



American Bakers Association

Serving the Baking Industry Since 1897

April 17, 2006

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

Re: Whole Grains Label Statements
Docket No. 2006D-0066
71 Fed. Reg. 8597 (February 17, 2006)

These comments are submitted on behalf of the members of the American Bakers Association (ABA). For over 100 years, ABA has represented the interests of the wholesale baking industry and its suppliers -- companies that work to provide over 80 percent of the wholesome and nutritious bakery products purchased by American consumers. Many ABA members market products formulated with whole grains to provide consumers appealing options for increasing their consumption of whole grain foods, consistent with national dietary guidance. Accordingly, ABA appreciates this opportunity to comment on FDA's Draft Guidance for Whole Grain Label Statements (Draft Guidance), to help ensure that such guidance does not restrict lawful claims and that it reflects definitions consistent with accepted industry standards.

I. Whole Grain Label Statements

ABA shares FDA's goal of providing truthful and useful information to consumers about whole grains in order to encourage them to consume three servings of whole grain products per day as recommended by the 2005 Dietary Guidelines for Americans (Dietary Guidelines). Indeed, ABA members have explored numerous ways to provide meaningful information on whole grain product labels to advise consumers about how the products can help them meet this goal. Whole grain food producers must retain maximum flexibility to convey truthful and nonmisleading information about whole grain content in a manner that motivates and resonates with consumers.

Toward this end, ABA strongly urges FDA to eliminate from the Draft Guidance the apparent categorical prohibition on claims that "imply a particular level of

the ingredient, i.e., ‘high’ or ‘excellent source.’”¹ As a threshold matter, FDA has no legal authority to impose a ban on these types of claims as a class.² Under the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA’s implementing regulations, the agency is authorized to regulate terms such as “high” or “good/excellent source” only with respect to claims about “nutrients.”³ As FDA has recognized, most notably by Dr. Barbara Schneeman at the press conference announcing the availability of the Draft Guidance, whole grains are not “nutrients.” Dr. Schneeman further acknowledged that the Dietary Guidelines state that whole grains are more than just fiber. FDA has also recognized the benefits of whole grains as distinct from those provided by fiber by allowing a health claim for whole grain foods and reduced risk of heart disease and certain cancers in addition to comparable health claims for fiber.⁴ The agency therefore cannot maintain that claims characterizing the level of whole grains in food are implied fiber nutrient content claims. Because whole grain claims are not nutrient content claims, FDA lacks legal authority to regulate the use of terms such as “high” or “good/excellent source” in whole grain claims.

FDA’s legal authority with respect to whole grain claims is limited to prohibiting claims that are false or misleading. As Dr. Schneeman acknowledged at the press conference, claims characterizing the level of whole grains in a food cannot be deemed false or misleading -- and therefore prohibited -- as a class, but would need to be evaluated on a case-by-case basis in the overall context of the individual package. Accordingly, the FDCA misbranding provisions do not authorize FDA to ban “high” or “good/excellent source” claims for whole grains categorically, for such claims can be made in a manner that is truthful and nonmisleading. Similarly, while the Draft Guidance does not address claims that a product is “made with” whole grains, ABA notes that such claims may also be made where they are truthful and nonmisleading. Again, this is necessarily a case-by-case determination, and ABA believes that such claims are supportable where the product contains a meaningful amount of whole grains.

FDA also lacks authority to ban all claims that imply a particular level of whole grains in the food under basic First Amendment principles. The First Amendment prohibits the government from broadly banning a class of speech where case-by-case

¹ Draft Guidance at 2 and 5.

² Notably, FDA cites no legal authority for its prohibition of claims that imply a particular level of whole grains, even while it cites the governing statute and agency regulations extensively with respect to other parameters for whole grain label statements.

³ 21 U.S.C. 403(r)(1)(A); 21 C.F.R. 101.54.

⁴ FDA/CFSAN, “Health Claim Notification for Whole Grain Foods,” available at <http://www.cfsan.fda.gov/~dms/flgrains.html>; 21 C.F.R. 101.76 (fiber/cancer health claim); 21 C.F.R. 101.77 (fiber/heart disease health claim).

enforcement would suffice to address limited instances of deception.⁵ Although FDA makes clear that its Draft Guidance is not binding on the agency or the public, and that companies may use an alternative approach that satisfies applicable law, this disclaimer does not cure the First Amendment violation inherent in the prohibitory language of the Draft Guidance itself. Even that unfounded and unenforceable assertion of a categorical ban on claims characterizing the level of whole grains in food creates an unjustifiable “chilling effect” on speech protected by the First Amendment.

As FDA has no legal authority to prohibit all claims that imply a particular level of whole grains in food, the agency should simply eliminate the phrase, “and do not imply a particular level of the ingredient, i.e., ‘high’ or ‘excellent source,’” from pages 2 and 5 of the Draft Guidance. Revised in this manner, the Guidance will enable and encourage producers of whole grain foods to employ a range of messages to provide meaningful information to consumers about the role that such foods can play in a healthy diet. While some quantitative claims, such as “100% Whole Grain,” may be useful to consumers in making purchasing and consumption decisions, other statements such as “1g Whole Grains” may be of little value, and could even be deemed misleading in that they may overstate the benefits of minimal amounts of whole grains. There is no basis in the FDCA or public health policy for allowing quantitative claims about whole grains but banning claims that might help consumers understand the relevance of the amount of whole grains in the food.

It is neither necessary nor supportable for FDA to take a categorical approach to such claims in this Draft Guidance. Eliminating this unsupported statement leaves intact FDA’s prohibition on whole grain claims that are false or misleading, as authorized by Section 403(a) of the FDCA, and thus accurately reflects both the agency’s authority and its priorities in this context.

Finally, we note that FDA cannot establish binding rules or policy in a guidance document. Any definitions of terms such as “high” or “good/excellent source” of whole grains can be established only by the promulgation of regulations.

II. Whole Grain Definitions and Product Formulations

ABA commends FDA for taking steps to recommend a definition of whole grains acceptable to FDA (but not binding), and supports the agency’s incorporation of the AACC International’s (AACC) definition of “whole grains.” To clarify the scope of whole grains covered by the Draft Guidance, ABA suggests that the agency include or reference a definitive list of grains that can be considered whole grains. ABA recommends that FDA adopt the AACC’s comprehensive list of cereals and

⁵ *E.g., Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 649 (1985) (holding that where deception can be policed on a case-by-case basis, a prophylactic ban by the government cannot stand).

pseudocereals that, when consumed in whole form (including the bran, germ and endosperm), are considered whole grains.

With respect to product formulation, ABA is concerned that FDA's recommendation that products labeled "100 percent whole grain" should not contain grain ingredients other than those the agency considers to be whole grains could be interpreted as discouraging the use of vital wheat gluten in such breads. Vital wheat gluten is needed in whole grain breads to create a taste and texture that consumers find palatable, and is generally considered a functional ingredient, rather than a grain ingredient. FDA should make clear that it does not intend to discourage the use of vital wheat gluten. Such action would prevent manufacturers from producing appealing whole grain breads, which is surely not the agency's goal.

Finally, FDA should delete its recommendation that pizza or bagels labeled as "whole grain" or "whole wheat" should contain only whole grain flours or whole wheat flour. Such a position would unjustifiably suggest that these nonstandardized foods should conform to requirements previously reserved only for standardized foods. Indeed, USDA's Food Safety and Inspection Service (FSIS) recognized distinct requirements for standardized and nonstandardized foods in its Interim Policy Guidance on whole grain claims.⁶ That Guidance permits grain components not subject to standards of identity to be characterized as whole grain where they are comprised of at least 51 percent whole grain. As FDA recognizes in its Draft Guidance, whether a "whole grain" statement could be construed as meaning "100 percent whole grain" depends upon the context in which the claim appears on the label. Again, this requires a case-by-case assessment of whether the product labeling is truthful and nonmisleading, rather than a categorical approach.

In sum, ABA suggests that FDA revise its Draft Guidance by:

- Eliminating the apparent categorical prohibition on claims that imply a particular level of whole grains, including "high" or "good/excellent source" claims;
- Incorporating AACC's list of cereals and pseudocereals that, when consumed in whole form, are considered whole grains;
- Clarifying that FDA does not intend to discourage the use of vital wheat gluten in products labeled "100 percent whole grain"; and
- Deleting the recommendation that pizza or bagels labeled as "whole grain" or "whole wheat" should contain only whole grain flours or whole wheat flour.

⁶ Available at http://www.fsis.usda.gov/OPPDE/larc/Claims/Food_Guide_MYPyramid_Policy.pdf.

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ABA appreciates this opportunity to provide comments on this Draft Guidance, which is of substantial importance to the baking industry. ABA would be happy to provide any further information on this matter that might be helpful to the agency.

Respectfully submitted,

A handwritten signature in black ink, reading "Lee Stander". The signature is written in a cursive style with a long horizontal flourish at the end.

Senior Vice President
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A handwritten signature in black ink, reading "Robb Macell". The signature is written in a cursive style with a long horizontal flourish at the end.

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