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INDEPENDENT BAKERS ASSOCIATION

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

RE: [Docket No. 2006D-0066] Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements; Availability
71 Federal Register 8597, February 17, 2006.

Dear Sir or Madam:

The Independent Bakers Association (IBA), a trade organization representing 400 small to mid-sized mostly family-owned wholesale bakeries and allied industry members, submits comments on the docket referenced above.

Overview

IBA is extremely concerned with the FDA's impending whole grain labeling criteria because of the anticipated rulemaking by the United States Department of Agriculture allowing the inclusion of bread into the Women, Infants and Children (WIC) programs. While the WIC program is administered by the individual states governments, they only accept foods that meet the USDA's selection criteria. The USDA may only consider approval of whole grain breads for selection by the WIC program, thus the FDA's upcoming decision on whole grain labeling is of the utmost importance consumers whom participate in the WIC program and to our members.

IBA agrees that the FDA accurately articulated US dietary and food guidance and the authoritative statement regarding recommended daily dietary intake of whole grains for the 2005 Dietary Guidelines for Americans –

Consume 3 or more ounce-equivalents of whole-grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products. In general, at least half the grains should come from whole grains.

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IBA also agrees that label statements concerning whole grains should be accurate, truthful, non-misleading and in accordance with the Federal Food, Drug, and Cosmetic Act (FDCA) – section 403(a). IBA supports using factual statements about whole grains, such as “X% whole grain” or “Y grams of whole grains,” and health claims related to whole grains and the reduced risks of coronary heart disease and certain cancers, based on notifications FDA received under section 403(r)(3)(C) of the FDCA. IBA, for reasons outlined in the Recommendation section of our comments, believes that numerous alternative label statements concerning whole grains are applicable and useful to the consumer. IBA believes that the consumer benefits from additional whole grain label statements that characterize the level or dietary context for whole grain consumption beyond what the FDA included in its draft guidance statement.

Recommendations

IBA believes that additional food label statements beyond the FDA’s draft guidance that characterize the level of whole grain in food products will greatly enhance the public’s ability to make informed food choices. Such label statements will also provide the food industry with additional labeling tools to inform consumers about whole grains in a manner consistent with dietary and food guidance.

American consumers eat a varied diet and the 2005 Dietary Guidelines and the USDA’s MyPyramid encourage a varied diet balanced among single and multi-component foods and beverages within food groupings. Increased consumption of food products with whole grains is called for by the national dietary recommendations established by the 2005 Dietary Guidelines. The 2005 Guidelines note that whole grains “can reduce the risk of several chronic diseases and may help with weight maintenance” and states that children should “increase whole grains into their diets as they grow.” The 2005 Dietary Guidelines call for increasing children’s consumption of whole grains is central to the USDA’s decision to introduce bread products rich in whole grains to the WIC list of approved food products. Whole grains are emphasized by both the Guidelines and MyPyramid not only for their nutrient contributions, but also for the crucial role they play meeting dietary fiber recommendations.

In addition to recommending whole grains, the Guidelines and MyPyramid also encourage the consumption of enriched and fortified grain products, especially emphasizing those that include folic acid. In order to increase consumption of whole grains, the MyPyramid website advises:

- Substituting whole wheat or oat flour for up to half of the flour in common homemade foods, such as waffles, pancakes, muffins, and other flour based foods.
- Substituting whole grain flour or oatmeal when making cookies, cakes and other baked treats.

This advice supports the position that foods partially made with whole grains make an important contribution to a healthful diet. Since both the Guidelines and MyPyramid recommend reading food labels and ingredient lists to determine whether whole grains are present in food products, IBA believes it is crucial that the FDA expand food producers’ ability to inform consumers of the whole grain content in their products. IBA believes that such additional food label statements, beyond what the draft guidance characterizes, will enhance the public’s ability to make informed food choices. Expanded

label statements, which are consistent with dietary and food guidance, would benefit both food consumers and producers.

IBA believes that the concept, introduced in the 2005 Dietary Guidelines and MyPyramid, of expressing one ounce equivalents is adequate for use in food label statements about whole grains. The MyPyramid food guidance system recommends varying amounts of whole grains for daily consumption depending on age, level of activity and gender. The range varies from 1.5 to 4 ounces of whole grains per day. IBA also notes that in the sample week-long menus provided by the USDA's MyPyramid guidelines the average amount of whole grain consumption per day is 3.4 ounces.

Keeping in mind the above mentioned 3.4 ounces recommended daily intake of whole grains established by the MyPyramid guidelines, research by the USDA's Economic Research Service indicates that US consumers fall well below this level of consumption. The ERS data reveals that Americans, on average, are only consuming 1 in 10 of their grain intake as whole grains- well below the average recommended by the 2005 Dietary Guidelines and the MyPyramid. Further research revealed by the ERS indicates that while 71% of Americans believe they are consuming the recommended amount of whole grains, in reality 40% of Americans consume no whole grains at all. The ERS study states, "Most consumers are unclear on what a serving of whole grains is." This fact only adds to the IBA's conviction that enhancing food producers' ability to add information concerning whole grains to food label statements will enhance the public's ability to make informed decisions concerning their daily intake of whole grains.

IBA believes that allowing food producers to indicate that level of whole grains in food products, in addition to the above mentioned "X% whole grains" or "Y grams of whole grains," would not only be beneficial to consumers, but completely consistent with FDA label statement standards for other ingredients. An example of this is the FDA final rule on the "healthy" nutrient content claim for sodium, in which the agency decided that the nutrient level can have either a positive or negative effect on food product development. In the FDA's final ruling in regards to sodium, the Agency stated a "healthy" nutrient content claim "will encourage the manufacture of a greater number of (food) products that are consistent with dietary guidelines for a variety of nutrients." IBA agrees with the FDA decision, and believes that it should be extended to encompass whole grains as well.

IBA believes that extending the label statements to include whole grains would have the same affect on food producers as extending the ability of producers to label "healthy" amounts of sodium. IBA believes that such action by the FDA on whole grains would greatly enhance food producers' ability to develop new products to deliver to the American consumer containing whole grains in a continuing effort to achieve the whole grain intake recommendations included in the 2005 Dietary Guidelines and MyPyramid.

Summary

IBA is committed to truthful, accurate, and non-misleading food label statements that enhance consumers' ability to make informed decisions regarding the national food and dietary standards established by the 2005 Dietary Guidelines and the USDA MyPyramid food guidance system. IBA believes that the 2005 Dietary Guidelines establish the Dietary importance of whole grains in a healthy diet. IBA believes that consumers would

benefit greatly if the FDA established a whole grains characterization labeling system, such as the Agency's standards in regards to minerals, such as sodium.

Our recommendations support the value of a labeling system that encourages not only nutrition labeling, but also included associated label claims. The addition of truthful, accurate, and non-misleading associated food labeling claims can only enhance American consumers' ability to make informed, healthy food choices that follow the recommendations established by the 2005 Dietary Guidelines and the USDA's MyPyramid.

FDA guidance on whole grains is critical to bread becoming an integral part of the foods available through the WIC program.

Thank you for allowing the opportunity to comment on this crucial issue.

Sincerely,



Nicholas A. Pyle, President
Independent Bakers Association

CC: IBA Executive Committee
IBA Board of Directors