relationships specified in the 1990 amendments. Of the 10, FDA authorized health claims for calcium and osteoporosis (58 FR 2665); dietary lipids and cancer (58 FR 2787); sodium and hypertension (58 FR 2820); dietary saturated fat and cholesterol and risk of coronary heart disease (58 FR 2739); fiber-containing grain products, fruits, and vegetables and cancer (58 FR 2537); fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease (58 FR 2552); and fruits and vegetables and cancer (58 FR 2622). The regulations on general requirements for health claims and on the claims specified above became effective May 8, 1993.

In the Federal Register of January 6, 1993 (58 FR 2066), FDA also issued ''Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments,'' (the implementation final rule). The implementation final rule provided 30 days for interested persons to comment on technical issues arising in any of the final rules implementing the 1990 amendments. In the Federal Register of August 18, 1993 (58 FR 44020 to 44096), FDA published technical amendments to the final rules in response to the comments it received.

In the Federal Register of October 14, 1993 (58 FR 53254), FDA proposed to authorize the use of a health claim about the relationship between folate and the risk of neural tube defects on the labels or in labeling of foods in conventional food form and dietary supplements. This action was in response to provisions of the 1990 amendments and the Dietary Supplement Act of 1992 (Pub. L. 102–571). In the Federal Register of January 4, 1994 (59 FR 395), FDA announced that the proposed regulation to authorize use of the health claim about the association between folate and neural tube defects in food labeling was considered a final regulation for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances.

II. The Petition of the National Food Processors Association

The National Food Processors Association (NFPA) submitted a citizen petition dated October 25, 1994, requesting initiation of rulemaking for the adoption of amendments to the regulations governing nutrient content and health claims. This petition was assigned FDA Docket No. 94P–0390.

For nutrient content claims, NFPA requested specific amendments to §§ 101.13 and 101.65 allowing use of synonyms and implied nutrient content claims, without FDA preclearance, that are understood by consumers to have the same meaning as a defined term, where such claims are made in accordance with the requirements for the defined term, and the defined term also appears in the product's labeling.

NFPA also requested several amendments to the health claim regulations. Among other changes, NFPA requested that FDA permit the use of an abbreviated or implied health claim with a referral statement directing consumers to the complete claim elsewhere in labeling. Currently, all required information must appear in one place without other intervening material.

It also requested that health claims be permitted for foods with levels of nutrients that FDA had determined increase the risk of other diseases to the general population. Among the general requirements for health claims, FDA established in § 101.14(a)(5) levels of total fat, saturated fat, cholesterol, and sodium in a food above which the food is disqualified from making a health claim. These are identified as ''disqualifying nutrient levels.'' In its petition, NFPA suggested that FDA amend the regulation so that a food with a nutrient at a disqualifying level would be prohibited from making a health claim only if the nutrient is directly and adversely associated with the disease to which the claim refers. Absent such an association, NFPA requested that the presence of a nutrient above a threshold level not disqualify a product from bearing a health claim but instead require disclosure of that fact in labeling.

Finally, NFPA requested an amendment to § 101.14(e)(6), which prohibits a food in conventional food form from bearing a health claim unless the food contains 10 percent or more of the Reference Daily Intake or Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition (the ''10 percent nutrient contribution requirement''). NFPA requested that this prohibition be replaced by a requirement that any food bearing a health claim that refers to an added nutrient disclose the fact of that nutrient addition in labeling.

FDA issued a letter on May 11, 1995, granting most of the requests to initiate rulemaking on the foregoing aspects of the petition (hereinafter referred to as the May 11, 1995, letter). However, the agency denied certain aspects of NFPA's petition, including NFPA's request that FDA change the levels in § 101.14(a)(5) from disqualification levels to disclosure levels. Although the agency recognized that it has the authority under section 403(r)(3)(A)(ii) of the act to exempt any claim from the disqualifying nutrient levels if it finds that the claim would ''assist consumers in maintaining healthy dietary practices,'' the agency concluded that a generic change in its regulations would not be consistent with the underlying goals of the NLEA.

FDA acknowledged, however, that disclosure rather than disqualification may be appropriate under certain circumstances. The agency said it will seek more limited criteria to define the conditions under which disclosure rather than disqualification could be permitted.

III. The Petition of the American Bakers Association

A citizen petition, dated July 27, 1995, was submitted to FDA by the ABA (Docket No. 95P–0241/CP 1), requesting that FDA amend, among other things, the regulatory provision in § 101.14(e)(6) to permit enriched cereal-grain products that conform to the standards of identity in part 136, 137, or 139 (21 CFR part 136, 137, or 139), and bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard, to bear health claims. The petition specifically requested that FDA amend § 101.14(e)(6) to read:

> Except for dietary supplements, enriched grain products that conform to a standard of identity in part 136, 137, or 139, and bread that conforms to the standard of identity for enriched bread in § 136.115, except that it contains whole wheat or other grain products not permitted under that standard, or where provided for in other regulations in part 101, subpart E.

In the alternative, ABA suggested that the agency expand the list of qualifying nutrients to include complex carbohydrates, niacin, or thiamin or allow the 10 percent nutrient contribution requirement to apply to all foods for which the summation of the Daily Value of the applicable nutrients is 10 percent rather than requiring that the 10 percent be based on a single serving.

Because of the similarities in the NFPA and ABA petitions regarding the 10 percent nutrient contribution and health claims, FDA is responding to part of the ABA petition in this document, which implements FDA's May 11, 1995, letter response to the NFPA petition. Other issues raised in the ABA petition will be handled separately.