamin C, vitamin E, and beta-carotene for the purpose of making nutrient content claims about antioxidants.

One comment stated that the endorsement of vitamin C, vitamin E, and beta-carotene could send a misleading message to consumers that these nutrients will prevent disease, that scientists have reached a consensus on the mechanisms underlying disease prevention, and that the consumption of a few common antioxidants in and of itself provides health benefits. The comment stated that, as a result, consumers may be tempted to take supplements of individual antioxidants, which may have deleterious health consequences or at least no significant benefits.

One comment requested that FDA establish criteria for determining the biological endpoints to be achieved by the use of antioxidants. The comment also suggested that FDA establish a definition for the total antioxidant activity of whole foods.

In the high potency/antioxidant proposal and in an earlier rulemaking (56 FR 60624, November 27, 1991), the agency summarized the antioxidant properties of vitamin C, vitamin E, and beta-carotene. The agency stated that there was scientific evidence that these nutrient substances were able to trap and deactivate reactive oxygen molecules and, thus, prevent the damage caused by these reactive molecules (also called free radicals).

No evidence was presented in the comments that nutrient content claims for vitamin C, vitamin E, and beta-carotene will be construed by consumers to be an endorsement that the nutrients that are the subject of such claims will prevent disease or, by themselves (that is, in the absence of a healthy total daily diet), provide inordinate health benefits. Therefore, there is no basis for the agency not to confirm its proposal that these nutrients can be subjects of nutrient content claims for antioxidants.

In the high potency/antioxidant proposal, the agency tentatively concluded that only vitamin C, vitamin E, and beta-carotene possessed direct antioxidant activity. The agency tentatively concluded that nutrients such as zinc, manganese, copper, selenium, riboflavin, and niacin should not be classed as antioxidants for the purpose of making nutrient content claims (60 FR 67184). This tentative conclusion was based on the fact that these nutrients are precursors of coenzymes that are involved in oxidative reactions but do not have direct antioxidant activities, and that they may have effects that are both antioxidant and pro-oxidative in character.

FDA acknowledges that there is new literature on antioxidants, some of which calls into question the relevance of the distinction between direct and indirect antioxidants (e.g., see Refs. 5 through 15). Based on the comments and a review of this literature (e.g., see Refs. 5 through 15), FDA is persuaded that it is reasonable to allow all nutrients that have antioxidant activity or that participate in antioxidant reactions to be the subject of nutrient content claims for antioxidants, so long, of course, as an RDI has been established for the nutrient. Based on the state of the science, FDA is not able to justify establishing a more limited list of nutrients.

However, FDA is not specifying the nutrients that may be the subject of the claim in the codified language of § 101.54 because some nutrients with reported antioxidant activity (e.g., copper, manganese, iron) are pro-oxidative at certain levels (60 FR 67184). A manufacturer making an antioxidant claim for a nutrient must have substantiation that the nutrient functions as an antioxidant at the levels present and under the intended conditions of use. The agency advises that antioxidant claims on products that contain levels of a nutrient sufficient to cause the nutrient to act as a pro-oxidant are false and misleading under section 403(a) of the act.

Based on its conclusion that nutrients that exhibit antioxidant activity through an indirect mechanism in fact have an antioxidant function when present at certain levels, and that manufacturers should be able to inform consumers about their presence, FDA is broadening the number of nutrients that can be the subject of a nutrient content claim that characterizes the level of antioxidants. Accordingly, the agency is revising proposed § 101.54(g)(1) and (g)(2) to delete the language that would have limited the nutrients that could be the subject of antioxidant content claims to vitamin C, vitamin E, and beta-carotene and to include in its stead general language that refers to nutrients that have recognized antioxidant activity.

The agency is defining the conditions for the use of the term ''antioxidant'' in nutrient content claims in § 101.54(g). This section provides that the term antioxidant may be used for a substance for which there is scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or that prevent free radical-initiated chemical reactions. This definition captures the attributes of those nutrients that the agency has previously concluded are direct antioxidants (i.e., vitamin E, vitamin C, and beta-carotene) (56 FR 60624 and 60 FR 67184), as well as the attributes of those nutrients that the agency has described as indirect antioxidants (60 FR 67184).

While the agency believes that this definition for antioxidant, which responds to comments and which is based on available scientific discussions, is the most appropriate definition at this time, it is clear that a widely accepted and well-established definition for antioxidants has not been developed within the scientific community. In the near future, the NAS Institute of Medicine (IOM) will be conducting a comprehensive assessment of human nutrient requirements for dietary antioxidants. This review will consider both the nature of the definition of a dietary antioxidant as well as the linkage between dietary reference intakes and antioxidant activity. FDA expects to carefully review the outcomes and final report of the IOM to the extent that they are relevant to this final rulemaking. The agency may consider reexamining its conclusions on nutrient content claims for antioxidants based on discussions provided in the IOM report when it becomes available. The agency will consider proposing an affirmative list of antioxidant nutrients and limiting nutrient content claims to such a list following the release of the IOM report.

The agency is revising proposed § 101.54(g)(3) to specify the levels of nutrients needed to qualify for antioxidant nutrient content claims. Section 101.54(g)(3) states that the level of each nutrient that is the subject of the claim must be sufficient to qualify for the claim (e.g., to bear the claim ''high in antioxidant vitamin C,'' the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, to bear the claim ''good source of antioxidant beta-carotene,'' 10 percent or more of the RDI for vitamin A must be present in the food as beta-carotene per reference amount customarily consumed. When a product contains more than one antioxidant nutrient, each antioxidant nutrient that is being described must meet the level of nutrient specified in the nutrient content.

It is important that the antioxidant nutrients be identified as part of a nutrient content claim for antioxidants because the names are facts that are material in light of the antioxidant representation. The comments reveal that a variety of nutrients and dietary ingredients could be considered antioxidants. Since these final rules allow the manufacturer to determine what nutrients in a product meet the definition in § 101.54(g) for antioxidants and are to be the subject of the nutrient content claim, the claim would be confusing to consumers without a clear identification of which nutrients in the product are being described. Consumers cannot be expected to know which nutrients are antioxidants. There are no regulatory provisions for providing this information in the nutrition label, and it will not necessarily be revealed in the ingredient statement. In addition, some products may contain several antioxidants, with only a few of them being present at levels appropriate for the claim. In this case, the claim clearly needs to identify which nutrients meet the criteria for the claim being made.

The agency concludes that without the disclosure of the nutrients proximate to the claim, a claim on the label or in labeling of food that describes the level of antioxidants would be misleading under section 201(n) of the act. Accordingly, FDA is adding new § 101.54(g)(4) that states that the names of the nutrients that are the subject of the claim must be included as part of the claim (e.g., ''high in antioxidant vitamins C and E'').

For flexibility, the agency concludes that the names of the nutrients may be included as part of the claim either directly, by mentioning them in the claim, or indirectly, by use of an asterisk. Because the claim may refer to many nutrients, and space constrains may make it difficult to fit the entire list within the claim, FDA is willing to provide the same flexibility in how antioxidant claims are made that it is allowing for the disclaimer required with statements made under section 403(r)(6) of the act. (For further discussion of the placement of the disclaimer, see the nutrient content claims document published elsewhere in this issue of the **Federal Register**.) As with the disclaimer, the agency concludes that the list of nutrients should be on the same panel or page as the claim. This placement establishes an obvious relationship between the claim and the list of antioxidant nutrients. The placement of the list of nutrients on another panel would obscure material facts necessary for understanding the claim.

With respect to type-size requirements, section 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act requires that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, ''have appropriate prominence which shall be no less than one-half the size of the claim.'' The agency concludes that, for consistency in identifying material information, the standard embodied in these provisions should be applied to the disclosure of the antioxidant nutrients.

The agency recognizes that sometimes claims may be small, particularly in labeling, and one-half the type size of the claim may result in a type size that is too small to be easily read. Thus, there is a need for a minimum type size for the list of antioxidant nutrients. One-sixteenth of an inch is specified in § 101.2(c) (21 CFR 101.2(c)) as the minimum type size for most mandatory information on the principal display panel or information panel, e.g., designation of ingredients, name and place of business, and warning and disclaimer statements. Further, one-sixteenth of an inch is the minimum size required in § 101.105(i) for net quantity of contents statements. Consequently, the agency concludes that a minimum type size of one-sixteenth of an inch for the disclosure of the antioxidant nutrients is necessary to ensure that it is prominently displayed. However, for the sake of increased prominence, it is preferable to use one-half the size of the claim when it results in a type size of larger than one-sixteenth of an inch.

Accordingly, FDA is adding new § 101.54(g)(4) which permits the term ''antioxidant'' or ''antioxidants'' (as in ''high in antioxidants'') to be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients must appear in letters of type size of no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

The issue of biological endpoints, raised by one of the comments, is beyond the scope of this rulemaking. It was not clear whether the comment that requested that FDA establish criteria for biological endpoints to be achieved by the use of antioxidants was asking FDA to establish a standard biological measurement (or biomarker) to determine whether a substance has antioxidant activity in vivo, or asking FDA to set forth criteria for establishing when the use of antioxidants provides protection from disease. In either case, such issues are outside the scope of what FDA proposed to do in this rulemaking.

The same comment also suggested that FDA establish a definition for the total antioxidant activity of whole foods. FDA recognizes that foods may contain a mixture of substances, both nutrients and nonnutrients, that participate in antioxidant processes. However, there are no reliable methods available that measure the antioxidant activity of all substances that participate in antioxidant reactions when an entire food is consumed. The development of a definition of total antioxidant activity of whole foods is beyond the scope of this regulation, which is intended to permit the use of the term ''antioxidants'' in claims that characterize the level of these nutrients in a food, including a dietary supplement.

8. A couple of comments stated that the term ''antioxidant'' is a statement provided for under section 403(r)(6) of the act. These comments requested clarification on whether the use of the term ''antioxidant'' is part of a statement about a product's biological function. The comments stated that factual statements about the biological function of antioxidants should be permitted, provided that the labeling does not include unauthorized health or nutrient content claims.

Another comment stated that FDA lacks authority to define the term ''antioxidant'' for use in nutrient content claims under section 403(r)(2)(A)(i) or (r)(2)(F) of the act. The comment argued that dietary ingredients without established RDI's are expressly excluded by section 7(c) of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) from the nutrient content claims provisions found in section 403(r)(2)(A)(i) of the act. The comment interpreted section 7(c) of the DSHEA to mean that nutrient content claims can be made for dietary ingredients that do not have RDI's.

One comment suggested that the codified language be revised to state clearly that the term ''antioxidant'' is being described solely as part of a nutrient content claim. For example, the comment suggested that proposed § 101.54(g) be revised to read ''the term 'antioxidants,' *when used as part of a nutrient content claim,* may only be used on the label or in labeling * * *.'' (Emphasis added.) The comment also suggested that proposed § 101.54(g) be revised to include the statement ''This section does not apply to dietary supplement statements of nutritional support.''

FDA agrees with the first comment that ''antioxidant'' describes the biological activity of a substance. As stated above, FDA has defined ''antioxidant activity'' in § 101.54(g)(2) (under its authority under sections 403(r)(2) and 701(a) of the act). However, FDA does not agree that ''antioxidant'' is necessarily a statement that is made under section 403(r)(6) of the act. If an antioxidant effect is a nutritional effect, that is, if it is attributable to the nutritional value of consuming a substance, a claim about that substance's antioxidant effect may be made as long as it is truthful and not misleading and not made in violation of section 403(r)(1)(A) (on nutrient content claims) or (r)(1)(B) (on health claims) of the act.

Section 403(r)(6) of the act is relevant only if the antioxidant effect is not attributable to the nutritive value of the dietary ingredient, or if a manufacturer chooses to take advantage of this provision even though the antioxidant effect is attributable to a substance's nutritive value (see discussion on section 403(r)(6) of the act in the nutrient content claims document published elsewhere in this issue of the **Federal Register**.) Section 403(r)(6) of the act, which was added by the DSHEA, encompasses label statements on dietary supplements that claim a benefit related to a classical nutrient deficiency disease, describes how a nutrient or dietary ingredient affects the structure or function in humans, characterizes the documented

mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient. Manufacturers may make claims regarding the antioxidant properties (or biological properties) of a substance under section 403(r)(6) of the act as long as all of the requirements of this section of the act are met (e.g, notification, substantiation, disclaimer).

The agency rejects the comment that suggested that section 403(r)(2)(F) of the act is relevant to this rulemaking. Section 403(r)(2)(F) of the act creates a narrow exception to section 403(r)(2)(A)(i) of the act. Section 403(r)(2)(F) of the act pertains only to claims about the percentage of a dietary ingredient for which FDA has not established a reference value. Thus, section 403(r)(2)(F) of the act has no relevance to this proceeding. (See the nutrient content claims document published elsewhere in this issue of the **Federal Register** for further discussion of percentage claims.)

As discussed in comment 6 of this document, FDA is persuaded to revise the paragraph heading for § 101.54(g) to state that the section refers to nutrient content claims using the term ''antioxidants'' to clarify that the section addresses nutrient content claims for antioxidants. The agency concludes that this revision clarifies that the scope of § 101.54(g) is limited to nutrient content claims without making the additional changes in codified language suggested by the comment.

B. Beta-carotene

9. Several comments agreed with the inclusion of beta-carotene in the antioxidant definition. Several other comments opposed its inclusion. The latter comments provided two reasons for their opposition: (1) There is little scientific evidence that beta-carotene functions as an antioxidant in the human body, and (2) findings from clinical prevention trials suggest potential harm to smokers from the consumption of beta-carotene supplements. One comment stated that in the Alpha-Tocopherol, Beta Carotene (ATBC) Lung Cancer Prevention Trial (the ATBC Trial), an intake of 20 milligrams (mg)/day synthetic beta-carotene over a 5- to 8-year period was associated with an 18 percent increased incidence of lung cancer and an 8 percent increase in total mortality in male smokers (Ref. 16). The comment also noted that the Beta-Carotene and Retinol Efficacy Trial (CARET) was terminated early because interim results indicated that beta-carotene and vitamin A supplements provided no benefit and may have caused harm to participants (Ref. 17). The comment reported that in the CARET trial, 30 mg beta-carotene and 25,000 International Units (IU) vitamin A were administered daily to male and female smokers and former smokers or to men exposed to asbestos. The comment noted that the interim result, a 28 percent increased lung cancer risk in the treatment group, was consistent with the results of the ATBC Trial. The comment asserted that results of these studies do not support the hypothesis that beta-carotene provides any beneficial disease prevention or antioxidant effect in these populations. Furthermore, the comment maintained that the evidence from the Physician's Health Study, which showed no protective effect from beta-carotene supplementation against cancer or cardiovascular disease (Ref. 18), clearly does not support an antioxidant role for beta-carotene in the prevention of these diseases.

Another comment argued that the scientific evidence does not support the hypothesis that beta-carotene supplements are effective in the prevention of cancer or cardiovascular disease in well-nourished populations. The comment, however, asserted that the question of a possible increase in risk of disease among smokers who take beta-carotene supplements had not been definitively proven.

One carotenoid expert asserted that carotenoids are more appropriately defined as ''physiologic modulators'' rather than as ''antioxidants.'' An antioxidant expert contended that there is inadequate scientific evidence to support the hypothesis that beta-carotene functions as an antioxidant in the human body and urged FDA not to include beta-carotene in this classification until scientific evidence is available to support its purported action as an antioxidant.

A couple of comments stated that there is no evidence demonstrating a significant in vivo antioxidant function for beta-carotene, compared to the demonstrated in vivo antioxidant function for vitamins C and E. The comments stated that the results of the beta-carotene intervention trials do not support an antioxidant function for beta-carotene but, instead, indicate that beta-carotene supplementation may cause harm to smokers, possibly through a pro-oxidant mechanism. These comments stated that there is no consensus among experts that beta-carotene has in vivo antioxidant activity.

Another comment cited the findings of the ATBC trial and suggested that beta-carotene may act as a pro-oxidant at high levels. The comment further stated that negative health effects or pro-oxidant activity results have not been attributed to high intakes of mixed carotenoids provided from fruits and vegetables. The comment also stated that foods with naturally occurring beta-carotene contain a mixture of carotenoids and carotenoid isomers that may confer a health protective effect to foods compared to supplements containing only beta-carotene. The comment agreed with the inclusion of beta-carotene in the antioxidant definition but suggested that the agency prohibit dosages that would result in pro-oxidant stress. The comment suggested that when beta-carotene is the subject of the claim, the product should contain at least 20 percent, but no more than 100 percent, of the RDI for vitamin A as added beta-carotene.

As discussed in the previous comment, FDA is not specifically identifying beta-carotene as an antioxidant in this final rule. However, FDA does not agree with the comments that stated that beta-carotene should not be considered a recognized antioxidant and therefore should be ineligible to be included in nutrient content claims for antioxidants. There is substantial scientific evidence that beta-carotene, in addition to its established metabolic role as a precursor to vitamin A, acts as an antioxidant (Refs. 19 through 22). The agency is aware, however, that most of the scientific evidence for beta carotene having antioxidant activity is from in vitro, rather than in vivo, studies. Although there is no direct scientific evidence that beta-carotene has in vivo antioxidant activity, or that it may have a beneficial health outcome that is directly attributable to its antioxidant capacity, the in vitro antioxidant activity of beta-carotene suggests mechanisms for how it and other antioxidant substances may act in the body. For example, the results from a recent study suggest that vitamin E, vitamin C, and beta-carotene collaborate to deactivate free radicals (Ref. 23). Investigators reported that, using an in vitro model, free radicals are passed from one antioxidant molecule to the next in the following sequence: From vitamin E to beta-carotene to vitamin C. These investigators hypothesized that the resulting water-soluble, vitamin C radical would be voided from the body before causing harm. According to this scheme, smokers, who tend to have lower levels of vitamin C than nonsmokers, do not have sufficient vitamin C to scavenge the carotenoid radicals. The investigators raised the

possibility of low vitamin C levels in smokers as an explanation for the increased risk of lung cancer following beta-carotene supplementation that was found in the ATBC and CARET trials.

Findings from clinical trials do not reveal the exact mechanism of action of substances in vivo, but they do provide information on whether a compound can achieve a particular clinical outcome or endpoint. Clinical trials can provide clues on whether the substance acted in the hypothesized fashion.

Because of the adverse results of the ATBC and CARET trials, the agency recognizes that beta-carotene may have other than antioxidant effects in certain situations. It may be that beta-carotene acts as a pro-oxidant in certain situations, e.g., in smokers given large doses of supplemental beta-carotene, but as an antioxidant in others, e.g., in nonsmoking, healthy adults who consume diets high in beta-carotene.

The agency believes that additional research on the in vivo antioxidant mechanism of beta-carotene is needed, and if future scientific evidence does not support an in vivo antioxidant effect for beta-carotene, the agency is prepared to reconsider whether this substance meets the definition of antioxidant. Thus, while the results from in vitro studies do not conclusively prove that beta-carotene is an in vivo antioxidant, they provide enough scientific evidence that the agency concludes that it is reasonable, at this time, to permit beta-carotene to be the subject of nutrient content claims about the level of antioxidants in food.

FDA agrees with those comments that stated that the results of the ATBC and CARET trials raise serious concerns about the safety of beta-carotene supplementation for smokers and others at high risk of lung cancer. Based on the comments discussed above and on FDA's review of the scientific literature, the agency advises that it has serious concerns about the safety of dietary supplements that are intended to provide 20 mg or more beta-carotene daily, the lowest dose for which an adverse effect was observed in the ATBC trial. The agency encourages manufacturers and distributors of dietary supplements containing beta-carotene to consider the safety of dosages in excess of this amount in developing and marketing such products and to consider including cautionary label statements to ensure that such high-dose beta-carotene dietary supplements do not present a significant or unreasonable risk of injury or illness to consumers under the conditions of use recommended or suggested in labeling or under ordinary conditions of use. FDA points out that it agrees with the comment that stated no negative health effects have been attributed to high intakes of carotenoids, including beta-carotene, from fruits and vegetables.

C. Complete and Complex

10. Several comments objected to the proposed definition of ''complete'' and ''complex.'' One comment recommended that the proposed standard for ''complete'' or ''complex'' antioxidant formula be strengthened by mandating that vitamin C and vitamin E be present at 100 percent or more of RDI levels, and that at least 100 percent of the RDI for vitamin A be present as beta-carotene.

One comment recommended that FDA permit the use of the term ''antioxidant complex'' with an asterisk to refer to another asterisk next to a list of all antioxidant ingredients other than vitamin E, vitamin C, and beta-carotene. The comment suggested that the asterisk correspond with a same panel reference to the following statement: ''This product contains ————, which are antioxidants. An RDI reference amount has not been established for these nutrients.'' The comment stated that ''complete antioxidant complex'' is inherently misleading, and that only ''antioxidant complex'' should be used as a collective term. The comment maintained that ''complete antioxidant complex'' conveys the impression that the product contains all known antioxidant compounds and contains those compounds at 100 percent of their RDI's.

One comment stated that the purpose of the definition is limited solely to define nutrient content claims, and FDA is not purporting to define what other dietary ingredients play an antioxidant role in the body and which claims (other than defined nutrient content claims) may be made. For this reason, the comment objected to the proposed definitions of ''complex'' and ''complete'' because they do not characterize a level, which is the prerequisite for a claim under section 403(r)(1)(A) of the act. The comment maintained that limiting the use of these terms to even an expanded list of nutrients with RDI's would be misleading in light of the growing scientific recognition of the antioxidant capabilities of a number of other dietary ingredients.

Another comment stated that authorizing a claim such as ''complete antioxidant formula'' will result in an infringement of a federally-registered trademark. Several associations of advertising agencies stated that the use of such terms undercuts the value of certain trademarked terms.

Based on the comments, FDA is persuaded that terms such as ''complete antioxidant complex'' and ''complete antioxidant formula,'' discussed in the high potency/antioxidant proposal (60 FR 67184 at 67191), may convey the impression that all known antioxidants are present in a product. The agency is persuaded that products bearing the term ''complete'' in association with the term ''antioxidants'' may be misleading given the dictionary definition of ''complete'' (i.e., having all necessary parts, whole) (Ref. 24). This term might be misleading because a complete list of antioxidants would be difficult to compile and would likely be controversial because of lack of consensus of which substances are antioxidants. On the other hand, the term ''complex'' means composed of interconnected or interwoven parts (Ref. 24) and conceivably might be applied to a number of antioxidants in the same product. Additionally, FDA is persuaded that such terms do not necessarily describe the level of a nutrient and therefore are outside the realm of nutrient content claims.

As mentioned, the agency recognizes that there are dietary ingredients that are antioxidants, but for which label reference values have not been established. Because nutrient content claims can only be made for those dietary ingredients for which reference values have been established, antioxidants without such reference values could not be the subject of a nutrient content claim.

Although nutrient content claims can only be made for those dietary ingredients for which reference values have been established, the agency has no objection to manufacturer's grouping these substances parenthetically next to the term ''antioxidants'' or to listing them in association with an asterisk elsewhere on the product label. However, as discussed in comment 6 of this document, there are constraints on the use of the word ''contains'' because it is a synonym for ''good source,'' a defined nutrient content claim.

In light of the conclusion that ''complete'' and ''complex'' do not necessarily describe a nutrient level, the potential for misunderstanding these claims (i.e., for assuming that all antioxidants are present), and because of possible, unanticipated trademark issues, FDA is withdrawing proposed § 101.54(g)(3) on collective nutrient content claims. If such terms are used on a food label, FDA will evaluate whether their use is false or misleading

under sections 403(a) and 201(n) of the act.

D. Referral Statements

11. One comment argued that while referral statements are required on conventional foods, such statements are not necessary on dietary supplements, especially when the lack of space on most labels is considered. The comment argued that, unlike conventional foods, almost all dietary supplements are purchased specifically for their ingredients, and that consumers can be expected to analyze nutrition information without being reminded to do so.

FDA is not persuaded to change the requirement for the referral statement, nor does it have the authority to do so. Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, the following statement: ''See ———— for nutrition information.'' Under section 403(r)(2)(B)(i) of the act, the blank must identify the panel on which the information described in the statement may be found. While the DSHEA implicitly recognizes that statements that characterize the percentage level of a dietary ingredient for which FDA has not established a reference value are nutrient content claims, and thus exempts them from the requirement in section 403(r)(2)(A)(i) of the act, it does not exempt such statements from the requirement in section 403(r)(2)(B) for referral statements. Further, because the use of nutrient content claims is entirely voluntary, the agency is not persuaded to establish special provisions for small package size. Therefore, FDA has made no change in its regulations in response to this comment.

E. Ingredient Statements

12. One comment requested clarification on the use of the term ''antioxidant'' in an ingredient statement. The comment stated that an ingredient statement should be allowed to include the term ''antioxidant mix'' or ''antioxidant formula'' within appropriate limits because it is the common or usual name of a mixture of vitamins C and E and beta carotene. The comment maintained that food manufacturers can purchase prepackaged mixtures containing these three nutrients. The comment suggested that the term ''antioxidant mix'' has become an established common or usual name of a mixture of these vitamins and argued that the ingredient statement should be permitted to identify an antioxidant mixture followed by the individual ingredients in parenthesis, ''Antioxidant mix (ascorbic acid (vitamin C), DL–Alpha-tocopherol Acetate (vitamin E), Beta Carotene)''.

Section 403(i)(1) of the act states that a food is misbranded unless its label states the common or usual name of the food. The comment did not provide any information to persuade the agency that the term ''antioxidant mix'' is an established common or usual name. Therefore, FDA rejects the suggestion that the term ''antioxidant mix'' be allowed in ingredient labeling. Interested parties may petition the agency to consider the term ''antioxidant mix'' as a common or usual name. FDA points out that any such petition should include substantiation that the term is recognized by consumers as a common or usual name.

IV. Effective Date

13. Several comments requested that the date of application be 18 months after publication of the final rule. One comment requested 12 months; another suggested 24 months. The comments expressed concern that manufacturers have adequate time to bring products into compliance.

This final rule is one of four final rules on food labeling published in this issue of the **Federal Register**. Three of the final rules pertain to dietary supplements, the fourth final rule pertains to the uniform compliance date for food regulations. Comments were received on the three dietary supplement rulemakings requesting an extension of their respective dates of application. Because FDA wishes to minimize the impact of label changes on manufacturers, the agency is persuaded that it is reasonable to extend the effective date for these rulemakings to 18 months following the publication date. This amount of time is consistent with the time period allowed for the labels of conventional foods to comply with the 1990 amendments. FDA is addressing the issue of the effective date in greater detail in the final rule entitled ''Food Labeling: Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' published elsewhere in this issue of the **Federal Register**.

V. Other Provisions

FDA did not receive any comments that dealt specifically with the other provisions of the proposal. In the absence of any basis for doing otherwise, FDA is adopting those provisions, in particular, the amendment to § 101.60(c)(1)(iii)(A) (21 CFR 101.60(c)(1)(iii)(A)), as proposed.

VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the high potency/antioxidant proposal (60 FR 67184). 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 impact statement is not required.

VII. Paperwork Reduction Act

In the high potency/antioxidant proposal, FDA stated its tentative conclusion that the proposed rule contains no reporting, recordkeeping, labeling or other third party disclosure requirements and asked for comments on whether the proposed rule imposed any paperwork burden. No comments were received addressing the question of paperwork burden. FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320(c)(2)).

VIII. Benefit-Cost Analysis

FDA has examined the economic implications of the final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866.

FDA believes that many dietary supplements currently marketed use the terms ''high potency'' and ''high in antioxidants'' to describe the level of nutrients in the products. Without rulemaking to define these terms, manufacturers will not be able to

continue to use them. This regulation will require that any manufacturer of dietary supplements currently using the terms ''high potency'' or ''antioxidant'' bear the costs of removing such statements from their labels only if the products do not meet the definition that the agency is adopting. FDA has information on the use of the terms ''high potency'' and ''antioxidant'' on the labels of dietary supplements provided by A. C. Nielsen. Using the item names in the Nielsen data base, FDA can determine products using the terms for the following Nielsen product categories: ''Nutritional Supplements'' (94); ''Vitamins-Tonic-Liquid & Powder'' (3); ''Vitamins-Multiple'' (217); ''Vitamins-B Complex with Vitamin C'' (46); and ''Minerals'' (98). Although FDA does not have information on the Nielsen category ''Vitamins-Remaining,'' the agency can make some plausible assumptions. Although FDA does not know the exact size of the missing product category, based on other information provided by Nielsen, it does know that this category is at least as big as the largest of the other categories. Therefore, it is reasonable to assume that the number of products using the terms ''high potency'' or ''antioxidant'' is at least equal to the greatest of the other categories. Therefore, FDA estimates that there are at least 675 supplements of vitamins and minerals that use these terms in their labeling.

FDA has no information to determine how many of those products will be reformulated, nor how many labels will be redesigned, as a result of this regulation. Firms whose labels do not meet the definitions for the claims established in this rulemaking will decide between reformulation and relabeling based on the relative costs of each. FDA cannot predict the cost of reformulating because it will depend on the nutrients involved and, in the case of ''high potency'', the degree to which the level of the nutrient is below the definition for the claim. FDA estimates that the cost of a label redesign for these types of products is approximately $2,200 per label. If the labels of all 675 products are redesigned, then the costs of this regulation will be $1.5 million. However, to the extent that firms can combine label changes attributable to this rule with those attributable to the dietary supplement nutrition labeling regulations (and the fact that FDA has made those regulations effective on the same day as the regulations in this rulemaking means that firms will have a complete ability to do so), then the costs of this rule will be greatly reduced. Based on these estimates, FDA concludes that the costs of this rule will not be significant.

By defining the terms ''high potency'' and ''high in antioxidants,'' this rule will benefit consumers by ensuring the consistent use of these claims. However, because FDA cannot predict the extent to which manufacturers will take advantage of the opportunity to use these claims nor the value that consumers place on the consistent use of these claims, FDA cannot quantify the benefits of this final rule.

IX. Small Entity Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires that agencies analyze options that would minimize the economic impact of that rule on small entities. Pursuant to the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary of Health and Human Services certifies that this final rule might have a significant impact on a substantial number of small entities.

A. Estimate and Description of the Small Entities

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For dietary supplements of vitamins and minerals, a business is considered small if it has fewer than 750 employees.

As stated in the previous section, FDA has determined that there are approximately 675 products that may require label redesign or product reformulation if they do not meet the definitions established by this regulation. Using Dun's Market Identifiers, FDA has determined that half of these products are produced by 120 small entities.

B. Description of the Impacts

As stated earlier, FDA has no information to determine how many of these products will be reformulated, nor how many labels will be redesigned as a result of this regulation. Firms whose labels do not meet the definitions for the claims established in this rulemaking will decide between reformulation and relabeling based on the relative costs of each. In addition, affected firms may choose to reformulate the product if the loss of the claim will result in a significant reduction in sales. FDA cannot predict the cost of reformulating because it will depend on the nutrients involved and, in the case of ''high potency,'' the degree to which the level of the nutrient is below the definition for the claim. As stated in section VIII of this document, FDA has determined the cost of redesigning each label to be $2,200.

The smallest affected entity for which FDA has information has three employees, annual sales of $120,000, and produces one product potentially affected by this regulation. If the product will require label redesign, then the cost of this regulation to that firm will be a one-time cost of $2,200, or 1.8 percent of the firm's annual sales. FDA considers this potential cost to be significant.

C. Compliance Requirements and Necessary Skills

The Regulatory Flexibility Act also requires agencies to describe the projected reporting, recordkeeping, and other compliance requirements of the rule and the type of professional skills necessary for preparation of the report or record. As stated elsewhere in this preamble, there are no reporting or recordkeeping requirements of this rule. Manufacturers desiring to use ''high potency'' or ''antioxidant'' claims on the labels of their products are only required to ensure that the products meet the definitions of the claims.

In the case of ''high potency,'' manufacturers must review the levels of the nutrients for which the claim is made and ensure that they are sufficient. Because manufacturers are required to report the levels in the nutrition facts panel, no further analysis of the product is necessary. If the levels of the relevant nutrients are insufficient, then the firm must either avoid using the claim or alter the levels of the nutrient to meet the established definition.

In the case of the term ''antioxidant'' when used in nutrient content claims, firms must simply know whether or not the nutrient is one of the nutrients that may be labeled ''antioxidant'' when used in a nutrient content claim. No special skills are required in this case.

D. Alternatives

FDA has examined the following alternatives to the rule which may minimize the significant economic impact on small entities consistent with the stated objectives.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to

exempt them from the provisions of this rule. However, the majority of the firms engaged in the manufacture of vitamin or mineral supplements are small. Even accounting for the fact that large firms produce more products on average than small firms, exempting small firms would exempt a large proportion of products. Although this option would clearly eliminate the burden on small firms, it would also result in a significant reduction in the value to consumers of standardizing these terms. Therefore, FDA concludes that selecting this alternative would defeat the purpose of the regulation.

2. Lengthen the Compliance Period

As discussed elsewhere, the agency is persuaded to make this final rule effective 18 months following its publication date because the agency wishes to minimize the impact of label changes on manufacturers. FDA considered establishing a longer compliance period for small entities. However, within the 18-month compliance period, all but the very smallest entities will be required to change their labels in response to nutrition labeling and ingredient labeling requirements. Thus, lengthening this compliance period will not result in any reduction in costs to these firms because they are not likely to opt to relabel their products twice when they have the ability to combine the necessary changes into one relabeling effort.

X. References

The following references have been placed on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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 101.54 is amended by revising the section heading and adding new paragraphs (f) and (g) to read as follows:

§ 101.54 Nutrient content claims for ''good source,'' ''high,'' ''more,'' and ''high potency.''

* * * * *

(f) ''*High potency*'' claims. (1)(i) The term ''high potency'' may be used on the label or in the labeling of foods to describe individual vitamins or minerals that are present at 100 percent or more of the RDI per reference amount customarily consumed.

(ii) When the term ''high potency'' is used to describe individual vitamins or minerals in a product that contains

other nutrients or dietary ingredients, the label or labeling shall clearly identify which vitamin or mineral is described by the term ''high potency'' (e.g., ''Botanical 'X' with high potency vitamin E'').

(2) The term ''high potency'' may be used on the label or in the labeling of a multiingredient food product to describe the product if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in § 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

(3) Where compliance with paragraphs (f)(1)(i), (f)(1)(ii), or (f)(2) of this section is based on a nutrient that has been added to a food (other than a dietary supplement), that fortification shall be in accordance with the policy on fortification of foods in § 104.20 of this chapter.

(g) *Nutrient content claims using the term ''antioxidant.''* A nutrient content claim that characterizes the level of antioxidant nutrients present in a food may be used on the label or in the labeling of that food when:

(1) An RDI has been established for each of the nutrients;

(2) The nutrients that are the subject of the claim have recognized antioxidant activity; that is, when there exists scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions;

(3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the § 101.54(b), (c), or (e) claim (e.g., to bear the claim ''high in antioxidant vitamin C,'' the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, for the claim ''good source of antioxidant beta-carotene,'' 10 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed; and

(4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., ''high in antioxidant vitamins C and E''). Alternatively, when used as part of a nutrient content claim, the term ''antioxidant'' or ''antioxidants'' (as in ''high in antioxidants'') may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients shall appear in letters of a type size height no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

3. Section 101.60 is amended by revising paragraph (c)(1)(iii)(A) to read as follows:

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

* * * * *

(c) * * *

(1) * * *

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, or, if a dietary supplement, it meets the definition in paragraph (b)(2) of this section for ''low calorie'' but is prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim; or

* * * * *

Dated: September 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24732 Filed 9–22–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0094]

Uniform Compliance Date for Food Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to comments.

SUMMARY: The Food and Drug Administration (FDA) is responding to comments that were submitted in response to a final rule establishing January 1, 2000, as the uniform compliance date for food labeling regulations that the agency issues between January 1, 1997, and December 31, 1998. FDA received three comments in response to that final rule. The agency is not making any changes in the final rule in response to these comments. January 1, 2000, remains the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has periodically announced uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. In 1992, FDA suspended this practice pending the issuance of regulations implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). In the **Federal Register** of December 24, 1996 (61 FR 67710), FDA issued a final rule (hereinafter referred to as the December 24, 1996, final rule) establishing January 1, 1998, as its new uniform compliance date for all food labeling regulations that are issued after its publication and before January 1, 1997. FDA announced that it was reinstating its previous practice of periodically announcing, as final rules, uniform compliance dates for food labeling regulations. In the **Federal Register** of December 27, 1996 (61 FR 68145) (hereinafter referred to as the December 27, 1996, final rule), FDA established January 1, 2000, as the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998. Because FDA had already provided notice and opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date (see 61 FR 67710, December 24, 1996), the agency found any further rulemaking unnecessary. Nonetheless, under 21 CFR 10.40(e)(1), FDA provided an opportunity until March 13, 1997, for interested persons to comment on whether the uniform compliance date of January 1, 2000, should be modified or revoked. In the December 27, 1996, final rule, FDA advised that it would publish a notice setting out the agency's conclusions concerning any comments that it received in response to the final rule or initiate notice and comment rulemaking to modify or revoke the uniform compliance date that the final rule established.

FDA received three letters, each containing one or more comments, from trade associations in response to the December 27, 1996, final rule. A summary of these comments and the