IV. The Proposals

As the petitioners have requested, the agency is reconsidering its position on several of the issues raised in the NFPA and ABA petitions. The agency is well within its legal authority to reconsider the issues in the NFPA petition and propose changes to the current food labeling regulations. ''An agency may always change its mind and alter its policies.'' (See *Conference of State Bank Examiners* v. *Office of Thrift Supervision*, 792 F. Supp. 837, 845 (D.D.C. 1992)). While the burden is on the agency to justify the change from the status quo, that justification need not consist of an affirmative demonstration that the status quo is wrong. The agency need only supply ''a reasoned analysis for the change.'' (See *Center for Auto Safety* v. *Peck*, 751 F.2d 1336, 1349 (D.C. Cir 1985) (citing Motor *Vehicle Mfrs. Ass'n* v. *State Farm Mutual*, 463 U.S. 29, 41, 103 S.Ct. 2856, 2865–2866 (1983))). The agency can justify its departure from past policy ''with reference to the objectives underlying statutory scheme it purports to construe.'' (See *Simmons* v. *I.C.C.*, 829 F.2d 150, 156 (D.C. 1987)).

One of the primary purposes of the 1990 amendments was to educate consumers about healthful dietary practices. The legislative history states, ''Health claims supported by significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet'' (Ref. 1).

If the current regulations hinder food companies who want to use one of the FDA-authorized claims, as NFPA has alleged, this public health objective will be frustrated. As the agency has stated, if valid health claims are not being used, ''there is a cost imposed on society in that some valuable information may not be conveyed to consumers'' (58 FR 2927 at 2940). Consumers cannot change their dietary practices if they do not have the necessary information.

The agency is pleased that many food companies are using the health claims on the labels of their products. While the agency has not done an extensive survey, FDA notes that dozens of health claims have appeared on products such as cereal, cookies, frozen dessert bars, egg products, and frozen vegetables. Nonetheless, the agency is concerned that health claims are not being used as extensively as they could be, despite the fact that many foods qualify for such claims.

FDA also notes that food companies are submitting petitions seeking approval of new claims. Since the final regulations have been published, the agency has received two such petitions, one regarding sugar alcohols and dental caries and one regarding oat products and coronary heart disease. A proposed regulation to authorize a health claim regarding sugar alcohols and dental caries was published in the Federal Register on July 20, 1995 (60 FR 37502) (hereinafter referred to as the sugar alcohols proposal). The agency expects to complete in the very near future its evaluation of the petition regarding oat products and coronary heart disease.

Accordingly, the agency is proposing changes to the regulations regarding the use of synonyms for nutrient content claims, the 10 percent nutrient contribution requirement for health claims, the use of abbreviated health claims, the specific requirements for individual health claims, and disqualifying levels for health claims to facilitate additional use of these claims.

A. Synonyms in Nutrient Content Claims

Section 403(r)(1)(A) and (r)(2) of the act state that claims that either expressly or by implication characterize the level of a nutrient (nutrient content claims) may be made in the label or labeling of a food only if the characterization of the level made in the claim uses terms that are defined in regulations of the agency. Based on these provisions, the agency has defined expressed claims as any direct statement about the level (or range) of a nutrient in the food (§ 101.13(b)(1)). In addition, it has defined implied claims as nutrient content claims that describe the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran'') (§ 101.13(b)(2)(i)) or that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an expressed claim or statement about a nutrient (e.g., ''healthy, contains 3 grams of fat'') (§ 101.13(b)(2)(ii)).

The agency has specifically defined a number of expressed nutrient content claims (''free,'' ''low,'' ''reduced,'' ''light,'' ''good source,'' ''high,'' and ''more'') and provided for their synonyms, e.g., ''no,'' ''little,'' ''contains,'' and ''rich in.'' The agency also provided for certain implied nutrient content claims (§ 101.65(c) and (d)). Finally, the agency has defined the implied nutrient content claim ''healthy'' (§ 101.65(d)(2)).

The agency considered the use of additional synonyms for the defined terms in the 1993 nutrient content claims final rule (58 FR 2302 at 2320). At that time the agency provided for a limited number of specific synonyms and declined to provide for either long lists of synonyms or conditions for use of unevaluated terms. The agency concluded that permitting additional synonyms to be used in conjunction with either a defined claim or a disclosure statement explaining the synonym's intended meaning would not assist consumers in maintaining healthy dietary practices (58 FR 2302 at 2320). The agency stated that there is no provision in the act that allows for the use of undefined synonyms in the absence of action by the agency. Because of time constraints, in developing the final regulations FDA was unable to fully study the suggested schemes for use of terms without preclearance to determine whether a scheme could be devised that would constitute approval by the agency without preclearance of each term.

The agency also considered but rejected (58 FR 2302 at 2373) the suggestion that implied claims that are defined on the label be permitted. The agency did provide for certain implied claims on products that meet the definition for certain expressed claims and gave specific examples of some of these claims in the preamble (58 FR 2302 at 2374) and in the regulations (§ 101.65(c)(3)) (e.g., ''high in oat bran'' for foods that are a good source of fiber; ''no oil'' for fat free foods).

In the October 25, 1994, petition, as stated above, NFPA requested that the agency reconsider allowing synonyms and implied nutrient content claims to be used without FDA preclearance under certain circumstances. NFPA maintained that FDA's strict interpretation and application of the 1990 amendments totally frustrated the achievement of the various statutory goals of improving consumer education about diet and health and thereby reducing the incidence of diet-related diseases.

NFPA argued that, because the regulations sharply limit the terminology that can be used to make nutrient content claims for food products and require ''premarket clearance'' of terminology that FDA has not specifically authorized by regulation, the regulations ban a host of truthful and nonmisleading labeling statements. The petitioner requested that FDA propose amendments that would permit nonmisleading terms or statements that are reasonably understood by consumers to be synonyms of a term defined in subpart D of part 101 to be used in product labeling when the defined term also is used in the labeling. Requesting similar amendments for implied claims, NFPA