

an alternative mechanism to ensure that health claims are not made on inappropriate foods. The NFPA petition did not suggest any alternatives to the 10 percent nutrient contribution requirement to preclude misleading health claims on inappropriate foods.

The agency also tentatively concludes that the alternatives suggested in the ABA petition would not ensure that health claims were made only on foods that are consistent with dietary guidelines. Relying on either of the two alternatives suggested in the ABA petition would not adequately assist consumers in placing foods that bear health claims in their proper dietary context.

The ABA's suggestion that the nutrients required to be present at 10 percent be expanded to include thiamin, niacin, or carbohydrates would not encourage consumers to increase their intake of vitamins and minerals that have been identified as those of continuing public health significance. Public health concerns for deficient intakes of thiamin, niacin, or carbohydrates have lessened considerably in the last 20 years, whereas the inadequate intakes of vitamin A, vitamin C, calcium, and iron remain a public health concern especially because of the possible association between several of these nutrients and the risk of chronic disease. Furthermore, expanding the list of nutrients required to be at 10 percent to include thiamin, niacin, or carbohydrates would permit only certain foods to bear health claims, such as enriched cereal grain products. Certain fruit and vegetable products that are promoted in dietary guidelines but that are currently prohibited from bearing health claims would still not be able to bear a health claim. Consequently, the agency tentatively concludes that expanding the list of nutrients would not sufficiently address the concern that the current regulation precludes certain foods that contribute to a healthful diet, and whose consumption is encouraged by the dietary guidelines, from bearing health claims.

Likewise, permitting the 10 percent nutrient contribution requirement to be based on the daily consumption of a food group would not enhance the likelihood of consumers achieving dietary goals. In fact, such a requirement would be contrary to dietary goals because it would reduce the likelihood that a consumer would reach 100 percent of the DV if daily consumption of an entire food group only supplies 10 percent of one of the listed nutrients. One reason for requiring that a serving

of the food provide 10 percent of one or more of the listed nutrients is to assist the consumer in achieving daily intakes recommended in current dietary guidelines. Permitting a food that does not meet the 10 percent nutrient requirement to bear a claim on the basis that the total daily consumption of foods from that category would provide 10 percent of the nutrient would be inconsistent with one of the basic principles of the requirement. Accordingly, the agency has not been persuaded by the arguments raised in the petitions to propose to eliminate the 10 percent nutrient contribution requirement, to expand the list of nutrients that will qualify a food to bear a health claim, or to allow the 10 percent nutrient requirement to apply to a daily consumption of grain products rather than to the nutrient profile of a specific food.

Regarding the request that FDA permit fortification to meet the 10 percent nutrient contribution requirement, the agency is concerned that fortification of foods solely to bear a health claim could result in deceptive or misleading labeling and, thereby, be in violation of section 403(a) of the act. As fully addressed in the 1993 health claims final rule (58 FR 2478 at 2522), fortification of a food of little or no nutritional value for the purpose of bearing a health claim has the great potential of misleading and confusing consumers if foods like confections, soda, and sweet desserts are fortified to qualify for a health claim when, at the same time, dietary guidance as contained in the Food Guide Pyramid, for example, states that "[T]hese foods provide calories and little else nutritionally. Most people should use them sparingly" (Ref. 3). Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines. Consequently, FDA has not been persuaded that foods should be permitted to be fortified to qualify to bear a health claim. Accordingly, FDA is denying NFPA's request to permit fortification to specifically qualify a food to bear a health claim.

The agency notes, as discussed in the 1993 health claims technical amendments (58 FR 44036 at 44037), that some foods either have been traditionally formulated in accordance with the fortification policy or to meet standards of identity that include fortification and, in that form, contain 10 percent or more of one of the six nutrients listed. In such cases, the agency notes that the food would not be precluded by § 101.14(e)(6) from being fortified to qualify for a health claim.

Although the agency has not been persuaded that elimination of the 10 percent nutrient contribution requirement is in order, or that it should permit fortification so that a food could qualify to bear a health claim, the agency has been persuaded by the arguments raised in the petitions that it should act to modify the 10 percent nutrient contribution requirement. As stated above, the agency acknowledges that the 10 percent nutrient contribution requirement has had the unintended effect of precluding some foods that contribute to a healthful diet, and whose consumption is encouraged by the dietary guidelines, from bearing health claims. As discussed above, the agency's primary goals in establishing the 10 percent nutrient contribution requirement were to preclude foods of little or no nutritional value from bearing health claims and, at the same time, to enhance the likelihood of consumers constructing overall daily diets that conform to current dietary guidelines.

FDA recognizes that precluding certain fruits, vegetables, and grain products from bearing health claims because of the 10 percent nutrient contribution requirement is contrary to that goal. The agency agrees with the arguments raised in the petitions that certain fruits, vegetables, and grain products that otherwise meet the requirements of the specific health claim should be able to bear the claim even though they do not contain 10 percent of one of the six listed nutrients because these foods comprise a major part of a balanced and healthful diet, and because current dietary guidance promotes consumption of these foods. Moreover, diets high in fruits, vegetables, and grain products have been associated with various specific health benefits, including lower occurrence of coronary heart disease and of some cancers (Refs. 4 and 5) and therefore, are exactly the types of foods that should be included in the diet to reduce the risk of specific diet-related diseases. Precluding such foods from bearing health claims could confuse consumers and undermine the utility of health claims.

Furthermore, the foods described in the petitions are not the types of foods FDA intended to preclude from bearing health claims when it established the 10 percent nutrient contribution requirement. In fact, these foods can contribute significantly to a balanced and healthful diet and to achieving compliance with dietary guidelines even though they do not meet the 10 percent nutrient contribution requirement. Consequently, the agency