



2550 M Street, NW  
Washington, DC 20037-1350  
202-457-6000

Facsimile 202-457-6315  
[www.pattonboggs.com](http://www.pattonboggs.com)

December 20, 2004

Stuart M. Pape  
(202) 457-5240  
[spape@pattonboggs.com](mailto:spape@pattonboggs.com)

**FACSIMILE AND FEDEX**

Dr. Barbara O. Schneeman  
Director  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Nutritional Products, Labeling and Dietary Supplements  
CPK1, Rm. 4C096  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: Revised Definition of Whole Grains for General Mills' Citizen Petition  
(Docket No. 04P-0223)

Dear Dr. Schneeman:

On May 11, 2004, General Mills, Inc. ("GMI") submitted to the Food and Drug Administration ("FDA") a Citizen Petition requesting the Agency to establish the descriptive claims "excellent source," "good source," and "made with" for whole grain content under the Agency's authority to prevent false and misleading food labeling statements.<sup>1</sup>

Prior to GMI's petition, the food industry, academics and scientists were examining ways to increase consumer consumption and awareness of the benefits of whole grains. In particular, Oldways, a nonprofit organization well known as the think tank for food issues, developed the Whole Grains Council. The Whole Grains Council is a consortium of industry, scientists, and chefs brought together to, among other things, define whole grains in a manner that benefits good science and allows the industry to embrace the concepts.

<sup>1</sup> General Mills Citizen Petition for Whole Grain Claims (Docket No. 04P-0223).

2004P-0223

LET 2

Dr. Barbara O. Schneeman

December 20, 2004

Page 2

Recently, the Whole Grains Council issued its definition of whole grains:

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, bulgur, corn and whole cornmeal, emmer, faro, grano (lightly pearled wheat), Kamut<sup>®</sup> grain, millet, oatmeal and whole oats, popcorn, quinoa, sorghum, spelt, triticale, whole rye, whole or cracked wheat, wheat berries, and wild rice.<sup>2</sup>

GMI supports this comprehensive and consensus-derived definition developed by the Whole Grains Council. Although it did not limit the type of grains that may be considered whole grains, GMI believes that it is necessary to revise its petition to reflect this new definition. The definition of whole grains created by the Whole Grains Council appropriately identifies the essential characteristics. It also is sufficiently broad to encompass various sources of whole grains, which will assist both consumers and food manufacturers increase levels of whole grains. Accordingly, for purposes of its petition, GMI adopts the whole grain definition developed by the Whole Grains Council.

Further, by including the Whole Grains Council's definition, GMI is supporting a uniform understanding of the term by consumers and food manufacturers. A consistent meaning of the term whole grains will reduce the possibility of consumer confusion and provide a useful tool to easily identify products with meaningful whole grain contents. It also provides a standard for food manufacturers, which levels the playing field among competitors.

Additionally, GMI encourages FDA to take a nonrestrictive approach to the type of grains that may be considered whole grains. As you may know, GMI announced on September 30, 2004, that it had reformulated its entire portfolio of Dig G cereals to be either a "Good" or "Excellent" source of whole grains. Indeed, consumer groups

---

<sup>2</sup> See, Whole Grains Council Definition of Whole Grains at <http://www.wholegrainscouncil.org/consumerdef.html>.



Dr. Barbara O. Schneeman

December 20, 2004

Page 3

commended GMI for this initiative, which will assist consumers in increasing their whole grain intake by 1.5 billion extra servings. However, even this significant product change does not ensure that every consumer will meet the three servings of whole grains recommended in the 2005 Dietary Guidelines Advisory Committee report.<sup>3</sup>

With the focus on whole grains, it is critical that FDA address the issue in a timely and effective manner before inappropriate claims proliferate. GMI respectfully requests that the FDA provide guidance on the proper use of the descriptive claims "excellent source," "good source," and "made with" for whole grains.

If you have any questions or require additional information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stuart M. Pape', written in a cursive style.

Stuart M. Pape  
Counsel to General Mills, Inc.

cc: Dr. Lester Crawford, Acting Commissioner of Food and Drugs  
Docket Management Branch

---

<sup>3</sup> See, 2005 Dietary Guidelines Advisory Committee Report (August 19, 2004)