

February 28, 2005

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: FDA Docket No. 2004P-0223: Petition to Establish  
Descriptive Claims for Whole Grain Content**

To Whom It May Concern:

Nutriant, a Kerry Company, wishes to comment on the above-referenced citizen petition ("the petition"), which seeks to establish criteria for the descriptive claims "excellent source," "good source," and "made with" for whole grain content under FDA's authority to prevent false and misleading food labeling statements. We respectfully submit that the definition of "whole grains" described in this petition, as revised on December 20, 2004, should include soybeans as an example of a generally accepted whole grain. The inclusion of soybeans in the definition of "whole grains" is both appropriate, based on the definition proposed, and reflective of how soybeans and whole grain soy products are regarded in the regulatory and trade communities. Nutriant is a leading manufacturer of quality soy products, including soy flours that may be used to produce nutritious whole grain soy foods such as breads, muffins, cereal, and pasta.

**Petition Background**

On May 12, 2004, General Mills, Inc. submitted a citizen petition to establish criteria for the descriptive claims "excellent source," "good source," and "made with" for whole grain content in foods. The purposes of the petition are to "encourage consumption of whole grain foods, eliminate consumer confusion about whole grain products, and provide an incentive for manufacturers to increase the whole grain content of their products and, thus, provide a substantial benefit to public health." <sup>1/</sup> The petition proposed to define "whole grain" in the following manner:

Whole grain is a substance that includes all edible parts of the grain including the bran, germ and endosperm. When used as a component of a food, all three edible parts of the grain must be present in the same proportion either naturally or through technological processes. Food ingredients that may be considered whole grains are amaranth, barley,

<sup>1/</sup> Citizen Petition on Whole Grain Descriptive Claims submitted by General Mills, Inc., FDA Docket No. 2004P-0223 (May 11, 2004) ("the petition").

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buckwheat, bulgur, corn, oats, rice, rye, and wheat. 2/

This definition is based upon a definition of whole grain developed by the American Association of Cereal Chemists (AACC), a non-profit international organization of nearly 4,000 members who are specialists in the use of cereal grains in foods. 3/ AACC has been an innovative leader in gathering and disseminating scientific and technical information to professionals in the grain-based foods industry worldwide for over 85 years.

On December 20, 2004, General Mills revised its petition to reflect a new definition of "whole grains" issued by the Whole Grains Council. 4/ The Whole Grains Council definition, which seeks to describe whole grains in a consumer-friendly manner, states that—

Whole grains or foods made from them contain all the essential parts and naturally-occurring nutrients of the entire grain seed. If the grain has been processed (e.g., cracked, crushed, rolled extruded, lightly pearled and/or cooked), the food product should deliver approximately the same rich balance of nutrients that are found in the original grain seed.

Examples of generally accepted whole grain foods and flours are" amaranth, barley, (lightly pearled), brown and colored rice, buckwheat, bulgar, corn and whole cornmeal, emmer, faro, grano (lightly pearled wheat), Kamat® grain, millet, oatmeal and whole oats, popcorn, quinoa, sorghum, spelt, triticale, whole rye, whole or cracked wheat, wheat berries, and wild rice. 5/

General Mills expressed support for the Whole Grains Council definition, characterizing it as sufficiently broad to encompass various sources of whole grains.

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2/ *Id.* Attachment 1 (Proposed Descriptive Claims for Whole Grain, 21 C.F.R. § 101.9X).

3/ AACC definition of "whole grains," available at <http://www.aaccnet.org/definitions/wholegrain.asp> (accessed February 10, 2005). The AACC definition provides that "whole grains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components – the starchy endosperm, germ and bran – are present in the same relative proportions as they exist in the intact caryopsis."

4/ The Whole Grains Council is a consortium of industry, scientists, chefs and members of the Oldways Preservation Trust committed to increasing consumption of whole grains for better health.

5/ Whole Grains Council definition of "whole grains," available at <http://www.wholegrainscouncil.org/ConsumerDef.html> (accessed February 10, 2005).

Indeed, General Mills encouraged FDA to “take a nonrestrictive approach to the type of grains that may be considered whole grains.” 6/

### **Soybeans Are Whole Grains**

Nutriant is in complete agreement with the purposes of the citizen petition submitted by General Mills. We, too, believe that consumers would benefit from clear and consistent messages regarding whole grains, and should be encouraged to eat more whole grain foods. Nutriant also believes that the definitions offered by General Mills are reasonably interpreted to include soybeans, which have long been considered to be a grain product by both government regulators and industry alike. Accordingly, to promote clarity and consistency in the area of whole grain claims, we urge FDA to include soybeans as a specific example in any definition or listing of “whole grains” offered for regulatory purposes.

Nutriant’s request that FDA identify soybeans as whole grain is based on regulatory precedent and industry practice and understanding of whole grain foods. In the regulatory arena, USDA’s Grain Inspectors, Packers, and Stockyard Administration (GIPSA) has established a regulatory standard that defines soybeans as “*Grain* that consists of 50 percent or more of whole or broken soybeans ....” 7/ This standard is established under the United States Grain Standards Act, which expressly defines “grain” to include soybeans, and is listed as one of the Official United States Standards for Grain. 8/

The commodities industry and prominent elements of the food industry also view soybeans as a whole grain. Notably, soybeans are considered to be a grain by the U.S.-focused National Grain and Feed Association 9/ and the worldwide Grain and Feed Trade Association. 10/ In addition, the American Bakers Association, which is dedicated to promoting public policy that is in the best interest of the wholesale baking industry, recognizes soybeans as “whole grains.” 11/ Furthermore, prominent whole grain experts, such as Carl Hosoney, who oversaw development of an AACC definition for “whole grains,” supports the inclusion of soybeans within this definition. 12/

The role of soybeans as a valuable source of whole grains is underscored by the numerous applications available for whole grain soy foods. Whole grain soy flours, for instance, may be used to produce such nutritious foods as whole grain soy breads, muffins, breakfast cereals, pastas, and other products. Soy-based grain foods, therefore, can make a meaningful contribution to consumer intakes of whole grain.

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6/ Letter from S. Pape, Counsel to General Mills, Inc., to B. Schneeman, FDA (Dec. 20, 2004).

7/ 7 C.F.R. § 810.1601 (emphasis added).

8/ 7 U.S.C. § 75(g); 7 C.F.R. Part 810.

9/ See [http://www.ngfa.org/trygrains\\_soybeans.asp](http://www.ngfa.org/trygrains_soybeans.asp).

10/ See <http://www.gafta.com/>.

11/ See Letter from Lee Sanders, dated February 24, 2005 (attached as Appendix A)

12/ See *supra* note 3 and accompanying text; Letter from Carl Hosoney, dated February 1, 2005 (attached as Appendix B).

## Conclusion

As summarized herein, soybeans are considered to be a whole grain by USDA, the federal agency that regulates grain commodities; the commodities industry, including its primary trade associations; and key elements of the food manufacturing industry that make whole grain products for consumers. Moreover, Carl Hoseney, who was integral to the development of the AACC definition of "whole grains," supports the inclusion of soybeans within this definition. Thus, we respectfully submit that any definition established for "whole grains" in a regulatory context – such as that proposed by citizen petition submitted by General Mills – specifically include soybeans within the definition.

Nutriant appreciates FDA's consideration of these comments. Please do not hesitate to contact me if you have any questions regarding Nutriant's comments on this issue.

Sincerely,



Terry A. Gieseke  
Business Development Director  
Nutriant, A Kerry Company

Attachments (2)



# American Bakers Association

*Serving the Baking Industry Since 1897*

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February 24, 2005

To Whom It May Concern:

Several members of the American Bakers Association have expressed strong interest in the development of whole grain soy flours. Such products would enable bakers to deliver the health benefits of soy as part of whole grain bakery products.

The American Bakers Association (ABA), the national trade association representing the wholesale baking industry, has a membership consisting 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.

Based on the existing U.S. Department of Agriculture's Grain Inspection Service standard for whole grains, which includes soybeans, ABA understands soybeans to be considered a "whole grain". In the Code of Federal Regulations, specifically 7 C.F.R. § 810.1601, soybeans are defined as "Grain that consists of 50% or more whole or broken soybeans".

The more widely recognized inclusion of soybeans as a "whole grain" - and, accordingly, the inclusion of whole grain soy flour in the listing of available whole grain ingredients - could provide the grain-based foods industries a viable option for delivering the healthy values of both whole grains and soy in common foods. Perhaps equally important, a definition regarding whole grain soy flour and reduced fat whole grain soy flour could prevent consumer confusion and the potential for mislabeling.

The recognition of whole grain soy flour and reduced fat whole grain soy flour could further enable the baking industry to offer new, innovative products to follow and meet the new 2005 US Dietary Guidelines for Americans emphasis for consumption of three or more ounce-equivalents of whole-grains products per day, as well as, satisfy the health interests of consumers.

Sincerely,

Lee Sanders  
ABA Vice President  
Regulatory and Technical Services



*Serving the World of Cereal Science*

***R&R Research Services, Inc.***

***8831 Quail Lane***

***Manhattan, KS 66502***

***(785) 537-5199 • (785) 537-7477 (fax)***

February 1, 2005

To Whom it May Concern:

In 1999 I chaired the American Association of Cereal Chemists (AACC) Committee that defined whole grain. Given this recognized expertise in whole grains, Nutriant, A Kerry Company, asked my opinion regarding two whole grain soy flours it intends to market in the near future.

As background, based on the strong interest of several members of the baking and cereal industry, Nutriant has developed both full fat and "low fat" whole grain soy flours. For a variety of factors, I concur that these new products can be accurately described as "whole grain".

First, the AACC defined "whole grain" as: "*Whole grains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis.*" In line with the AACC definition, Nutriant's whole grain soy flours consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components – the endosperm (cotyledon), germ and bran – are present in the same relative proportions as they exist in the intact caryopsis. This relative proportion of endosperm, germ and bran is maintained in both the full fat and the low fat versions of the whole grain soy flour. The Nutriant manufacturing process is organically certified and all natural and does not include the use of hexane or other solvents that might disrupt the relationship of the components. The grain components have not been chemically separated and re-assembled.

I have reviewed the soy flour product description sheets and discussed the products with the R&D Director at Nutriant. Based on this review, I concur that the Nutriant whole grain soy flour and low fat whole grain soy flour meet the AACC definition for whole grains.

Second, the U.S. Department of Agriculture (USDA), the federal agency that regulates grain commodities, considers soybeans to be a grain and has established a regulatory standard for soybeans under the United States Grain Standards Act. This regulatory standard, codified in 7 CFR § 810.1601, defines soybeans as "Grain that consists of 50% or more whole or broken soybeans...."

Because Nutriant's soybean flours meet the AACC definition of "whole grain" and soybeans are defined as "grain" by USDA, it is my opinion that these products may be accurately described as "whole grain."

Sincerely,

R. Carl Hosney  
Chairman AACC Committee on Whole Grains  
President, R&R Research