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))