**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

**[Docket Nos. 94P–0390 and 95P–0241]**

# Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products. These changes are intended to benefit public health by encouraging manufacturers to use health claims and nutrient content claims that will assist consumers in maintaining a healthy diet. The agency's current regulations were issued in January of 1993 to implement the Nutrition Labeling and Education Act of 1990. This document proposes refinements to those regulations to allow additional synonyms for nutrient content claims without specific preclearance by the agency, permit health claims on certain foods that do not currently qualify because they do not contain 10 percent of certain required nutrients, permit the use of shortened versions of authorized health claims under certain circumstances, eliminate some of the required elements for health claims, and provide additional guidance for petitioners seeking exemption from the disqualification of some foods from bearing a health claim because they contain high levels of certain nutrients. FDA is proposing these amendments in response to petitions submitted by the National Food Processors Association (NFPA) and the American Bakers Association (ABA).

**DATES:** Written comments by March 20, 1996. The agency is proposing that any final rules that may issue based upon this proposal become effective on the date of publication.

**ADDRESSES:** Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 301–443–1751.

**FOR FURTHER INFORMATION CONTACT:** F. Edward Scarbrough, Center for Food Safety and Applied Nutrition (HFS–2), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. The Nutrition Labeling and Education Act of 1990*

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. Among the more notable aspects of the 1990 amendments were that they confirmed 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 that characterizes the level of a nutrient of the type required to be included in nutrition labeling unless the claim uses terms that are defined and designated in regulations adopted by FDA and is made in accordance with all other regulatory requirements. Similarly, section 403(r)(1)(B) of the act 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 the requirements of the act.

The 1990 amendments instruct the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) to issue regulations defining nutrient content claims that characterize levels of nutrients in food. The 1990 amendments also instruct the Secretary (and, by delegation, FDA) to issue regulations authorizing health claims only if he or she determines,

> ''based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence'' (section 403(r)(3)(B)(i) of the act).

Section 403(r)(3)(B)(ii) and (r)(3)(B)(iii) of the act describe the information that must be included in any health claim authorized under the act. The act provides that the claim shall be an accurate representation of the significance of the substance in affecting the disease or health-related condition, and that it shall enable the public to comprehend the information and understand its significance in the context of the total daily diet. Section 403(r)(4)(A)(i) of the act also provides that any person may petition FDA to issue a regulation authorizing a nutrient content or health claim.

In addition, the 1990 amendments directed FDA to consider 10 disease-nutrient relationships as possible subjects for health claims.

### *B. FDA's Implementation of the 1990 Amendments*

In the Federal Register of January 6, 1993 (58 FR 2066–2941), FDA adopted final rules that implemented the 1990 amendments to the act. Among those final rules, § 101.13 sets out general principles for nutrient content claims and provides for their use on food labels. Other regulations in subpart D of part 101 (21 CFR part 101) establish specific requirements for nutrient content claims. These regulations define specific terms such as ''free,'' ''low,'' ''good source,'' ''high,'' ''reduced,'' ''less (or fewer),'' ''more,'' and ''light'' or ''lite,'' and establish values for these terms for various nutrients. They also designate certain synonyms that can be used in place of these defined terms (58 FR 2302). In addition, § 101.69 establishes procedures for petitioning the agency to authorize additional nutrient content claims and provide for additional synonyms which, if authorized, will be listed in the relevant regulations (§ 101.69) (e.g., ''extra'' as a synonym for ''more'').

FDA also adopted final rules that implemented the health claims provisions of the act (58 FR 2478). Section 101.14 establishes general principles for health claims. This regulation prescribes the circumstances in which a substance is eligible to be the subject of a health claim (§ 101.14(b)), sets forth the standard in section 403(r)(3)(B)(i) of the act as the standard that the agency will apply in deciding whether to authorize a claim about a substance-disease relationship (101.14(c)), sets forth general rules on how authorized claims are to be made in food labeling (§ 101.14(d)), and establishes limitations on the circumstances in which claims can be made (§ 101.14(e)). The agency also adopted § 101.70, which established a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(f)).

At the same time, the agency announced its decisions regarding health claims on the 10 disease-nutrient