situation, the referenced symbol and disclaimer shall be placed in a box.

(d) *Typesize.* The disclaimer in paragraph (b) of this section shall appear in boldface type in letters of a type size height no smaller than the larger of:

(1) One-half the type size of the largest statement of nutritional support; or

(2) One-sixteenth inch.

Dated: September 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–31193 Filed 12–27–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0347]

RIN 0910–AA23

Food Labeling; 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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to define the term ''high potency'' as a nutrient content claim for dietary supplements; define the term ''antioxidant'' for use in nutrient content claims on labels or in labeling of dietary supplements and conventional foods; and 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 in response to provisions of the Nutrition Labeling and Education Act of 1990. This proposed rule will benefit consumers by providing established definitions for use in food labeling for the terms ''high potency,'' ''antioxidant,'' and ''sugar free.''

DATES: Written comments by March 13, 1996. The agency proposes that any final rule that may issue based upon this proposal become effective January 1, 1997.

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

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.

SUPPLEMENTARY INFORMATION:

I. Regulatory History

A. The Nutrition Labeling and Education Act of 1990 and Subsequent Proposals

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). The 1990 amendments revised the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments is that they establish FDA's authority to regulate nutrient content claims on food labels and in food labeling. Section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)), which was added by the 1990 amendments, provides that a product is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level, in the food, of any nutrient of the type required to be declared as part of nutrition labeling, unless such claim has been specifically defined (or otherwise exempted) by regulation.

In the Federal Register of November 27, 1991 (56 FR 60421 and 56 FR 60478), FDA published two documents (''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms;'' and ''Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'') in which it proposed, among other things, to define nutrient content claims and to provide for their use on food labels. FDA intended that these proposals would apply to dietary supplements as well as conventional foods.

B. The Dietary Supplement Act of 1992, Final Labeling Rules, and the Dietary Supplement Health and Education Act of 1994

On October 6, 1992, the President signed into law the Dietary Supplement Act of 1992, Title II of Pub. L. 102–571 (the DS Act). Section 202(a)(1) of the DS Act established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements until December 15, 1993. Section 202(a)(2)(A) of the DS Act directed the Secretary of Health and Human Services to issue new proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances.

FDA published final regulations that implemented the 1990 amendments with respect to nutrient content claims in the Federal Register of January 6, 1993, in a document entitled ''Food Labeling; Nutrient Content Claims; General Principles, Petitions, and Definition of Terms'' (hereinafter referred to as ''the 1993 nutrient content claims final rule''). As a result of the DS Act, this final rule applied only to the use of such claims on conventional foods (58 FR 2302 as corrected at 58 FR 17341). FDA made technical corrections to these final regulations in documents published in the Federal Register on August 18, 1993 (58 FR 44020).

In response to the requirements of the 1990 amendments and the DS Act, FDA published in the Federal Register of June 18, 1993 (58 FR 33731), 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) to: (1) Include dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances under the coverage of the general principles for nutrient content claims; (2) provide for the use of expressed and implied nutrient content claims on labels or in labeling of dietary supplements; and (3) provide for petitions for nutrient content claims for dietary supplements. FDA received approximately 500 letters in response to its 1993 nutrient content claims proposal. FDA issued final regulations on nutrient content claims for dietary supplements on January 4, 1994 (59 FR 378) (hereinafter referred to as the 1994 nutrient content claims final rule).

On October 25, 1994, the President signed into law the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (Pub. L. 103–417). Among other things, the DSHEA provided a statutory definition for ''dietary supplements,'' provided for some flexibility in the manner in which ingredient and nutrition labeling information is to be provided for dietary supplements, and made provision for statements that characterize the percentage level of dietary ingredients for which Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's) have not been established. However, these changes do not bear directly on this rulemaking.

In the 1994 nutrient content claims final rule, FDA used the terms ''dietary supplements of vitamins, minerals, herbs, and other similar nutritional

substances'' and ''food in conventional food form.'' With the passage of the DSHEA, however, Congress has defined the term ''dietary supplement'' and has modified the act in sections 201(ff) and 411(c)(1) (21 U.S.C. 321(ff) and 350(c)(1)) to make clear that the form of the food is not necessarily determinative of whether it is a dietary supplement or not. Therefore, in this document, FDA will use the more simple terms ''dietary supplement'' and ''conventional food.''

II. FDA Authority

Section 403(r)(2)(A)(i) of the act states that claims that characterize the level of a nutrient may be made only if the claim uses terms that are defined in regulations. In response to this section, the agency is proposing to amend its regulations on nutrient content claims to define the term ''high potency'' as a nutrient content claim for use on labels and in labeling of dietary supplements and the term ''antioxidant'' for use in nutrient content claims for dietary supplements and conventional foods.

FDA has authority to take these actions regarding nutrient content claims under sections 201(n) and 403(a), as well as section 403(r), of the act (21 U.S.C. 321(n) and 343(a)). These sections prohibit labeling that: (1) Is false or misleading in that it fails to reveal facts that are material in light of other representations made in the labeling or that are material with respect to the consequences that may result from use of the food, and (2) uses terms to characterize the level of any nutrient in a food that have not been defined by regulation by FDA.

III. Proposed Rules

A. ''High Potency''

1. Background

In the 1993 nutrient content claims 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 are established meanings for these terms, and, if so, whether they characterize the level of the nutrients in the food. The agency received about 10 comments from trade associations, manufacturers of dietary supplements and conventional foods, academicians, and consumer groups regarding the term ''high potency.''

FDA was persuaded, based on comments that suggested definitions for the term, that ''high potency'' is a claim that characterizes the level of a nutrient or nutrients and, therefore, meets the definition in § 101.13(b) of a nutrient content claim (59 FR 378 at 391). However, given the time constraints under which FDA prepared the final rule, and the range and diversity of the suggested definitions, the agency was not able to adopt a definition of ''high potency'' in the final rule on nutrient content claims for dietary supplements. FDA announced its intention to review the suggestions for a definition of ''high potency'' and, based on information received in the comments, to propose an appropriate definition for this term (59 FR 378 at 391). In this document, the agency is proceeding with its commitment to propose a definition for ''high potency.''

2. Limitation to Dietary Supplements

In the 1994 nutrient content claims final rule, the agency determined that, in many respects, the regulations issued in the 1993 nutrient content claims final rule (58 FR 2302) are directly applicable to dietary supplements (59 FR 378 at 380). However, FDA acknowledged that dietary supplements differ in several respects from conventional foods in their history of use and in their perceived function in the diet (59 FR 378 at 380). This fact and the fact that certain dietary supplements are likely to contain much higher levels of nutrients than conventional foods led FDA to conclude that nutrient content claims that are specific for dietary supplements may be appropriate (59 FR 378 at 380). Comments to the nutrient content claims proposal for dietary supplements stated that the term ''high potency'' seems more appropriate for dietary supplements than for conventional foods (59 FR 378 at 390).

In considering the coverage of this term, FDA has relied, in part, on the National Academy of Sciences' (NAS) Institute of Medicine's (IOM) recommendations found in ''Nutrition Labeling, Issues and Directions for the 1990's'' (Ref. 1). In discussing claims, the IOM suggested that the terms that should be defined are those that are most commonly used (Ref. 1, p. 296). FDA has no evidence that the term ''high potency'' is used with any frequency on conventional foods, that the term was used on conventional foods before the enactment of the 1990 amendments, or that consumers expect or would understand it in association with conventional foods. In contrast, the term ''high potency'' was in widespread use on the labels of dietary supplements before the enactment of the 1990 amendments, continues to be used on dietary supplements, and appears to convey information to the consumer about the level of the nutrients in dietary supplements.

Lacking a clear history of use, or any other indication of the usefulness, of the term ''high potency'' on conventional foods, the agency tentatively concludes that this term should be limited to use on dietary supplements. Accordingly, FDA is proposing to amend part 101 (21 CFR part 101) by adding new § 101.13(b)(6), which states that the term ''high potency'' may be used only on dietary supplements.

FDA recognizes that defining a nutrient content claim exclusively for use on labels and in labeling of dietary supplements is a departure from previous practice. However, the agency tentatively concludes that limiting this claim to dietary supplements is the appropriate course for the reasons stated above. Comment is requested on this tentative conclusion.

3. Definition of ''High Potency'' as a Nutrient Content Claim

a. *Describing a nutrient.* FDA received several comments that presented a wide range of views on how ''high potency'' should be defined. One comment to the proposed rule on nutrient content claims suggested that the term ''high potency'' have the same definition as ''high'' (i.e., 20 percent or more of the RDI), but did not provide any elaboration on why this suggested definition is appropriate. Other comments asserted that this term could be used to establish an hierarchy of absolute claims (i.e., ''good source,'' ''high,'' and ''high potency'') to describe dietary supplements. This hierarchy, the comments suggested, will enable consumers to use the claims to quickly differentiate between varying nutrient levels in dietary supplements.

A few comments suggested that the term be defined to mean that the product contains 200 percent of the RDI. These comments argued that while a multivitamin supplement at 100 percent of the RDI might be ''high potency'' compared to a conventional food, it is not ''high potency'' when compared to other dietary supplements. These comments suggested that defining ''high potency'' as twice the RDI or more would more accurately reflect the level of nutrients found in dietary supplements. One of these comments stated that, in addition to requiring that single nutrient supplements be twice the RDI for that nutrient, FDA should require that the principal display panel disclose what multiple of the RDI the supplement contains. For example, the comment suggested that the principal display panel of a 250 milligram (mg)

vitamin C supplement carry an asterisk next to the words ''high potency'' with the following disclosure: ''Contains four times the RDI for vitamin C.'' The comment went on to state that under this scheme, some nutrients, such as calcium and selenium, would not qualify to carry a ''high potency'' claim because they are rarely sold at 200 percent of the RDI. The comment suggested that if the supplement industry begins to market those nutrients at higher doses to make ''high potency'' claims, FDA could establish a lower minimum level, such as 50 percent of the RDI for selenium and 50 percent of the RDI for calcium. The comment stated that those minimum levels would apply to those nutrients only.

Several comments, however, argued that the term ''high potency'' should mean 100 percent or more of the RDI because that is the current industry practice, and it has been helpful in directing consumers in their choice of products. One comment from the dietary supplement industry stated that, in their experience, the term ''high potency'' has generally been used for the last 20 years to refer to formulations that are at levels above the U.S. Recommended Daily Allowances (U.S. RDA's).

FDA acknowledges that many dietary supplements, particularly dietary supplements of vitamins or minerals, are likely to contain much higher levels of nutrients than conventional foods (Ref. 2). Currently approved nutrient content claims are of limited value in identifying those dietary supplements that contain amounts of vitamins or minerals at or above the Daily Value (DV). Claims such as ''good source'' and ''high'' are adequate to describe nutrient levels found in the majority of conventional foods, but they do not allow for differentiation of dietary supplement products containing much higher levels of nutrients. Therefore, the agency is in agreement with the comments that suggested that the term ''high potency'' should be defined in a way that permits such differentiation.

Accordingly, FDA rejects the comment that suggested that ''high potency'' be defined as 20 percent or more of the RDI. Such a definition would make ''high potency'' synonymous with ''high'' and thus would not help consumers differentiate between relatively low nutrient levels in many dietary supplements in the marketplace and those at higher levels.

FDA is not persuaded by the comments that suggested that 200 percent of the RDI is an appropriate definition for ''high potency.'' While the agency acknowledges that dietary supplements of vitamins and minerals often contain levels that meet or exceed 200 percent of the RDI per unit, that fact alone does not justify defining ''high potency'' at that level.

Supplement users report a variety of reasons for taking dietary supplements, including ensuring adequacy of intake of specific nutrients (Refs. 3, 4, and 5). FDA is interested in ensuring, and the nutrient content claim provisions were intended to ensure (see, e.g., section 403(r)(2)(A)(ii)(II) of the act) that consumers have useful label information that will help them maintain healthy dietary practices, in part by constructing nutritionally adequate diets. However, the agency is not persuaded that proposing a definition for ''high potency'' at 200 percent or more of the RDI will contribute to this goal. The RDI's are based on the NAS Recommended Dietary Allowances (RDA's), which are intended to reflect ''the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged by the Food and Nutrition Board, NAS to be adequate to meet the known nutrient needs of practically all healthy persons'' (Ref. 6). FDA is aware that the NAS is in the process of reevaluating the basis on which RDA's are determined and is considering expanding the RDA concept to include reducing the risk of chronic disease (Ref. 7). Until that debate is resolved, the agency tentatively concludes that it is appropriate to define ''high potency'' at a level that will assist consumers interested in using dietary supplements in obtaining an adequate intake as determined by established RDI values.

The agency tentatively concludes that 100 percent of the RDI per serving is a reasonable definition of ''high potency'' because this level is high enough ''to meet the needs of practically all healthy persons.'' RDI values represent the highest NAS RDA values from among the various age/sex groups specified by the NAS for persons 4 or more years of age (58 FR 2206 at 2210). Thus, a person consuming a ''high potency'' vitamin or mineral will be assured of meeting his or her need for the nutrient described as ''high potency.'' Such action would be a healthy dietary practice.

FDA tentatively concludes that the proposed definition of ''high potency'' makes sense for two additional reasons. First, as stated in the comments, it is consistent with current industry practice. Second, as a matter of common sense, providing of 100 percent of the RDI for a vitamin or mineral is to provide an amount of the vitamin or mineral that is highly potent.

FDA's tentative conclusion does not mean, however, that the agency is opposed to the presence of more than 100 percent of the RDI of a nutrient per serving. Manufacturers can formulate and describe the level of a nutrient as multiples of the RDI (e.g., using the terminology ''Daily Value'' to represent RDI's on the label, a vitamin C tablet containing 500 mg would declare ''833 percent of the Daily Value of vitamin C''). Nonetheless, because the purpose of nutrient content claims is to assist consumers in maintaining healthy dietary practices, and given the recommendations of the NAS on which the RDI's are based, FDA tentatively concludes that it is appropriate to tie a ''high potency'' claim to the RDI itself.

In addition to the nutrients for which RDI's have been established, FDA is proposing that the claim ''high potency'' may be used to describe protein and dietary fiber for which DRV's have been established in § 101.9(c)(9). Because dietary guidelines recommend that consumers moderate or reduce dietary levels of four other nutrients for which DRV's have been established (i.e., total fat, saturated fat, cholesterol, and sodium) to reduce the risk of developing certain chronic diseases (Ref. 8), FDA does not expect, and, therefore, is not proposing, that ''high potency'' claims be used to apply to them.

Additionally, the agency is not proposing that ''high potency'' claims be used to apply to two other nutrients, total carbohydrate and potassium, for which DRV's have been established. Section 101.54(a) precludes the use of the claims listed in that section in relation to total carbohydrate.[1] In the case of potassium, tablets containing potassium chloride or other potassium salts, which supply 100 mg or more of potassium per tablet, are considered to be drugs. (See 21 CFR 201.306.)

The agency is not aware of any reason why ''high potency'' claims should not be allowed to be used with protein and dietary fiber. FDA established the DRV's at levels for each nutrient that represent scientific consensus on the characteristics of foods Americans should choose both to have a healthier diet and to reduce risk factors for chronic diseases and conditions (58 FR

[1]In the 1993 nutrient content claims proposal, FDA stated that consensus reports and dietary recommendations generally encourage the increased consumption of complex carbohydrates, while suggesting that sugars be consumed in moderation (56 FR 60421 at 60444). The agency concluded that a nutrient content claim such as ''high in carbohydrate'' may provide misleading dietary advice because the claim does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars (56 FR 60421 at 60444).

2206 at 2217). Nutrient content claims that assist consumers in constructing diets by identifying foods, including dietary supplements, that contain protein and dietary fiber at such levels should be allowed.

FDA tentatively concludes that, consistent with the agency's treatment of the claim for nutrients for which RDI's have been established, ''high potency'' should be defined for protein and dietary fiber at 100 percent of the DRV. The agency notes that throughout its rulemakings on nutrient content claims, it has used identical values for nutrients for which a DRV has been established as for those that are the subject of an RDI (e.g., ''good source'' claims are defined in § 101.54(c) as 10 to 19 percent of the RDI or DRV per reference amount customarily consumed).

Accordingly, FDA is proposing in § 101.54(f)(1) that the term ''high potency'' may be used on the label or in labeling of a dietary supplement to describe a nutrient that is present at 100 percent or more of the RDI for vitamins and minerals or the DRV for protein or dietary fiber per reference amount customarily consumed.

In response to the comment that suggested that FDA require that the principal display panel disclose what multiple of the nutrient's RDI is present (e.g., ''Contains 400 percent of the Daily Value of Vitamin C''), FDA is not persuaded that this action would be helpful to consumers. The referral statement, ''See ———————— for nutrition information,'' which directs the consumer to the nutrition panel is required for all nutrient content claims as specified in § 101.13(g). As proposed in a companion document published elsewhere in this issue of the Federal Register and entitled ''Food Labeling; Statement of Identity; Nutrition Labeling and Ingredient Labeling of Dietary Supplements,'' the nutrition label for dietary supplements of vitamins and minerals will have to provide quantitative information on the levels of specific nutrients as well as the percent Daily Value (DV) for each nutrient. Consequently, the consumer will have easy access to information regarding the levels of specific nutrients and may adjust their level of intake accordingly.

In addition, not requiring any additional information or disclosure beyond the referral statement is consistent with rules for the use of other expressed nutrient content claims, e.g., ''good source'' and ''high'' claims, which do not have to disclose the fraction of the RDI present. While FDA tentatively concludes that there is no need for additional disclosure requirements for products bearing a ''high potency'' claim, the agency points out that manufacturers may voluntarily place a statement on the label that discloses the amount or percentage of nutrients in relation to the DV as provided for in § 101.13(i) and (q)(3) (e.g., ''50 percent of the RDI for calcium,'' ''10 mg of iron'').

In response to the comment that suggested that the agency consider establishing a definition for ''high potency'' at lower levels for some nutrients if manufacturers start increasing amounts of the nutrients so that they can meet the criterion for the claim ''high potency,'' the agency believes that such action is unnecessary and potentially confusing to consumers. The agency tentatively concludes that the term ''high potency'' should have the same definition for all nutrients. In instances in which the product does not meet the proposed criteria for the claim ''high potency,'' the product may qualify to use another nutrient content claim, such as ''good source'' (defined in § 101.54(c) as 10 to 19 percent of the RDI or DRV) or ''high'' (defined in § 101.54(b) as 20 percent or more of the RDI or DRV). For example, when calcium is present in a dietary supplement at 20 percent or more of the RDI, the manufacturer can use the nutrient content claim ''high'' to describe the level of calcium. In addition, as stated above, under § 101.13(i) and (q)(3) the manufacturer may declare the amount or percentage of the nutrient on the label.

b. *Describing a dietary supplement product.* The comments stated that in addition to being used to describe the level of a nutrient in a product, the term ''high potency'' is also often used to describe multinutrient dietary supplement products themselves. Several comments discussed the use of a ''high potency'' claim on multinutrient products, and whether all nutrients in such a product would have to be present at levels that would meet the criterion for the claim. One comment stated that the claim should be permitted on any supplement that contains 100 percent of the RDI for each vitamin and mineral that is included in the product and for which an RDI has been established. The comment went on to state that the presence or absence of vitamins, minerals, or other substances for which no RDI's have been established should not affect a product's eligibility to bear the claim, so long as those nutrients for which RDI's have been established are present at required levels.

In contrast with this comment, a few comments stated that multinutrient products should be termed ''high potency'' when the majority of nutrients with RDI's are present at levels equal to or in excess of the RDI. Another comment stated that FDA should allow ''high potency'' claims on multinutrient supplements when more than one-third of the nutrients that they contain meet the minimum level required for a ''high potency'' claim. The latter comment stated that it is not reasonable to require that all of the nutrients in a multiingredient supplement be present at the level that is defined as ''high potency'' because many nutrients are not, and should not, be sold in such high doses. For example, the comment stated that ''high potency'' claims should be allowed on a multinutrient supplement that contains high levels of vitamins A, C, E, B6, B12, thiamin, riboflavin, and niacin, but smaller amounts of vitamin D, iron, calcium, magnesium, zinc, and copper. The comment stated that the latter nutrients are typically sold at lower doses, and some may pose a risk at high levels.

FDA has considered the comments that ''all,'' ''most,'' or ''one-third'' of the nutrients in a dietary supplement be present at 100 percent of the RDI or DRV for the supplement to qualify to bear the term ''high potency.'' A review of an informal FDA survey of labels of dietary supplements that bear the term ''high potency'' revealed that most multinutrient products that used the claim contained a majority, but not all, nutrients at 100 percent or more of the RDI (Ref. 9). FDA agrees with the comment that it may be impracticable to include 100 percent of the RDI or DRV for several nutrients for technological reasons. For instance, the bulkiness of calcium, phosphorus, magnesium, and fiber may make it difficult to provide sufficient amounts of those nutrients for them to be included in ''high potency'' tablets if they must be present at 100 percent of the RDI or DRV.

FDA tentatively concludes that it is not necessary to prohibit the use of a ''high potency'' claim on multinutrient dietary supplements if the supplements do not contain 100 percent or more of the RDI for each vitamin and mineral that is present, or 100 percent of the DRV for protein or dietary fiber, when present. The agency is persuaded by the comments that the public will be better served from a public health perspective if some nutrients are allowed to be present in such products at levels that are below 100 percent of the RDI or DRV. Without such an allowance, those nutrients that cannot be included at 100 percent levels because of technological difficulties could not be included at all if the dietary supplement is to bear a

''high potency'' claim. The exclusion of these nutrients will not necessarily help consumers to engage in healthy dietary practices.

Having tentatively concluded that some nutrients may be present in a ''high potency'' multinutrient dietary supplement at less than 100 percent of the RDI or DRV, the agency must determine what percentage of nutrients must be present in the product at 100 percent of the RDI or DRV for the product to qualify to make a ''high potency'' claim. A logical starting point is determination of: (1) How many nutrients have had RDI's and DRV's established for them, and (2) of those nutrients, how many cannot, or should not, be expected to be present at 100 percent of the RDI or DRV for technological reasons or because of public health concerns.

In the RDI/DRV final rules published on January 6, 1993 (58 FR 2206), FDA established RDI's in § 101.9(c)(8)(iv) for 19 vitamins and minerals (i.e., vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, and copper) and DRV's in § 101.9(c)(9) for eight nutrients (i.e., total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein). In addition, in a companion document entitled ''Food Labeling: Reference Daily Intakes'' published elsewhere in this issue of the Federal Register, FDA is establishing RDI's for six additional vitamins and minerals (i.e., vitamin K, selenium, chloride, manganese, chromium, molybdenum). Thus, there are a total of 33 nutrients for which RDI's or DRV's have been established. Of these 33 nutrients, 4 (i.e., calcium, phosphorus, magnesium, and fiber) have already been mentioned as being difficult to include in dietary supplements in amounts equal to 100 percent of the DV because of technological problems related to their bulk.

Other nutrients that should not be expected to be present at 100 percent of the DV include total fat, saturated fat, cholesterol, and sodium. It would be nonsensical to associate the term ''high potency'' with these nutrients because, as discussed earlier, dietary guidelines recommend that intake of these nutrients be limited or moderated in the diet (Ref. 8). In addition, it is not useful to include chloride at high levels in multinutrient supplements. Salt is the primary source of dietary chloride, and the typical American diet already contains significant levels of chloride because of high intakes of salt (Refs. 6 and 10). (See the discussion of the exemption of chloride in § 101.3(e)(4)(ii) in the final rule entitled ''Food Labeling: Reference Daily Intakes'' published elsewhere in this issue of the Federal Register.) Lastly, as discussed earlier, potassium would be considered a drug at such high levels, so it should not be included in dietary supplements at 100 percent of the DRV.

Therefore, FDA tentatively concludes that there are 11 nutrients (calcium, phosphorus, magnesium, dietary fiber, total carbohydrate, total fat, saturated fat, cholesterol, sodium, chloride, and potassium) for which it would be impracticable or imprudent to require that, when present in a multinutrient product, they be present at levels at or above 100 percent of the RDI or DRV for the product to qualify for the use of the nutrient content claim ''high potency.'' This amounts to one-third of the nutrients for which RDI's and DRV's have been established (11 out of 33 nutrients). Accordingly, the agency believes that it would be reasonable to expect that the remaining two-thirds of the nutrients for which RDI's and DRV's have been established could be present at 100 percent of the RDI or DRV in a ''high potency'' multinutrient dietary supplement product that contained all 33 nutrients for which RDI's and DRV's have been established.

FDA finds merit in the comment that suggested that not all nutrients need be present at or above the RDI for the product to qualify for the claim. This comment suggests that the agency establish a standard for ''high potency'' that applies to supplements that do not contain all of the 33 nutrients for which RDI's and DRV's have been established as well as those that do. FDA tentatively concludes that two-thirds represents a reasonable standard; it provides flexibility for supplements that do not contain all 33 nutrients, and it provides a consistent standard for all supplement products. Finally, it is a familiar fraction that is easy to use. With a two-thirds standard, the manufacturer would have latitude to decide, in formulating a product that will qualify to bear a ''high potency'' claim, which nutrients to include at 100 percent of the RDI or DRV. The alternative would be to require that any of the 22 nutrients that can be present at 100 percent of the DRV be present at that level if the supplement is to bear a ''high potency'' claim. FDA is concerned, however, that such a requirement would set too high a standard and not provide appropriate flexibility. Comment is requested on the agency's tentative conclusion.

Based on these factors, the agency is proposing in § 101.54(f)(2) that the term ''high potency'' may be used on the label or in the labeling of a dietary supplement to describe the product (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'') if the product contains 100 percent or more of the RDI or DRV for at least two-thirds of the vitamins, minerals, protein, and dietary fiber present in the product. This proposed requirement will mean that each nutrient (i.e., vitamin, mineral, protein, or dietary fiber) in a dietary supplement containing only one or two nutrients will have to be present at 100 percent or more of the RDI or DRV because two-thirds of one or two nutrients does not result in a whole number that is different from the original number (e.g., 2 times 2/3 equals 1.34; the product 1.34 indicates that more than one nutrient is needed to meet the criterion; therefore both nutrients would have to meet or exceed 100 percent of the RDI or DRV).

The agency recognizes that dietary supplements that consist of an assortment of dietary ingredients are widely available in the marketplace. FDA agrees with the comment that stated that the presence or absence of dietary ingredients for which RDI's or DRV's have not been established (e.g., omega-3 fatty acids, choline, boron) (hereinafter referred to as ''other dietary ingredients'') should not affect the claim so long as those nutrients with RDI's or DRV's are present at levels required for the claim. The presence or absence of other dietary ingredients for which RDI's and DRV's have not been established is immaterial to the claim, and, therefore, the agency finds no basis for proposing alternate requirements for such products. It is important to note that because the definition that FDA is proposing is based on the presence of a nutrient at 100 percent of the RDI or DRV, dietary supplements that do not contain nutrients for which RDI's or DRV's have been established will not be able to use the term ''high potency.''

c. *Disclosure requirement.* One comment stated that the label of a ''high potency'' multivitamin product should disclose the names or number of nutrients that are present at high levels. For example, the comment suggested that the label could carry an asterisk next to the claim, with the following disclosure: ''contains high levels of [number] vitamins.''

The agency rejects this comment. The agency tentatively concludes that such a requirement for the label or labeling of a ''high potency'' multinutrient dietary supplement is not needed to prevent consumers from being misled by the claim. Section 403(s) of the act, added by the DSHEA, states that a dietary

supplement is misbranded if its label or labeling fails to list the quantity of each dietary ingredient present. (See implementing regulations proposed in a companion document published elsewhere in this issue of the Federal Register entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements.'') In accordance with the proposed and current nutrition labeling regulations, information on what, and how many, nutrients are present at 100 percent or more of the RDI or DRV can be readily determined from the nutrition label.

In addition, it would be cumbersome for a product containing 100 percent of the RDI for several nutrients for which RDI's or DRV's have been established to list all of those nutrients on the principal display panel. Many comments to the agency's proposals on the labeling of dietary supplements have addressed the lack of available space to meet current labeling requirements on multinutrient dietary supplement products. Therefore, the agency tentatively concludes that it is unnecessary, and would be impracticable, to require a list on the principal display panel of the number or names of all nutrients present at 100 percent or more of the RDI or DRV.

4. Synonyms

Although the agency asked for specific comment on the term ''high potency,'' several comments in response to the nutrient content claims proposal for dietary supplements used the term ''full potency'' in discussions. FDA requests comment on whether the term ''full potency'' is generally viewed by consumers as a synonym to ''high potency,'' and if there are other terms that appropriately can be defined as synonymous with ''high potency.'' If reasonable synonyms are suggested in the comments, and the comments establish that use of these terms will not be misleading, the agency will consider defining them as synonyms with ''high potency'' in the final rule.

B. Nutrient Content Claims Using the Term ''Antioxidants''

1. Background

One comment to the 1993 nutrient content claims proposal (58 FR 33731) stated that FDA failed to address whether the currently used claim of ''high in antioxidants'' was within the scope of the proposed regulation. The agency stated in the 1994 nutrient content claims final rule that while this claim was not explicitly discussed in the 1993 nutrient content claims proposal. FDA considered it to be a nutrient content claim (59 FR 378 at 389). One problem noted with the claim, however, was that there is no established definition of the term ''antioxidants.''

In an informal survey of dietary supplement products sold in the Washington, DC area, FDA found that the claim ''high in antioxidants'' often refers to a variety of nutrients and other dietary ingredients that are present in widely varying amounts (Ref. 9). This inconsistent use of the claim can lead to consumer confusion. To ensure that consumers are not confused or misled, Congress found in passing the 1990 amendments that it is appropriate for FDA to establish specific definitions to standardize the terms used by manufacturers to describe the nutrient content of foods. Accordingly, in this document, FDA is proposing to define ''antioxidants'' so that it can be used in a clear and consistent manner in conjunction with currently defined nutrient content claims such as ''good source,'' ''high,'' and ''more'' and the proposed ''high potency'' claim. The agency is following up on the commitment that it made in the 1994 nutrient content claims final rule to propose to adopt a definition for the term (59 FR 378 at 389).

The term ''antioxidants'' is unique in comparison to the names of other nutrients associated with nutrient content claims. Unlike previously approved nutrient content claims that characterize the level of a particular nutrient (e.g., ''low sodium''), a term such as ''high in antioxidants'' ties a claim (i.e., ''high'') to a class of nutrients that share a specific characteristic (i.e., they are antioxidants) whose very name indicates a metabolic function. Because of this fact, it is important to make a clear distinction between the term when used as part of a nutrient content claim and possible uses of the term as part of a health claim or a statement of nutritional support.

Nutrient content claims expressly or implicitly characterize the level of a nutrient in a food and are regulated under § 101.13. Health claims are claims that expressly or by implication characterize the relationship of any substance to a disease or health-related condition. They are regulated under § 101.14. Moreover, statements of nutritional support, authorized by section 403(r)(6) of the act, which was added by the DSHEA, encompass label statements on dietary supplements that claim a benefit related to a classical nutrient deficiency disease, describe how a nutrient or dietary ingredient affects the structure or function in humans, characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function, or describe general well-being from consumption of a nutrient or dietary ingredient.

In the case of a claim such as ''high in antioxidants,'' a set of substances is clearly identified (i.e., ''antioxidants'') and a level of nutrients is stated (i.e., ''high''), but there is no disease or health-related condition stated or implied, and the descriptive or characterizing aspects of nutritional support statements are not present. Accordingly, such a term is properly regulated as a nutrient content claim.

2. Express Versus Implied Nutrient Content Claims

In the 1994 nutrient content claims final rule, FDA stated that it considered ''high in antioxidants'' to be an implied nutrient content claim that would come under § 101.65 (59 FR 378 at 389). However, after further consideration, the agency tentatively concludes that when the term ''antioxidants'' appears in association with expressed nutrient content claims (i.e., ''good source,'' ''high,'' ''more,'' and the proposed ''high potency''), the claim is more properly classified as an expressed claim. Therefore, the agency is defining the term ''antioxidants'' in § 101.54 *Nutrient Content Claims for ''Good Source,'' ''High,'' and ''More.''* This placement is consistent with the manner in which fiber claims (e.g., ''high in fiber'') are regulated. (See § 101.54(d).) Accordingly, the agency is proposing to add paragraph (g) to § 101.54 to address nutrient content claims using the term ''antioxidants.''

3. Definition of ''Antioxidants''

As stated, the agency is proposing to define the term ''antioxidants'' for use with nutrient content claims such as ''good source,'' ''high,'' and ''more'' that are defined in § 101.54, and with the proposed ''high potency.'' This task entails determining which nutrients are to be included within the coverage of the term ''antioxidants.''

In a previous rulemaking, FDA has reviewed the characteristics of three vitamins that function as antioxidants. Section 3(b)(1)(A)(x) of the 1990 amendments directed the agency to address the relationship between antioxidant vitamins and cancer. In its proposed regulations to implement the 1990 amendments, FDA considered the effects of vitamin C, vitamin E, and beta-carotene on cancer (56 FR 60624, November 27, 1991). In that document, FDA summarized the antioxidant properties of those nutrients.

FDA stated that vitamin C serves as an effective free-radical scavenger to protect cells from damage by reactive oxygen molecules (a free-radical being an atom containing an unpaired electron which tends to give the atom more reactivity, often leading to a pro-oxidative chain reaction which can damage cells). The basic biological function of vitamin E was found to be as an antioxidant where it acts as a defense against potentially harmful reactions with oxygen by deactivation of the free-radicals. In the case of beta-carotene, the agency stated that it was chosen because it is an antioxidant, and, although it is not recognized as a vitamin itself, it is a provitamin and makes important contributions to the vitamin A activity of most diets. Beta-carotene acts by trapping, deactivating, and destroying reactive oxygen molecules and preventing the damage that they can cause. FDA did not include vitamin A (retinol) and retinoic acid in its consideration because their biological functions are not achieved through an antioxidant role, and because vitamin A cannot function in a fashion similar to that of beta carotene (carotenoids) and vitamins C and E (Refs. 11 and 12).

In the final rule on antioxidant vitamins and cancer, FDA concluded that this selection of nutrients was appropriate (58 FR 2622, January 6, 1993).

In addition, a recent conference entitled ''Antioxidant Vitamins and Cancer and Cardiovascular Disease,'' initiated by FDA, supported this conclusion and affirmed that the biological role of other vitamins as direct antioxidants remains unsubstantiated (Ref. 13). Riboflavin and niacin, two of the B-vitamins, are precursors of coenzymes that are involved in large numbers of oxidation and reduction reactions. By themselves, however, these vitamins do not have direct antioxidant activities. Moreover, after conversion to their coenzyme forms, they have indirect effects that are both antioxidant and pro-oxidative in character (Refs. 14 and 15). When pro-oxidative conditions (i.e., the opposite of antioxidative) predominate, oxidative damage occurs to cells, lipids, proteins, and carbohydrates (Ref. 16). Thus, FDA tentatively concludes that these nutrients should not be classed as antioxidants.

As stated earlier, the 1990 amendments specifically required that the agency evaluate the relationship of antioxidant vitamins to cancer. Antioxidant minerals were not mentioned in the statute and were not considered by the agency. However, in this rulemaking to define ''antioxidants'' for use in nutrient content claims, FDA is not restricted in the nutrients that are to be encompassed by this term. Based on its informal survey, the agency notes that some dietary supplements, including both single nutrient and multinutrient products, use the term ''antioxidant'' on their label and in labeling to describe minerals such as copper, zinc, manganese, iron, and selenium (Ref. 9). Accordingly, FDA has reviewed the literature on the biological activities of these minerals.

As a result of its review, the agency tentatively concludes that there is no evidence that these substances have direct antioxidant properties, and that, in fact, some of them are pro-oxidative at certain levels. For example, copper, manganese, and zinc activate specific forms of the enzyme superoxide dismutase (SOD) which acts to remove the superoxide radical, and thus these minerals have indirect antioxidant effects (Refs. 17, 18, and 19). However, copper and manganese, in their free forms, are effective catalysts for oxidation reactions (i.e., pro-oxidants). Their role as an indirect antioxidant would be expected to predominate only at intakes at or below the quantities needed to saturate SOD. Higher intakes would be expected to have pro-oxidative effects (Refs. 17 and 18). Zinc does not have direct antioxidant or oxidant effects. It activates one form of SOD and thus has only indirect antioxidant activity (Ref. 19). Iron, another mineral, is an activator of catalase, which destroys peroxides, and thus has indirect antioxidant effects, but, again, iron itself catalyzes oxidative reactions (Ref. 20). Selenium is required for the activity of the enzyme glutathione peroxidase and thus has indirect antioxidant effects (Ref. 21).

The agency's tentative view is that it is appropriate to identify only those nutrients having a clear, direct antioxidant function in defining the coverage of the term ''antioxidants.'' Because none of the minerals discussed above function directly as antioxidants, the agency tentatively concludes that they should not be included in the definition of the term ''antioxidants'' for purposes of making a nutrient content claim. Accordingly, FDA is proposing in § 101.54(g)(1), in part, that ''antioxidants'' be defined as a collective term inclusive of vitamin C, vitamin E, and beta-carotene when used as a part of nutrient content claims (e.g., ''good source of antioxidants,'' ''high in antioxidants'') that describe food products. FDA also provides in the proposed regulation that the food must contain the requisite amounts of each of the three nutrients to qualify to bear the claim (e.g., for ''high in antioxidants,'' the product must contain 20 percent or more of the RDI for vitamin C and vitamin E per reference amount customarily consumed, and 20 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed).

Because there is a recent history of use of nutrient content claims for ''antioxidants'' on both dietary supplements and conventional foods, the agency is proposing in § 101.54(g)(1) that such claims be allowed on both types of foods. It should be noted, however, that because the agency is proposing in this document that the term ''high potency'' be limited to dietary supplements, the term ''high potency antioxidants'' could be used only on dietary supplements.

FDA notes that some herbs and other dietary ingredients use the term ''antioxidants'' in association with a nutrient content claim (e.g., ''raspberry leaf—high in antioxidants''). The agency advises that the regulations being proposed would not permit such nutrient content claims unless the product contains the nutrients identified in the proposed definition of ''antioxidants.''

4. Beta-carotene

Nutrient content claims are authorized for nutrients for which there are RDI's or DRV's. This approach has the advantage of linking nutrient content claims to established reference values, thereby providing a consistent and quantitative basis for defining terms. As a pro-vitamin, beta-carotene does not have an RDI or DRV. However, FDA stated in the final rule on nutrient content claims for dietary supplements that claims regarding beta-carotene (e.g., ''contains beta-carotene'') are claims that make implied representations about the level of vitamin A that is present in the food as beta-carotene (59 FR 378 at 384). Accordingly, the agency stated that it considers that the claim ''contains beta-carotene'' implies that there is enough beta-carotene in the food for the food to qualify as a ''good source'' of vitamin A (i.e., it contains 10 percent or more of the DV for vitamin A from beta-carotene) (59 FR 378 at 384). Such a claim is provided for in § 101.65(c).

The agency tentatively concludes that this standard should also apply to beta-carotene when it, either by itself or in association with other antioxidants, is the subject of an ''antioxidant'' claim. This standard allows beta-carotene to be tied to vitamin A, a nutrient with an RDI, as an implied claim, thereby

permitting nutrient content claims to be made about this substance. Therefore, proposed § 101.54(g)(1) includes a requirement that vitamin A present as beta-carotene be present at a sufficient level to qualify for the claim (e.g., for ''high in antioxidants,'' 20 percent or more of the DV for vitamin A must be present as beta-carotene; for ''high potency antioxidant,'' 100 percent or more of the DV for vitamin A must be present as beta-carotene).

FDA acknowledges that the antioxidant role of beta-carotene was not taken into account by the NAS in setting the RDA's for vitamin A (Ref. 6). Therefore, there is no reason to believe that the amount of beta-carotene potentially useful as an antioxidant is related to the RDI for vitamin A. However, the agency tentatively concludes that the above approach is a practical means of quantifying the level of beta-carotene that must be present for a food to qualify to bear an antioxidant nutrient content claim.

5. Disclosure Requirement

FDA is aware of the availability of products that do not contain all three of the nutrients included in the proposed definition of ''antioxidants'' (i.e., vitamin C, vitamin E, and beta-carotene) yet that highlight the antioxidant properties of a particular nutrient (e.g., ''Contains antioxidant vitamin E'') on the label or in labeling. FDA tentatively concludes that it is appropriate to allow products to bear such claims because the antioxidant properties of each nutrient are significant enough to highlight. However, the agency finds that when a food makes a claim for ''antioxidants'' yet fails to contain all three nutrients, the disclosure of the specific antioxidant nutrients that are present in the product is necessary to ensure that consumers are not misled into thinking that the product contains all three nutrients. Such a disclosure is necessary to reveal a fact that is material in light of the antioxidant claim (section 201(n) of the act), that is, to disclose which nutrients with antioxidant effects are present in the product at the highlighted level.

Accordingly, the agency is proposing in § 101.54(g)(2) that when a nutrient content claim using the term ''antioxidant'' is included on the label or in labeling of a product that does not contain all three antioxidants at the required levels, the claim may only be used on the label or in labeling when the food contains at least one of the nutrients at the requisite level, and the label or labeling discloses the antioxidants contained in the product in sufficient amounts to qualify for the claim (e.g., ''High in antioxidant vitamins C and E'').

6. Collective Claims

Collective claims such as ''complete antioxidant complex'' and ''antioxidant formula'' seem to convey that the product contains each antioxidant. Because FDA has identified three vitamins with direct antioxidant activity, it is reasonable to expect that a dietary supplement or conventional food making such a collective claim about antioxidants will contain each of these vitamins. Further, such claims imply that each nutrient is present at a level sufficient to make a significant contribution to the total daily diet, or at a minimum, is a ''good source'' of each nutrient.

Therefore, FDA tentatively concludes that collective claims about antioxidants, such as ''complete antioxidant complex'' or ''antioxidant formula'' state that the labeled product contains 10 percent or more of the RDI of vitamin C and vitamin E, and that 10 percent or more of the RDI for vitamin A is present as beta-carotene.

Accordingly, FDA is proposing to add § 101.54(g)(3) to provide for the use, under section 403(r)(2)(A)(i) of the act, of such collective antioxidant terms (e.g., ''complete antioxidant formula,'' ''antioxidant complex'') as nutrient content claims 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 when such a term is used. This definition, if adopted, would not preclude the presence of other nutrients (e.g., selenium and zinc) in the product, nor would this definition preclude manufacturers from making other nutrient content claims that characterize the level of other nutrients that have RDI's or DRV's. Further, manufacturers may also describe the nutritional properties of other ingredients as long as the statements are not false or misleading or do not constitute unauthorized health claims or unapproved drug claims.

C. Limitation of ''High Potency'' and Nutrient Content Claims Using the Term ''Antioxidant'' on Products for Infants and Toddlers

The agency points out that § 101.13(b)(3) states that except for percentage claims regarding vitamins and minerals described in § 101.13(q)(3), no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 (21 CFR parts 105 and 107).

The agency sees no reason why an exception should be made to extend the use of the terms discussed in this rulemaking to products for infants and toddlers. FDA is not aware of any evidence that the intake of dietary supplements at ''high potency'' levels, or that an increased intake of antioxidants, are appropriate for infants and toddlers. Relatively little attention has been given to the role of the diet of children less than 2 years of age in modifying the risk of chronic diseases, such as hypertension and cancer, found in adults (Refs. 10 and 22). Thus, FDA is not aware of any basis on which to conclude that these claims would be useful to the parents of young children. In fact, such terms would be misleading on foods for infants and toddlers because they imply benefits that have not been demonstrated.

In addition, the definitions of nutrient content claims for both ''high potency'' and for the several possible levels of ''antioxidants'' (e.g., ''good source,'' ''high,'' and ''more'') are dependent upon calculation of the percent of the RDI for the appropriate nutrient present in the product. However, no RDI's are currently established for infants and children less than 2 years of age. The agency has stated that it intends to address the issue of RDI's for infants, children less than 4 years, and pregnant and lactating women in future rulemaking (59 FR 427 at 430, January 4, 1994), and it reiterates that intention in the final rule on RDI's published elsewhere in this issue of the Federal Register. However, until it establishes these levels, there is no basis on which to define these terms for use on foods intended for infants and children less than 2 years of age.

D. Amendment to § 101.60 Concerning Nutrient Content Claims for the Calorie Content of Foods for Dietary Supplements

Section 101.60(c)(1) states that consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners as an indication that a product is low in calories or is significantly reduced in calories. This section also states that a food cannot be labeled ''sugar free'' or ''no sugar'' unless it meets the following conditions: (1) The food contains less than 0.5 gram (g) of sugars per reference amount and per labeled serving, (2) the food contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the

listing of the ingredient in the ingredient statement is followed by an asterisk that refers to a statement below the list of ingredients such as ''adds a negligible amount of sugar,'' and (3) it is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness, or is labeled ''not a reduced calorie food,'' ''not a low calorie food,'' or ''not for weight control.''

In the 1994 nutrient content claims final rule, FDA added paragraph § 101.60(a)(4) to state that ''calorie free'' and ''low calorie'' claims may not be made on dietary supplement products, except when an equivalent amount of a dietary supplement that the labeled food resembles and for which it substitutes (e.g., another protein supplement), normally exceeds the definition for ''low calorie'' in § 101.60(b)(2). The agency also similarly revised § 101.13(b)(5). This change in §§ 101.13(b)(5) and 101.60(a)(4) had the unintended effect of limiting the use of ''sugar free'' or ''no sugar'' claims on dietary supplements that would otherwise meet the requirements for ''low calorie'' in § 101.60(b)(2) but are not permitted to bear the claim because they do not substitute for a similar dietary supplement that normally exceeds the definition for ''low calorie.''

In the 1994 nutrient content claims final rule, FDA had found that, because the level of sugars in dietary supplements can vary substantially, claims about the sugars content of dietary supplements may be useful in helping consumers make purchasing decisions that will assist them in maintaining healthy dietary practices (59 FR 378 at 382). Thus, the agency concluded that extending the definitions of ''sugar free'' and ''reduced sugar'' to dietary supplements was appropriate irrespective of the calorie level of the dietary supplement. Therefore, FDA did not modify the requirements governing claims for sugars in § 101.60(c) for dietary supplements. In not making a change to § 101.60(c), however, FDA overlooked the impact of new §§ 101.13(b)(5) and 101.60(a)(4).

In order to allow for ''sugar free'' or ''no sugar'' claims on dietary supplements that meet the other criteria for the claim (i.e., contain less than 0.5 g of sugars per reference amount and contain no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless an appropriate statement is added after the ingredient list), the requirement that the product be labeled ''low calorie'' should have been modified for dietary supplements that were prohibited from making ''low calorie'' claims because no other dietary supplement that the labeled food resembles and for which it substitutes exceeded the definition for ''low calorie.'' FDA is proposing to make that change now. No modification is needed for dietary supplements labeled ''reduced calorie'' since that claim was not changed by the final rules on nutrient content claims for dietary supplements or for those dietary supplements that are not low or reduced in calories.

The agency is not aware of any reason why its position in § 101.60(c)(1) that consumers may be expected to regard ''sugar free'' and ''no sugar'' claims as indicative of a product that is low or reduced in calories should be different for dietary supplements than for conventional foods. Therefore, FDA is proposing to revise § 101.60(c)(1)(iii)(A) to excuse only dietary supplements that otherwise meet the definition of ''low calorie'' under § 101.60(b)(2) but that are prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim.

IV. Effective Date

FDA is proposing an effective date of January 1, 1997. This date is consistent with the effective date proposed in two companion proposals published elsewhere in this issue of the Federal Register entitled ''Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements'' and ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements.'' This date will allow firms to make all label changes associated with the DSHEA and with the two companion proposals at the same time.

V. Economic Impact

FDA has examined the economic implications of the proposed rule amending 21 CFR as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches which maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires analyzing options for regulatory relief for small businesses. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

Many currently marketed foods and dietary supplements use the terms ''high potency'' and ''high in antioxidants'' to describe the level of nutrients in the products. Without definitions for these terms, manufacturers will not be able to continue to use them. This proposed rule will require that any manufacturer 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 proposed definition. FDA does not believe that the number of products that would not meet the proposed definition is high.

VI. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirements; thus there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is asking for comment on whether this proposed rule to define the term ''high potency'' as a nutrient content claim for dietary supplements, to define the term ''antioxidant'' for use in nutrient content claims for dietary supplements, and to correct an omission pertaining to the use of ''sugar free'' claims on dietary supplements imposes any paperwork burden.

VII. Environmental Impact

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

VIII. Comments

Interested persons may, on or before March 13, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

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15. Swendseid, M. E., and R. A. Jacob, ''Niacin,'' edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 376–382, Lea & Febiger, Philadelphia, 1994.

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18. Nielsen, F. H., ''Ultratrace Elements,'' edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 269–286, Lea & Febiger, Philadelphia, 1994.

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22. U.S. Department of Health and Human Services, ''The Surgeon General's Report on Nutrition and Health,'' DHHS (Public Health Service) Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

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, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

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

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

2. Section 101.13 is amended by adding new paragraph (b)(6) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(6) The term ''high potency'' may only be used on the labels or in the labeling of dietary supplements as defined by section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

3. 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) The term ''high potency'' may be used on the label or in the labeling of dietary supplements to describe a nutrient that is present at 100 percent or more of the RDI for vitamins and minerals or of the DRV for protein and dietary fiber per reference amount customarily consumed.

(2) The term ''high potency'' may be used on the label or in the labeling of dietary supplements to describe a product that contains 100 percent or more of the RDI, or of the DRV, for at least two-thirds of the vitamins and minerals, and of the protein and dietary fiber, present in the product (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

(g) ''Antioxidants'' claims. (1) The term ''antioxidants'' is defined as a collective term inclusive of vitamin C, vitamin E, and the provitamin beta-carotene when used as part of a nutrient content claim (e.g., ''good source of antioxidants,'' ''high in antioxidants'') on labels or in labeling of conventional foods or dietary supplements. The levels of vitamin C and vitamin E and the level of vitamin A present as beta-carotene in the food that bears the claim all must be sufficient to qualify for the claim (i.e., for ''high in antioxidants,'' the product must contain 20 percent or more of the RDI for vitamin C and vitamin E per reference amount customarily consumed and 20 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed).

(2) The term ''antioxidants'' may only be used on the label or in labeling of a food that does not contain each of the three antioxidants (i.e., vitamin C, vitamin E, and beta-carotene) in sufficient amounts to qualify for the claim if the food contains at least one of these nutrients at the requisite level, and the claim discloses which antioxidants in the food meet the required level (e.g., ''High in antioxidant vitamins C and E'').

(3) A collective claim about antioxidant nutrients (e.g., ''complete antioxidant formula,'' ''antioxidant complex'') may be used on the label or in labeling of foods 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.

4. 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: December 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–31194 Filed 12–27–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0245]

RIN 0910–AA59

Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to require that dietary supplements be identified with the statement of identity ''Dietary Supplement'' on the principal display panel of the label and modify the nutrition labeling and ingredient labeling requirements for these foods. FDA is proposing these actions in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA). FDA is also responding to a citizen petition on type size requirements for these products.

DATES: Written comments by March 13, 1996; except that comments regarding information collection should be submitted by January 29, 1996, but not later than February 26, 1996. The agency is proposing that any final rule that may issue based upon this proposal become effective January 1, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Written comments regarding paperwork burden estimates should be sent to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Susan Thompson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5587.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the notable aspects of the 1990 amendments is that they added section 403(q) to the act (21 U.S.C. 343(q)). This section provided that most foods are misbranded unless they bear nutrition labeling.

In particular, section 403(q)(5)(F) of the act (originally section 403(q)(5)(E)) provided that if a food to which section 411 of the act (21 U.S.C. 350) applies (i.e., a dietary supplement of vitamins or minerals) contained any of the nutrients required to be listed in nutrition labeling, ''the label or labeling of such food shall comply with requirements of subparagraphs (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary.''

In response to this provision of the 1990 amendments, FDA published a proposal on nutrition labeling in the Federal Register of November 27, 1991 (56 FR 60366 at 60393). The document proposed, among other things, specific nutrition labeling requirements for dietary supplements of vitamins or minerals (proposed § 101.36) and to require that dietary supplements of herbs or other similar nutritional substances comply with the general regulation on nutrition labeling (§ 101.9) (21 CFR 101.9).

On October 6, 1992, the President signed into law the Dietary Supplement Act of 1992 (the DS act) (Pub. L. 102–571). In section 202(a)(1) (21 U.S.C. 343 note), the DS act established a moratorium until December 15, 1993, on the implementation of the 1990 amendments with respect to dietary supplements not in the form of conventional food. Section 202(a)(2) of the DS act required that the Secretary of Health and Human Services (the Secretary), and by delegation FDA, issue new proposed regulations applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993.

In the Federal Register of January 6, 1993 (58 FR 2079), FDA published a final rule on the nutrition labeling of food in conventional food form (§ 101.9). Because of the DS act, however, this final rule did not cover the nutrition labeling of dietary supplements.

In the Federal Register of June 18, 1993 (58 FR 33715), FDA published a new proposed rule on the nutrition labeling of dietary supplements, as required by the DS act. FDA received over 400 responses to that proposed rule. In the Federal Register of January 4, 1994 (59 FR 354), FDA published a final rule (hereinafter referred to as ''the 1994 dietary supplement final rule'') based on the June 1993 proposed rule. Consistent with section 403(q)(5)(F) of the act, the 1994 dietary supplement final rule included separate nutrition labeling requirements for dietary supplements of vitamins or minerals, which are set out in § 101.36, and for dietary supplements of herbs and other nutritional substances, which the agency said were subject to § 101.9.

In the Federal Register of January 4, 1994 (59 FR 427), the agency proposed to expand the list of nutrients for which there are Reference Daily Intake (RDI) values in § 101.9(c)(8)(iv) to include vitamin K, selenium, chloride, manganese, fluoride, chromium, and molybdenum. The final rule based on that proposed rule is published elsewhere in this issue of the Federal Register.

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or