DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N–0134]

RIN 0910–AA19

Food Labeling: Reference Daily Intakes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish Reference Daily Intakes (RDI's) for vitamin K, selenium, manganese, chromium, molybdenum, and chloride, but not for fluoride. The agency is also amending its regulations to modify the units of measure that are used to declare the amount of biotin, folate, calcium, and phosphorus in food. In addition, the agency is amending its regulations to make consideration of selenium, chromium, molybdenum, and chloride optional in making a determination as to whether a food is nutritionally inferior to a food for which it substitutes and that it resembles. These actions are intended to assist consumers in understanding the nutritional significance of foods in the context of a total daily diet and are in recognition of the fact that the National Academy of Sciences (NAS) established Recommended Dietary Allowances (RDA's) and Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's) for vitamin K, selenium, manganese, chromium, molybdenum, and chloride either in 1980 or 1989.

EFFECTIVE DATE: January 1, 1997.

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

In the Federal Register of January 4, 1994 (59 FR 427), FDA published a proposed rule in a document entitled ''Food Labeling: Reference Daily Intakes'' (hereinafter referred to as ''the January 1994 proposal''). This document grew out of earlier proposals that, among other things, sought to amend FDA's label reference value regulations to replace the United States Recommended Daily Allowances (U.S. RDA's) with Reference Daily Intakes (RDI's) for protein and 26 vitamins and minerals.

In the Federal Register of July 19, 1990 (55 FR 29476), FDA published its initial proposal on RDI's in a document entitled ''Food Labeling Reference Daily Intakes and Daily Reference Values'' (hereinafter referred to as ''the July 1990 proposal''). Following the passage of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (hereinafter referred to as ''the 1990 amendments''), FDA republished this proposal in modified form on November 27, 1991 (56 FR 60366) (hereinafter referred to as ''the supplementary proposal''). FDA summarized and reviewed the comments to these proposals in a final rule entitled ''Food Labeling; Reference Daily Intakes and Daily Reference Values'' (58 FR 2206, January 6, 1993, and corrected at 58 FR 17104, April 1, 1993) (hereinafter referred to as ''the RDI/DRV final rule'').

However, on October 6, 1992, before FDA issued the final rule, Congress passed the Dietary Supplement Act of 1992 (Title II of Pub. L. 102–571) (hereinafter referred to as the ''DS act''). Section 202(a)(1) of the DS act imposed a moratorium on the implementation of the 1990 amendments as they applied to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances until December 15, 1993. Section 203 of the DS act prohibited FDA from promulgating regulations before November 8, 1993, that required the use of, or that were based on, recommended daily allowances of vitamins or minerals, other than regulations establishing the U.S. RDA's specified in § 101.9(c)(7)(iv)(21 CFR 101.9(c)(7)(iv)) (1992), as in effect on October 6, 1992.

The label reference values in § 101.9(c)(7)(iv) (1992) were based to a large extent on the 1968 RDA's (Ref. 1), and thus they are more than 25 years old. These label values do not reflect the significant advances in scientific knowledge about essential nutrient requirements that have occurred over the last 20 years. Based on these advances, in 1980, the NAS established, for the first time, ESADDI values for vitamin K, biotin, pantothenic acid, copper, manganese, fluoride, chromium, selenium, molybdenum, sodium, potassium, and chloride (Ref. 2). In 1989, the NAS updated the values for vitamin K and selenium, making them RDA's rather than ESADDI's (Ref. 3). At the same time, the NAS continued to provide ESADDI values for manganese, fluoride, chromium, and molybdenum, but NAS dropped the suggested values for sodium, potassium, and chloride, giving instead estimated minimum requirements for healthy persons at various ages (Ref. 3).

With its discretion constrained by section 203 of the DS act, and yet faced with a need to establish a labeling scheme that manufacturers could implement as quickly as possible, FDA simply adopted in its new regulations the values in § 101.9(c)(7)(iv) as in effect in 1992 (see RDI/DRV final rule). This solution created a new problem. Section 101.9(c)(7)(iv) (1992) did not contain label reference values for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and fluoride, which were addressed in the 1989 RDA's (Ref. 3).

In its January 1994 proposal, FDA proposed to establish RDI's for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and fluoride for the following reasons: Such values are necessary to permit the declaration of these nutrients in the nutrition labeling of all foods; they will assist consumers in understanding the significance of the amount of these nutrients present in foods in the context of a total daily diet; and these values will permit nutrient content claims to be made for these nutrients.

FDA received approximately 65 letters in response to the January 1994 proposal. Each letter contained one or more comments. Many comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., nutrition education, freedom of choice, premarket clearance, and fortification policies) and will not be discussed here. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments, the agency's responses to the comments, and a discussion of the agency's conclusions with respect to the RDI's for the seven nutrients follows:

II. Authority for Additional Label Reference Values

Section 2(b)(1)(A) of the 1990 amendments provides that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations that require that the required nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. FDA, in its food labeling initiative, has tried generally to assist consumers in understanding the nutrition label information relative to a total daily diet (see 55 FR 29476) and to do so based on the most current scientific and public health knowledge.

1. The majority of comments agreed with establishing RDI's for the