

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 101**

[Docket No. 95N-0282]

**Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its nutrient content claims regulations to change the terminology used to describe dietary supplements; provide for the use of statements that characterize the percentage level of dietary ingredients that do not have Reference Daily Intakes (RDI's) or Daily Reference Values (DRV's); and withdraw the provision that dietary supplements of vitamins and minerals may not give prominence to any ingredient that is not a vitamin or a mineral on its label or in labeling. The agency is also proposing to specify how (i.e., text, placement, and type size) the disclaimer required by the Federal Food, Drug, and Cosmetic Act (the act) is to be presented with statements of nutritional support. Additionally, FDA is proposing to remove the definition of "dietary supplements" and to change the terminology used to describe dietary supplements in regulations governing health claims for food products. This action is being taken to implement in part the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

**DATES:** Written comments by March 13, 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, 301-245-1064.

**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. 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). The 1990 amendments amended the act in a number of important ways. One of the most notable aspects of the 1990 amendments is that they established FDA's authority to regulate nutrient content and health 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 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. Section 403(r)(1)(B) of the act, also added by the 1990 amendments, provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with sections 403(r)(3) of the act (which pertains to foods in conventional food form) or 403(r)(5)(D) (which pertains to dietary supplements).

In the Federal Register of November 27, 1991 (56 FR 60421 and 56 FR 60478), FDA published two documents, one general and the other on fat, fatty acid, and cholesterol claims, in which the agency proposed, among other things, to define nutrient content claims, to provide for their use on foods labels, and to establish procedures for the submission and review of petitions regarding the use of specific nutrient content claims. These proposals applied to dietary supplements as well as to foods in conventional food form. In the same issue of the Federal Register, FDA proposed general requirements on the use of health claims and on petitions to the agency to authorize health claims (56 FR 60537).

On October 6, 1992, the President signed into law the Dietary Supplement Act of 1992 (the DS Act) (Pub. L. 102-571). 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) 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, FDA published final regulations that implemented the 1990 amendments with respect to nutrient content claims

(hereinafter referred to as the "1993 nutrient content claims final rule") (58 FR 2302) and health claims (hereinafter referred to as the "1993 health claims final rule") (58 FR 2478) on foods in conventional food form. In the Federal Register of August 18, 1993 (58 FR 44020 and 44036), FDA made technical amendments to these final regulations.

In response to the requirements of the DS Act, FDA published in the Federal Register of June 18, 1993 (58 FR 33731), a 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 express 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 (hereinafter referred to as the "1993 nutrient content claims for dietary supplements proposal"). In the same issue of the Federal Register, FDA also proposed to make dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances subject to the general requirements that apply to all other types of food with respect to the use of health claims (hereinafter referred to as the "1993 dietary supplement health claims proposal") (58 FR 33700).

FDA received approximately 500 letters in response to its 1993 nutrient content claims for dietary supplements proposal. A summary of the comments, the agency's responses to the comments, and a complete discussion of the agency's conclusions with respect to nutrient content claims for dietary supplements were published in the Federal Register of January 4, 1994 (59 FR 378), in the final rule on nutrient content claims for dietary supplements (hereinafter referred to as the "1994 nutrient content claims for dietary supplements final rule"). FDA received over 1,200 letters in response to the 1993 dietary supplement health claims proposal. FDA summarized and responded to these comments in the final rule on health claims for dietary supplements in the same issue of the Federal Register (59 FR 395).

On October 25, 1994, the President signed into law the DSHEA (Pub. L. 103-417). The DSHEA, among other things, defined "dietary supplement" (adding section 201(ff) to the act (21 U.S.C. 321(ff))), made provision for statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's (adding section 403(r)(2)(F) to the act), and amended section 411 (b)(2) and (c)(1) of the act (21 U.S.C. 350 (b)(2) and (c)(1))

on the labeling of products that contain vitamins and minerals. In addition, the DSHEA added section 403(r)(6) to the act, which states that statements may be made for dietary supplements if:

the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient \* \* \*.

(section 403(r)(6)(A) of the act), and if certain other conditions are met. The manufacturer of the dietary supplement must have substantiation that the statement is truthful and not misleading (section 403(r)(6)(B)), and the nutritional support statement must prominently contain the following disclaimer:

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. (section 403(r)(6)(C)).

This proposal addresses how this disclaimer is to be presented on the label or in labeling of a dietary supplement. The agency is issuing this proposal in response to requests from the dietary supplement industry that FDA define how this statement is to be presented. In addition, this proposal seeks to bring the agency's nutrient content claim and health claim regulations into conformance with the DSHEA and provides for the use of statements that characterize the percentage level of dietary ingredients that do not have RDI's or DRV's on labels and in labeling of dietary supplements.

## II. Proposed Regulations

### A. Coverage

As discussed in the preamble to the 1994 nutrient content claims for dietary supplements final rule (59 FR 378 at 379), section 403(r)(1)(A) of the act states that a food intended for human consumption is misbranded if it bears a claim that expressly or by implication "characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food \* \* \*." The statute uses the same language in section 403(r)(1)(B) to describe the substances that could be the subject of a health claim, i.e., a health claim is a claim that "characterizes the relationship of any nutrient which is of

the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition \* \* \*." Under section 403(r)(1)(B), a health claim must be made in accordance with section 403(r)(3) or section 403(r)(5)(D). The latter section, which addresses health claims for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances, is relevant to this proceeding. The legislative history of the phrase "other similar nutritional substances" reveals that its coverage is broad (136 Congressional Record S16609 (October 24, 1990)).

Section 3(a) of the DSHEA amends section 201 of the act by adding section 201(ff), which defines a "dietary supplement" as a product, other than tobacco, intended to supplement the diet that bears or contains one or more of the following dietary ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the aforementioned dietary ingredients. In effect, the list of dietary ingredients in section 201(ff)(1) is an explication of the term "other similar nutritional substances" in section 403(r)(5)(D). Thus, based on the foregoing analysis, all dietary ingredients may qualify, in appropriate circumstances, as "nutrients of the type required by paragraph (q)(1) and (q)(2)" for purposes of section 403(r) the act.<sup>1</sup> To clarify this point in its regulations, FDA is proposing to amend § 101.13(b) (21 CFR 101.13(b)) by adding a reference to § 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals* (21 CFR 101.36), so that § 101.13(b) will read, in part, if this amendment is

<sup>1</sup> While all dietary ingredients can be "nutrients of the type required by paragraph (q)(1) and (q)(2) to be in the label or labeling of the food" in appropriate circumstances, all dietary ingredients are not nutrients as that term is generally understood, in that they do not all have nutritive value. The DSHEA recognizes this fact by using the phrase "nutrient or dietary ingredient" (e.g., see section 403(r)(6) of the act), indicating that the two terms are not mutually inclusive. Furthermore, all dietary ingredients are not necessarily "ingredients" within the traditional meaning of that term under section 403(i) of the act. For example, in a "calcium dietary supplement," calcium would be the "dietary ingredient," whereas calcium carbonate or some other calcium salt would be the "ingredient," i.e., the "source" of the dietary ingredient, calcium. In a dietary supplement of garlic, garlic could be the dietary ingredient, while the common or usual name of the ingredient might be "dried, powdered garlic." However, if the manufacturer promoted the same supplement for its allicin content, allicin could be the dietary ingredient and the source of allicin, i.e., the ingredient, would be "dried, powdered garlic."

adopted: "A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim) \* \* \*."

The broad range of substances that can be dietary ingredients under section 201(ff) has the potential to create ambiguities as to the coverage of the nutrient content claim regime. With respect to some substances that can be dietary ingredients, the context in which statements about them are made will determine whether they are nutrient content claims or not. For example, garlic can be the dietary ingredient. A claim on the label or in the labeling of a dietary supplement that it is "high in garlic," or that it "now contains more garlic," is a nutrient content claim within the meaning of the act, and the food is misbranded unless such a claim has been authorized by FDA through regulation. The claim characterizes the level of garlic in a food in which the garlic is a "nutrient which is of the type" required to be listed in the nutrition label because the food is intended to supplement the dietary intake of garlic. On the other hand, a label statement on garlic bread, for example, that the product now contains more garlic would not be a nutrient content claim if the bread is not labeled as a dietary supplement, and if it is clear from the context in which the claim is made that the claim refers to the taste of the product. As FDA has provided in § 101.65(b)(3) (21 CFR 101.65(b)(3)), a claim about the presence of an ingredient that is perceived to add value to the product, which would clearly be the case when one adds more garlic to garlic bread, is not an implied nutrient content claim.

### B. Terminology

#### 1. Nutrient Content Claims

Current § 101.13(a), on nutrient content claims, states:

This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including foods in conventional food form and dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances (dietary supplements).

As discussed above, new section 201(ff) of the act creates a new definition for the term "dietary supplement." To reflect this definition and to simplify its regulations in the manner that the new definition permits, FDA is proposing to amend § 101.13(a) to read as follows: "This section and the regulations in subpart D of this part apply to foods that are intended for human consumption

and that are offered for sale, including conventional foods and dietary supplements.”

## 2. Health Claims

Under the general principles governing health claims, § 101.14(a)(4) (21 CFR 101.14(a)(4)) currently states that “dietary supplement” means a food, not in conventional food form, that supplies a component to supplement the diet by increasing the total dietary intake of that component. This definition has been superseded by the definition of “dietary supplement” found in new section 201(ff) of the act. Further, because section 201(ff)(2)(A) makes it clear that dietary supplements can be in a variety of forms, including conventional food form, FDA is proposing to remove § 101.14(a)(4) and redesignate current § 101.14(a)(5) and (a)(6) as § 101.14(a)(4) and (a)(5), respectively.

A similar conforming change is necessary in § 101.14(b)(3)(i) in the preliminary requirements for a substance to be eligible to be the subject of a health claim. This regulation refers to the fact that the food in which a substance is found may be “in conventional food form or dietary supplement form.”

To bring this section into conformance with section 201(ff) of the act, FDA is proposing to revise § 101.14(b)(3)(i) to read as follows:

The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and \* \* \*.

Section § 101.14(d)(3) currently states:

Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements of vitamins or minerals, in accordance with § 101.36. The requirements of the introductory text of paragraph (d)(3) of this section are effective as of May 8, 1993, except:

(i)-(ii) [Reserved]

(iii) For dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances for which the requirements of paragraph (d)(3) of this section will be effective July 5, 1994.

In the Federal Register of March 31, 1994 (59 FR 15050), the effective date was corrected for the nutrient content claims provision to July 1, 1994. Because of the passage of the DSHEA, the agency published a notice in the Federal Register of February 9, 1995 (60 FR 7711), stating that it does not intend

to enforce the Nutrient Content Claim regulations for dietary supplements until after December 31, 1996.

As above, the terminology for dietary supplements (i.e., “dietary supplements of vitamins and minerals”) used in § 101.14(d)(3) is too narrowly drawn in light of new section 201(ff) of the act. In addition, since the effective date is past, there is no longer a need to include it in the regulations. Therefore, FDA is proposing to revise § 101.14(d)(3) to remove “of vitamins and minerals” as a qualifier of the types of dietary supplements and to remove the language setting out the effective date in the second sentence of § 101.14(d)(3). These changes also mean that there is no need for paragraphs (d)(3)(i) through (d)(3)(iii). Accordingly, proposed § 101.14(d)(3) reads as follows:

Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements, in accordance with § 101.36.

### C. Percentage Claims

Section 7(c) of the DSHEA amends section 403(r)(2) of the act by adding clause (F) which reads:

Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

This new provision refers to section 403(r)(2)(A)(i) of the act, which states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary. Thus, section 403(r)(2)(A)(i) of the act limits the type of nutrient content claims that can be made to those terms that are defined and authorized by regulation. The effect of section 403(r)(2)(F) of the act is to permit the use on the labels or in the labeling of dietary supplements of statements that have not been defined by FDA that characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established.

In the absence of any substantive legislative history on this provision, the agency interprets section 403(r)(2)(F) of the act as authorizing claims on the label or in labeling of a dietary supplement that disclose the percentage level in the dietary supplement of a dietary ingredient for which an RDI and DRV has not been established in a product (e.g., “40 percent omega-3 fatty acids”) as well as statements that

characterize the percentage of such dietary ingredients in relation to an equivalent or increased/decreased amount found in another food product (e.g., “100 percent of the allicin in a bulb of garlic,” “twice the allicin as (product alternative)” [where “twice” is another way of saying 200 percent]).

Section 3(b)(1)(A)(iv) of the 1990 amendments directed the agency to promulgate regulations that permit statements describing the amount and percentage of nutrients in food that are not misleading and that are consistent with the terms defined under section 403(r)(2)(A)(i) of the act. Consequently, FDA provided in § 101.13(i) for statements about the amount or percentage of nutrients when specified criteria are met. While this regulation did not specifically include a provision for the use of such statements with respect to dietary ingredients for which no RDI or DRV had been established, § 101.13(i)(3) allowed for the use of amount or percentage statements that do not implicitly characterize the level of the nutrient in the food (e.g., claims that do not imply whether the amount is high or low based on an established RDI or DRV value), and that are not misleading in any way. In “Food Labeling, Questions and Answers” (Ref. 1, p. 36, C23), FDA stated that statements about a nutrient for which there is no established daily value (i.e., no RDI or DRV) could be made under § 101.13(i)(3) as long as the claim specifies only the amount of the nutrient per serving and does not imply that there is a lot or a little of that nutrient in the product. The example “x grams of omega-3 fatty acids” was given.

Accordingly, percentage claims such as “40 percent omega-3 fatty acids” that do not in any way characterize the level of a nutrient in terms of defined claims such as “high,” “low,” or “reduced” were permitted on dietary supplements as well as conventional foods before the enactment of the DSHEA. To memorialize this fact and to implement the DSHEA by reflecting that labels or labeling of dietary supplements may bear statements that characterize the percentage level of a dietary ingredient for which an RDI or DRV has not been established even though those statements have not been defined by FDA, the agency is proposing to amend § 101.13 by adding new paragraph (q)(3)(ii) to read as follows:

Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which an RDI or daily reference value (DRV) has not been established (e.g., “40 percent omega-3 fatty acids,” “100 percent of the allicin in a bulb of garlic,” or “twice the allicin as (name of

product alternative)" \* \* \*) may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. \* \* \*

Because this provision allows for an exemption to the nutrient content claims rules and is somewhat similar to the exemption in § 101.13(q)(3) for percentage statements for vitamins and minerals, the agency is placing the new paragraph in § 101.13(q)(3) by redesignating current § 101.13(q)(3) as § 101.13(q)(3)(i) and adding new § 101.13(q)(3)(ii).

The agency believes that percentage statements on the label or in labeling of a dietary supplement that characterize the percentage level of a dietary ingredient for which there is no established RDI or DRV in relation to an equivalent or increased/decreased amount of the dietary ingredient in another food, such as "100 percent of the allicin in a bulb of garlic" and "twice the allicin as (name of product alternative)," would be misleading under sections 403(a) and 201(n) of the act if there is not a meaningful amount of the dietary ingredient in both foods being compared and a meaningful difference between the two foods being contrasted. However, because many dietary ingredients, which are the subject of clause (F), do not have established reference amounts for daily consumption, there is not a single, consistent way to describe the amount or difference that would be considered meaningful for the broad spectrum of these dietary ingredients. Therefore, firms will need to determine on a case-by-case basis whether the stated amount of a dietary ingredient for which an RDI or DRV has not been established, and the difference between the amount of such a dietary ingredient in two products, is meaningful. In making such a determination, published literature on the dietary ingredient, knowledge of the functional properties of the dietary ingredient, and any additional information available to the manufacturer, packer, or distributor should be taken into account.

It should be noted that while FDA is proposing in § 101.13(q)(3)(ii) to provide for statements that characterize the percentage level of dietary ingredients for which no RDI or DRV has been established, the proposed regulations do not provide for use of the defined terms, such as "more," "good source," "high," and "as much as." For example, the statement "300 percent of the bioflavonoids in a large grapefruit" is permissible, but a claim such as "high in bioflavonoids" is not. As discussed in the nutrient content claims for dietary supplements proposal and final rule,

FDA has concluded that if the defined term (i.e., the nutrient content claim) is to have any meaning, there must be a level that can be used as a reference in determining whether the claim is valid and appropriate. The RDI's and DRV's provide such levels. Thus, FDA has limited the use of "good source," "high," and other defined terms to use with nutrients for which RDI's or DRV's have been established.

By way of exception, "contains" and "provides" are listed in § 101.54(c)(1) (21 CFR 101.54(c)(1)) as synonyms for "good source" (e.g., "Contains vitamin C" is considered synonymous with "good source of vitamin C") and are therefore dependent on the establishment of an RDI or DRV for the nutrient to qualify for the claim. However, the agency has stated that these words may be used with nutrients that do not have RDI's or DRV's when specific amounts are given for the nutrient (Ref. 1, p. 37, C24). Accordingly, the agency has no objection to statements such as "Contains 4 grams of omega-3 fatty acids per serving" being made for dietary ingredients for which RDI's and DRV's have not been established provided the specific amount of the nutrient is stated.

It should be noted that section 403(r)(2)(F) of the act applies only to dietary supplements. Congress did not provide this exemption for conventional foods. Therefore, except for the statements discussed in the preceding paragraph that come under § 101.13(i)(3), statements that characterize the level of a dietary ingredient without an established RDI or DRV will continue to be prohibited on conventional foods.

While section 403(r)(2)(F) of the act states that section 403(r)(2)(A)(i) does not apply to statements on the labels of dietary supplements that characterize the percent level of dietary ingredients, there is nothing in the DSHEA that exempts such statements from the requirement in section 403(r)(2)(B) for referral statements (i.e., "See [location] for nutrition information") or from other requirements for nutrient content claims. Accordingly, FDA is proposing to require in § 101.13(q)(3)(ii) that a referral statement (or disclosure statement when fat, saturated fat, cholesterol, or sodium exceed specified limits) accompany the claim in accordance with § 101.13 (g) or (h).

In addition, the agency tentatively concludes that when percentage statements are made comparing or contrasting the amount of a dietary ingredient for which an RDI or DRV has not been established in a dietary

supplement to that in a reference food, information on the identity of the reference food and on the quantitative amount of the dietary ingredient in both foods are material facts. Consumers need this information to evaluate and understand the claim being made, and the claim would be misleading under sections 403(a) and 201(n) of the act without it (see 56 FR 60421 at 60446, and 58 FR 2302 at 2365). This situation is analogous to that encountered with relative claims for nutrients, where there is a requirement in § 101.13(j)(2)(iv) for quantitative information comparing the amount of the subject nutrient in the product with that in the reference food. Inclusion of this information is particularly important because, while the nutrition label on dietary supplements will include information about the amount of dietary ingredients for which RDI's and DRV's have not been established that are present in the food (see proposed § 101.36(b)(3) in the companion document entitled "Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements" published elsewhere in this issue of the Federal Register), the nutrition label on conventional foods will not (except for nutrients provided for in § 101.9(c) such as sugars and polyunsaturated fat that do not have RDI's and DRV's established). Accordingly, when conventional foods are used as the reference food, information about the amount of a dietary ingredient for which there is no RDI or DRV that is present in the food is likely to only be available when it is provided as accompanying information, in accordance with § 101.13(j)(2)(iv).

For these reasons, FDA is proposing in § 101.13(q)(3)(ii) to require that whenever statements characterizing the percentage level of a dietary ingredient for which there is no RDI or DRV are made in comparison to the amount in a reference food, the reference food be clearly identified, and information on the actual amount of the dietary ingredient in both foods be provided in accordance with § 101.13(j)(2)(iv). Section 101.13(j)(2)(iv)(B) requires that this quantitative information be placed adjacent to the most prominent claim or to the nutrition label, except that when the nutrition label is on the information panel, the quantitative information may be placed elsewhere on that panel in accordance with § 101.2 (21 CFR 101.2) (see 60 FR 17202, April 5, 1995).

#### D. Disclaimer for Statements of Nutritional Support

##### 1. Exclusion From Drug Definition

As mentioned previously, the DSHEA added section 403(r)(6) to the act, which provides for certain statements of nutritional support for dietary supplements, including a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." Section 201(g)(1)(C) of the act states that a "drug" is an article (other than food) intended to affect the structure or any function of the body of man or other animals. Section 10(a) of the DSHEA adds the following statement to section 201(g)(1) of the act:

A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

Under section 10(a) of the DSHEA and section 403(r)(6) of the act, for a firm to take advantage of the exclusion from the "drug" definition for a statement of nutritional support on the label or in labeling of a dietary supplement, it must meet each of the conditions established under section 403(r)(6), including having substantiation that the claim is truthful and not misleading and having the disclaimer required in section 403(r)(6) displayed in conjunction with the statement. To implement the latter requirement, FDA is proposing in § 101.94, as stated in proposed § 101.94(a), to set forth the requirements for the text, placement, and typesize of the disclaimer that must accompany the statement of nutritional support for it to be subject to the exemption in section 201(g)(1)(C) of the act.

##### 2. Text

Section 403(r)(6)(C) requires the following disclaimer to be prominently displayed in boldface type:

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.

Based on inquiries that FDA has received from the dietary supplement industry, FDA tentatively finds that aspects of the statutory requirements for the disclaimer (e.g. "prominent display") need to be defined and implemented through regulations. Prominence is a relative term, and without regulations, the agency would be forced to evaluate prominence on a case-by-case basis. Such an approach would not provide firms with sufficient guidance to be assured that product

labels would not trigger regulatory action.

A literal reading of section 403(r)(6)(C) of the act suggests that *each* nutritional support statement must contain the disclaimer in its entirety, without any deviation from the statutory language. FDA tentatively concludes that, where a label contains only one nutritional support statement, there is no reason not to adopt such a reading of the act. Accordingly, the agency is proposing in § 101.94(b)(1) that where the label contains one statement of nutritional support provided for in section 403(r)(6) of the act, the label or labeling must prominently contain the disclaimer as required by the act without modification to the text.

However, where there are multiple nutritional support statements, or where the same statement appears several times, the agency recognizes that repeated use of the statutory text with each nutritional support statement could be confusing to consumers and burdensome to manufacturers. For example, if a dietary supplement includes three nutritional support statements on the same label panel, or in a piece of labeling such as a brochure, the literal reading of the act would require that each statement include the complete disclaimer. Because the statutory text is of some length, only very large label panels could conform to this requirement if they contained multiple statements.

FDA wishes to implement the statute in a practical way that still fully effectuates the purposes of the statute. In light of this fact, the agency tentatively concludes that it is appropriate to provide that the disclaimer required in section 403(r)(6)(C) of the act can be slightly modified to reflect the use of multiple statements of nutritional support. FDA is proposing in § 101.94(b)(2) to require that, where there is more than one statement of nutritional support, each statement contain the disclaimer as required by the act, or that the first sentence of the disclaimer be modified to the plural form to read as follows: "These statements have not been evaluated by the Food and Drug Administration." Under this proposal, the second sentence will remain as required by the act. For convenience, FDA will refer to this modified form of the disclaimer as "the plural disclaimer."

##### 3. Placement

The juxtaposition of the disclaimer to the statement of nutritional support as required by the act is one way to ensure prominence. Because the act states that

the statement of nutritional support must "contain" the disclaimer, the agency tentatively concludes that the disclaimer must be part of the statement of nutritional support. When there is only one such statement, this inclusion can be readily accomplished by presenting the disclaimer as part of the claim. Accordingly, FDA is proposing in § 101.94(c)(1) that the disclaimer be contained in each statement of nutritional support by placing the disclaimer immediately adjacent to the statement of nutritional support with no intervening material.

However, consistent with its desire to interpret section 403(r)(6) of the act in a practical way, FDA is proposing to provide for an alternative placement for the disclaimer on the label or in labeling in situations in which repetitive presentation of the disclaimer could be burdensome. In these situations, FDA wants to provide an approach to placement of the disclaimer that will give the disclaimer a prominence that will ensure that it will be read and understood by consumers but that will result in its presentation only once on the label panel or in labeling.

FDA tentatively concludes that where the label or labeling contains multiple statements of nutritional support, and the relationship between each of those statements and the disclaimer can be made obvious, the statutory requirement of prominent display of the disclaimer can be met without requiring that each statement of nutritional support actually include the disclaimer. FDA experience has been that one of the most effective ways of tying two label statements that are physically separated on the same label panel is through the use of a symbol such as an asterisk. Symbols have been used within nutrition labeling since its inception in 1973 and have proven to be an effective way of relating label information to explanatory footnotes. For example, asterisks have been used adjacent to names of vitamins and minerals present at very low levels to refer the consumer to a footnote stating "Contains less than 2 percent of the Daily Value (formerly the U.S. Recommended Daily Allowance)." FDA is unaware of any data indicating consumer difficulties with such use of symbols. The use of symbols would also help consumers differentiate between label statements to which the disclaimer is referring and other label claims to which the disclaimer does not apply (e.g., authorized health claims or nutrient content claims).

Accordingly, FDA is proposing in § 101.94(c)(2) that where there is more than one statement of nutritional support on a label panel or in labeling

other than a label, and the manufacturer, packer, or distributor wishes to comply with section 403(r)(6) of the act without having to place the disclaimer immediately after each statement of nutritional support, it can place a symbol (e.g., an asterisk) at the end of each statement of nutritional support that refers to the same symbol placed elsewhere on the same label panel or in the labeling that is followed by the disclaimer.

In a citizen petition dated March 20, 1995 (petition number 95P-0079/CP 1), the Nutritional Health Alliance (NHA) requested, among other things, that FDA issue regulations implementing section 403(r)(6) of the act. With respect to the placement of the disclaimer, NHA suggested that an asterisk follow each statement of nutritional support to refer the consumer to a specific place on the label, such as the information panel, where the disclaimer would appear only once.

Although FDA is proposing to provide most of what this petition seeks, the agency tentatively rejects the last aspect of this suggestion. Splitting the statement of nutritional support from the required disclaimer and allowing the disclaimer to appear on another panel does not establish an obvious relationship between the two pieces of information. The agency is concerned that the placement of the disclaimer on another panel would not reveal material facts in conjunction with the statement of nutritional support that are necessary for consumers to fully understand the significance of the statement. However, the agency will consider establishing provisions for the use of asterisks that refer to the disclaimer in a single specific location (such as the information panel), instead of on each panel bearing a statement of nutritional support, if the comments convince it that such an approach is consistent with the statute and would be useful to consumers. FDA requests any data that bear on the question of the effect that splitting a statement from a disclaimer in this manner will have on the likelihood that consumers will read the disclaimer. Specifically, the agency requests data on whether a consumer will track a symbol from one label panel or page of labeling to another to obtain the information about a statement of nutritional support that follows the symbol.

In addition, the requirement in the act for prominent display means that when the disclaimer does not appear immediately adjacent to a statement of nutritional support, it must be presented on the label or labeling in a manner that renders it as readily observable and as

likely to be read as the statement of nutritional support itself. In this regard, the agency's experience with the graphic requirements for the new nutrition label has been that a box around required label information greatly increases the prominence of the information placed inside the box (Ref. 2). Moreover, focus group discussions regarding warning labels show that messages put in a boxed area help consumers to distinguish the message from other information as well as draw attention to it (Ref. 3). Therefore, FDA is proposing in § 101.94(c)(2) to require that a box be drawn around the disclaimer when the disclaimer is not immediately adjacent to the statement of nutritional support.

For example, a side panel of a dietary supplement label may contain paragraphs of text that include more than one statement of nutritional support. Assuming that the manufacturer did not choose to place the disclaimer immediately after each statement of nutritional support, each such statement would be followed by a symbol, and the referenced symbol and disclaimer would be placed in a box on the same panel with the first sentence reading “\*These statements have not been evaluated by the Food and Drug Administration,” as proposed in section § 101.94(b)(2).

#### 4. Type Size and Style

With respect to the style of type to be used in the disclaimer, the DSHEA specifies that “boldface type” shall be used (section 403(r)(6)(C) of the act). FDA has reiterated this provision in proposed § 101.94(d).

With respect to type size requirements, FDA notes that even though section 403(r)(6) of the act does not include specific type size requirements for the accompanying information referred to as the disclaimer, other sections of the act, and the regulations promulgated thereunder, address a variety of requirements for information that is to accompany a claim. Sections 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act require 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 tentatively concludes that, for consistency, this requirement should be considered a key element of “prominent display” for the disclaimer.

FDA has long held that accompanying information should be in a size reasonably related to that of the

information that it modifies. This relative prominence, when codified, has (except in the case of provisions pertaining to nutrient content claim referral and disclosure statements in § 101.13) been one-half the type size of the information modified (see, e.g., §§ 101.22(i)(2) and 102.5(b)(2)(ii)). For nutrient content claims, FDA did establish type size requirements for referral and disclosure statements related to the area of the surface bearing the principal display panel rather than to the type size used for the nutrient content claim. However, nutrient content claims often have very large type size, whereas nutritional support statements will likely not appear in such large type because they are intended to convey more lengthy information. Certainly the statements that would qualify as nutritional support statements under section 403(r)(6) of the act that have appeared in dietary supplement labeling are of much greater length than most nutrient content claims.

Because nutritional support statements are likely to be more lengthy, firms are likely to use relatively small type for them. The agency is concerned that one-half the size of the type commonly used for long statements or paragraphs may be too small for consumers to read easily. Thus, FDA is proposing one-sixteenth of an inch as the minimum type size for the disclaimer in § 101.94(d).

One-sixteenth of an inch is specified in § 101.2(c) as the minimum type size for most other 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 tentatively concludes that a minimum type size of one-sixteenth of an inch for the disclaimer is necessary to ensure that it is prominently displayed in accordance with section 403(r)(6)(C) of the act.

#### *E. Prominence of Ingredients That Are Not Vitamins or Minerals*

Section 7(d) of the DSHEA strikes section 411(b)(2)(B) of the act. Before it was removed by the DSHEA, section 411(b)(2)(B) stated that the labeling and advertising of dietary supplements of vitamins and minerals could not give prominence to or emphasize ingredients that are not vitamins, minerals, or represented as a source of vitamins or minerals. Because of this provision, the agency stated that nutrient content claims about ingredients that are not

vitamins or minerals (e.g., "more fiber," "high protein") could not be made on dietary supplements of vitamins or minerals (59 FR 378 at 387). This limitation was carried through in the final rule for nutrient content claims for dietary supplements in § 101.54(b)(1), (c)(1), and (e)(1) that addressed "high," "good source," and "more" claims, respectively, for dietary supplements.

For example, § 101.54(b)(1) as amended by the nutrient content claims for dietary supplements final rule (59 FR 378 at 394) reads:

The terms "high," "rich in," or "excellent source of" may be used on the label and in the labeling of foods except meal products as defined in § 101.13(l), main dish products as defined in § 101.13(m), and *dietary supplements of vitamins or minerals to characterize the level of any substance that is not a vitamin or mineral*, provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(emphasis added).

Similar restrictions were added to § 101.54(c)(1) and (e)(1) by the 1994 nutrient content claims for dietary supplements final rule.

In response to section 7(d) of the DSHEA, FDA is proposing to amend § 101.54(b)(1) for "high" claims, § 101.54(c)(1) for "good source" claims, and § 101.54(e)(1) for "more," "fortified," "enriched," and "added" claims to remove these restrictions on claims on dietary supplements that characterize the levels of substances that are not vitamins and minerals. These restrictions are no longer required under the act.

### III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under 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 that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small

entities. In accordance with the Regulatory Flexibility Act, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The proposed rule does not significantly change the way in which claims are made with three exceptions: (1) Percentage claims for dietary supplements that do not have RDI's or DRV's are no longer prohibited; (2) dietary supplements of vitamins and minerals may now highlight an ingredient that is not a vitamin or mineral; and (3) labels or labeling of dietary supplements may include statements of nutritional support so long as those statements include an appropriate disclaimer, and the manufacturer has substantiation that the statement is truthful and not misleading. With regards to these actions, costs of redesigning labels will be incurred only by those firms wishing to take advantage of the DSHEA. With respect to the third, firms who wish to make nutritional support statements will incur the additional cost of redesigning labels to include the disclaimer. When the label or labeling contains more than one nutritional support statement, the cost of the disclaimer will depend on whether the disclaimer must be made on each label panel, page, or piece of labeling that contains a statement of nutritional support, or whether the disclaimer need only appear once.

FDA is unable to quantify the benefits from this proposed rule. It may be that some consumers will benefit from the additional information about dietary ingredients that will become available. However, because statements of nutritional support may now be made for some dietary ingredients without any publicly available information to demonstrate that the dietary ingredient is safe, or that it will have its claimed effect, it is uncertain whether this proposed rule will in fact provide any significant benefits to consumers. FDA requests comment on this issue.

### IV. Environmental Impact

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

### V. 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 amend its regulations establishing requirements for the use of nutrient content claims and health claims for dietary supplements and to specify how the disclaimer required by section 403(r)(6)(C) of the act is to be presented on the labels or labeling of dietary supplements imposes any paperwork burden.

### VI. Effective Date

FDA is proposing to make this regulation effective on January 1, 1997. This is consistent with section 7(e) of the DSHEA, which states that dietary supplements must be labeled in accordance with the amendments of that section after December 31, 1996.

### VII. 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.

### VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Office of Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, "Food Labeling, Questions and Answers," August, 1993.
2. Wilkening, Virginia L., Memo to the Record, June 30, 1995.
3. Macro International Inc., "Iron Supplement Warning Label Focus Group Report," U.S. Department of Health and Human Services, Food and Drug Administration, April 14, 1995.

### 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(a) is amended by revising paragraphs (a) and (b), redesignating paragraph (q)(3) as (q)(3)(i), and adding new paragraph (q)(3)(ii) to read as follows:

**§ 101.13 Nutrient content claims—general principles.**

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under § 101.9 or under § 101.36 (that is, a nutrient content claim), with the exception of such claims on restaurant menus, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

\* \* \* \* \*

(q) \* \* \*  
(3) \* \* \*

(ii) Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which an RDI or daily reference value (DRV) has not been established (e.g., “40 percent omega-3 fatty acids,” “100 percent of the allicin in a bulb of garlic,” or “twice the allicin as (name of product alternative)” [where “twice” is another way of saying 200 percent]) may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by a referral or disclosure statement in accordance with paragraphs (g) or (h) of this section. In addition, whenever a statement that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV is made in a way that draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, and the information on the actual amount of the dietary ingredient

in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section.

\* \* \* \* \*

3. Section 101.14 is amended by removing paragraph (a)(4); by redesignating paragraphs (a)(5) and (a)(6) as paragraphs (a)(4) and (a)(5), respectively; and by revising paragraphs (b)(3)(i) and (d)(3) to read as follows:

**§ 101.14 Health claims: general requirements.**

\* \* \* \* \*

(b) \* \* \*  
(3) \* \* \*

(i) The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

\* \* \* \* \*

(d) \* \* \*

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9; for restaurant foods, in accordance with § 101.10; or for dietary supplements, in accordance with § 101.36.

\* \* \* \* \*

4. Section 101.54 is amended by revising paragraphs (b)(1), (c)(1), and (e)(1) introductory text to read as follows:

**§ 101.54 Nutrient content claims for “good source,” “high,” and “more.”**

\* \* \* \* \*

(b) “High” claims. (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

\* \* \* \* \*

(c) “Good Source” claims. (1) The terms “good source,” “contains,” or “provides” may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

\* \* \* \* \*

(e) “More” claims. (1) A relative claim using the terms “more,” “fortified,” “enriched,” and “added” may be used

on the label or in labeling of foods to describe the level of protein, vitamins, minerals, dietary fiber, or potassium, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

\* \* \* \* \*

5. Section 101.94 is added to subpart F to read as follows:

**§ 101.94 Statements of nutritional support; disclaimer.**

(a) The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement of nutritional support that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and where the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act by complying with section 403(r)(6) of the act.

(b) Text for disclaimer. (1) Where there is one statement of nutritional support on the label or in the labeling, the disclaimer shall be placed in accordance with paragraph (c)(1) 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 statement of nutritional support on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (b)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (c)(2) 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.

(c) Placement. (1) Except as provided in paragraph (c)(2) of this section, the disclaimer shall be contained in each statement of nutritional support. The disclaimer shall be placed immediately adjacent to the statement of nutritional support with no intervening material.

(2) Where there is more than one statement of nutritional support on a label panel or in labeling other than a label, and the manufacturer, packer, or distributor wishes to comply with section 403(r)(6) of the act without having to place the disclaimer after each statement of nutritional support, it shall place a symbol (e.g., an asterisk) at the end of each statement of nutritional support that refers to the same symbol placed elsewhere on the same label panel or piece of labeling that is followed by the disclaimer. In this

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