



January 24, 2006

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Judi Adams, MS, RD  
President  
Grain Foods Foundation  
490 Bear Cub Drive  
Ridgway, Colorado 81432

Dear Ms. Adams:

This is in response to your letter, dated December 5, 2005, to Felicia Billingslea concerning the Food and Drug Administration (FDA) denial of a citizen petition to define "excellent source," "good source," and "made with" as descriptors for the whole grain content of foods. Your letter stated that a content claim for whole grains is not an implied fiber claim and that whole grains are a sum of their parts, not just one of their parts. You asked that we reconsider our current stance on content labeling for whole grains because the descriptors are simple and familiar terms, are important to help consumers make knowledgeable food choices, and to assure that the food contains significant amounts of whole grains before making any content claims.

As you are aware, FDA denied the citizen petition mentioned in your letter (Docket No. 2004P-0223) on November 8, 2005. The denial letter noted that there are important questions for the agency to resolve related to the classification of certain label statements on foods, including those for whole grains. We agree with you that the health benefits of whole grains are based on more than their fiber content. However, the agency first needs to decide the appropriate classification of certain types of label statements, such as those in the denied citizen petition, before proposing such statements.

You stated in your letter that you understood that analyzing for whole grain content is not feasible, but by using fiber as a marker, it could be done to some degree of accuracy. You also stated that FDA could require manufacturers to provide their formulations to ensure compliance. We are aware of the alternatives for measuring whole grain content. However, the petition denial was not based on analyzing whole grain content, but on the necessity of first deciding the appropriate classification of certain statements and whether whole grains is a food category or a substance.

As you know, the Center for Food Safety and Applied Nutrition (CFSAN) publishes annually its list of program priorities for the year. For FY 2005, CFSAN listed "Develop strategy to initiate rulemaking on claims for whole grains" as a "B" item. Activities on the "B-list" are those we plan to make significant progress on, but which we may not complete before the end

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of the fiscal year. We are working on possible approaches on how to provide useful information to the public on whole grains. In addition we are considering the development of guidance on what we consider the term "whole grains" to include. We wish to assure you that we are actively working on this initiative.

We hope this is helpful.

Sincerely yours,

A handwritten signature in cursive script that reads "Shellee Anderson".

Shellee Anderson  
Special Assistant  
Food Labeling and Standards Staff  
Center for Food Safety and  
Applied Nutrition