DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 95N–0025]

Food Labeling; General Requirements for Nutrition Labeling of Dietary Supplements; General Requirements for Nutrient Content Claims for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, given the need to modify its regulations on nutrition labeling and nutrient content claims for dietary supplements to respond to the 1994 Dietary Supplement Health and Education Act (the 1994 DSHEA), it does not intend to enforce those regulations until after December 31, 1996. FDA is issuing this notice of intent in response to inquiries from the dietary supplement industry.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, 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

The Nutrition Labeling and Education Act (the 1990 amendments) was enacted on November 8, 1990. This law amended the Federal Food, Drug, and Cosmetic Act (the act) to require that virtually all foods, including conventional foods and dietary supplements, bear nutrition labeling (section 403(q) of the act (21 U.S.C. 343(q)), and that if they bear claims about the level of nutrients that they contain, those claims be made in accordance with definitions adopted by FDA (see section 403(r) of the act). The 1990 amendments required that FDA issue proposed rules implementing these provisions within 12 months from the date of their enactment and final rules within 24 months (sections 2(b) and 3(b) of the 1990 amendments). The final rules were to be effective 6 months after they were issued, although FDA was authorized to delay application of the rules for up to 1 year if it found that compliance with the nutrition labeling and nutrient content claim provisions would cause undue economic hardship (section 10(a) of the 1990 amendments).

FDA issued proposed rules on November 27, 1991 (see 56 FR 60366 and 60421). On October 29, 1992, however, shortly before the final rules were to be issued, the Dietary Supplement Act of 1992 (the 1992 DS act) (Title II of Pub. L. 102–571) was enacted. This law took dietary supplements out of the rulemaking schedule that had been established under the 1990 amendments. It provided that FDA issue new proposals on the nutrition labeling of, and nutrient content claims for, dietary supplements by June 15, 1993, and that the agency issue final rules by December 31, 1993. However, the provisions of the 1990 amendments that made the final rules effective 6 months after issuance, and that gave FDA discretion to delay their applicability for 1 year, continued to apply to dietary supplements.

Consistent with the 1990 amendments and the 1992 DS act, on June 18, 1993 (58 FR 33715 and 33731), FDA issued proposed rules on the nutrition labeling and nutrient content claims for dietary supplements. On January 4, 1994 (59 FR 354 and 378), FDA issued the final rules. As stated above, under the 1990 amendments, these final rules were to be effective 6 months from December 31, 1993, or on July 1, 1994. However, in conjunction with the publication of the final rules, FDA made a finding that requiring compliance by that date would cause dietary supplement manufacturers undue economic hardship (59 FR 350, January 4, 1994). Therefore, FDA stated that these manufacturers need not comply with the final rules on nutrition labeling and nutrient content claims until July 1, 1995.

Having completed these rulemakings, FDA anticipated that dietary supplement firms would begin taking steps to come into compliance with the new rules, and dietary supplement manufacturers have apparently done so. For example, in 1994, a number of dietary supplement trade associations held conferences about the new rules, and FDA received inquiries from a number of firms about what steps are required.

In October 1994, however, a significant ambiguity was introduced into the regulation of the labeling of dietary supplements. At that time, the 1994 DSHEA (Pub. L. 103–417) was enacted. This new law amended both the nutrition labeling and nutrient content claim provisions of the act (see sections 7(b) and (c) of the 1994 DSHEA). It made limited changes in how nutrition information is to be presented in the labeling of dietary supplements, although it made implementation of these changes subject to regulations adopted by the Secretary of Health and Human Services (and, by delegation, FDA) (section 403(q)(5)(F) of the act). It also limited in one respect the nutrient content claims for dietary supplements that must be defined by regulation by FDA (section 403(r)(2)(F) of the act).

With respect to the effective date of these amendments and to the other labeling provisions enacted as part of the new law, the 1994 DSHEA stated that dietary supplements may be labeled in accordance with its provisions after its date of enactment, and that they must be labeled in compliance with its provisions after December 31, 1996 (section 7(e) of the 1994 DSHEA). The new law was silent, however, with respect to its effect on the July 1, 1995, applicability date established under the 1990 amendments and the 1992 DS act for FDA's regulations on the nutrition labeling and nutrient content claim requirements for dietary supplements.

II. Statement

In the wake of the new law, FDA has received inquiries from the dietary supplement industry about how the agency intends to enforce the law. One trade association wrote that its members are making efforts to comply with the July 1, 1995, effective date established under the 1990 amendments and the 1992 DS act, but that, as a practical matter, that effective date should not be enforced to allow the process of implementing the 1994 DSHEA to proceed in a reasonable fashion. The trade association cautioned that if FDA did not follow such a course, companies would be put in the untenable position of needing to relabel in July 1995, only to relabel again by the end of 1996 (Ref. 1).

FDA believes that it is appropriate, in response to these inquiries, to issue a statement on how it intends to enforce its nutrition labeling and nutrient content claim regulations with respect to dietary supplements in light of the passage of the 1994 DSHEA (Ref. 2). In formulating this statement, FDA has carefully considered Congress' goals in passing the 1994 DSHEA and the 1990 amendments, as well as the needs of the companies that are required to label their products in accordance with the act and of consumers to whom the information in question is to be provided.

In the 1990 amendments, Congress required that food labels bear information that will help consumers to maintain healthy dietary practices and established timeframes for the implementation of the legislation to