



American Bakers Association

Serving the Baking Industry Since 1897

January 18, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 1994P-0390 and 1995P-0241; Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and other Specific Requirements for Individual Health Claims; Reopening of the Comment Period
69 Federal Register 24541 (May 4, 2004)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The ABA and its members share FDA's goal of providing consumers with accurate, truthful and non-misleading information regarding the relationship of diet to health and disease and welcome this opportunity to comment further on several aspects of nutrition labeling as detailed below.

The 10 Percent Nutrient Content Requirement

In 1994, FDA proposed to revise Section 101.149 (c)(6) to allow health claims for enriched grain products that conform to a standard of identity, and for bread that conforms to the standard of identity for enriched bread except that it contains whole wheat or other grain products not permitted under the standard that do not meet the 10 percent nutrient contribution requirement but that meet all other aspects of the health claim requirements 60 Fed. Reg. 66206 (December 21, 1994). FDA proposed similar revision to Section 101.65(2)(iv) to allow use of the term "healthy" essentially for the same enriched grain products: 61 Fed. Reg. 5349 (February 12, 1996). ABA continues to support both of these proposals as consistent with government-sponsored dietary guidance that will assist consumers in selecting and maintaining a healthful diet. This message was the focus of ABA's 1995 citizen's petition.

ABA petitioned for and fully supports this proposal with regard to health claims for enriched grain products. In proposing the amendment to the "jelly bean" rule, FDA in its preamble explicitly recognized that grain products are fundamental to a healthful diet and are "exactly the types of food that should be included in the diet to reduce the risk of specific diet-related diseases." (60 Fed. Reg. at 66213). In light of the dietary confusion that exists today regarding the important role that enriched grain foods play in a healthy diet, it is critical that FDA move forward to promulgate these rules and then work to communicate the government

recommendations for a healthy diet which are outlined in the USDA/HHS Dietary Guidelines for Americans that have just been revised. FDA's proposals will benefit the public by enhancing the ability of consumers to formulate a diet that is consistent with the Dietary Guidelines by facilitating the use of health claims for enriched grain foods. For the same reasons, ABA fully supports the modification of the requirements for "healthy" claims, permitting enriched grain products to bear this claim.

This exemption does not appear to cover some of the fortified bakery products emerging in the market currently (e.g., enriched white bread that has been fortified with added soy fiber, calcium, and other nutrients). ABA believes that added flexibility is needed to enable nutritionally enhanced versions of standardized bakery products to qualify for health claims. FDA should consider whether the "before fortification" requirement should be eliminated in 101.14(e). Nonstandardized bakery products with the same levels of enrichment as enriched breads, and that are not otherwise disqualified, should be subject to the same rules as standardized enriched products. The labeling of these products as "healthy" would be entirely consistent with and supportive of the government's current dietary recommendations and intent.

With regard to a nutrient density approach, ABA understands that if a food has a DV of vitamin A, vitamin C, calcium, iron, protein or fiber per RACC which is the same as or higher than the percent caloric contribution of the food per RACC (based on a 2000 calorie diet) then it would qualify. Bread is 140 calories per RACC of 50 grams and provides 7% of daily calories, 4% calcium, 8% iron, 0% vitamin A, 0% vitamin C, 8% protein and 4% dietary fiber. Sodium and cholesterol are typically below disqualifying levels. This approach could work as well and results are consistent with "healthy" requirements. The nutrient contribution for two nutrients is higher than the caloric contribution on a DV basis.

Synonyms in Nutrient Content Claims

The use of additional descriptors for nutrient content claims would provide flexibility for food labeling and assists consumers in selecting healthy choices. The first Amendment prohibits the suppression of truthful and nonmisleading synonyms. In Section 130.10 ("Generic Standard of Identity") of FDA regulations, it permits nutritionally modified substitutes for standardized foods; retaining the status of standardized food and federal pre-emption benefits; where the name of the substitute food is the appropriate expressed nutrient content claims and the applicable standardized term (e.g., "high calcium enriched white bread" or "High fiber enriched white bread"). It should be noted that bakery produced enhanced with several added nutrients would be difficult to name in compliance with 130.10; added flexibility would provide meaningful and accurate labeling for consumers on bakery packaging.

With regard to "anchored synonyms", use of a defined term immediately adjacent to the enlisted descriptor could potentially confuse consumers with label clutter, and would not provide a clear and concise nutrition message. This cumbersome requirement would discourage virtually all use of unlisted synonyms, defeating the purpose of the FDA proposal. It would be most beneficial to allow a nutrient content claim to be "split" between the principal display panel (PDP) and the side panel where consumers traditionally have found additional and detailed nutritional information.

FDA could define further what terms are truly synonymous with authorized nutrient content claims, based upon FDA consumer research. Further definition by FDA would establish and maintain a level playing field for the entire food industry. It would be appropriate with advancing technology and the growing variety of food products that the Agency review the approved list of nutrient content descriptors every two years to coordinate with uniform compliance dates for efficient and timely label changes. On June 17, 1996, ABA submitted a list of additional nutrient content descriptors and their dictionary definitions that are synonymous with current FDA-approved descriptors (copy attached) that could be used as a starting point in a joint effort between FDA and industry to create a beneficial list for the agency, industry and consumers alike.

Disqualifying Levels

ABA suggests that, if fat, saturated fat, cholesterol or sodium are above the level as defined in “healthy” requirements this fact should be disclosed on the label. The First Amendment requires disclosure, not suppression, to assure that claims are not misleading.

Use of the Term ‘May’

Use of the word “may” to describe the relationship between a substance and a disease or health-related condition in unqualified health claims could be interpreted as a reflection on the soundness of the science supporting a claim as opposed to the fact that FDA considers diet to be only one factor in an individual’s risk of disease. Example: “Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.” FDA needs to permit stronger terminology for unqualified health claims than for qualified claims. In the above example, the term “can” or the phrase “contributes to the reduction” should be permitted.

FDA must review use of the term “may” on an individual claim basis with facts and data to determine its own merit rather than to try to force a cookie cutter approach for all claims.

Abbreviated Health Claims

Abbreviated health claims should be permitted to appear on the principle display panel (PDP) when the abbreviated claim is truthful and non-misleading and the complete health claim appears elsewhere on the label. ABA is very concerned about FDA’s current policy. While FDA has proposed to authorize abbreviated versions of certain claims, the Agency continues to express health claim decisions with reference to specific claim language that the agency has developed. ABA has serious concerns about the First Amendment implications of the current policy and urges the Agency to consider alternative approaches which focus on identifying material facts that FDA believes must be disclosed and permitting some material facts to be presented off-label (e.g., internet – “for more information see website/link” on food labels).

Petitions for Health Claims

While ABA commends the FDA for the important strides it has made in making needed reforms in health claim regulation, much more is needed. The pre-market clearance system, even for qualified health claims (versus SSA health claims) continues to impose undue burdens on health claims, and results in prescriptive health claim language that hampers the effectiveness of these messages in reaching and motivating consumers.

FDA is obligated to implement the NLEA/health claim provisions of the FD&C Act in a manner that does not impose unconstitutional burdens on the creative/effective expression of health claims that are accurate and substantiated by appropriate scientific evidence. Therefore, ABA believes that FDA should expand the use of pre-market notifications as a tool in regulating certain types of health claims.

ABA also urges FDA to undertake further regulatory reforms to reduce the undue burdens of the current health claim pre-clearance system. Reforms should expand the opportunity for health claims to be authorized under pre-market notification procedures (e.g., for foods that are part of a diet that meets national dietary guidance).

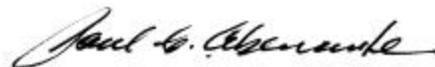
FDA should invite the submission of proposals concerning the appropriate use of pre-market notification for authorizing health claims, in view of legal requirements and the desired public health and marketing outcomes the NLEA health claims policy is intended to advance.

ABA appreciates this additional opportunity to comment on the reopening of this proposed rulemaking on health claims, which is of great interest to the baking industry. The Association is hopeful that the concerns outlined above regarding a variety of issues will be useful to the Agency as it moves forward to establish further policy. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



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Enclosure