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Division of Dockets Management (HFA-305)
Food and Drug Administration
5620 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2006D-0066: Draft Guidance for Industry and FDA Staff: Whole Grains Label Statements

I appreciate the opportunity to provide comments on the new FDA draft guidance on whole grain label statements.

The health benefits of whole grain foods are widely recognized by health professionals and nutrition scientists, and are emphasized in the recent editions of the Dietary Guidelines and MyPyramid (2005). Specifically, these government publications recommend Americans consume diets with at least half of recommended grain servings coming from whole grain. There is, however, a significant gap between the daily recommended amounts and actual consumption.

FDA's guidance should not only provide consistent and scientifically-based direction to manufacturers, but also strive to assist consumers in identifying foods that contain significant amounts of whole grain.

My comments focus on two areas:

- Definition of whole grain
- Label statements to help consumers identify significant sources of whole grain

Definition of whole grain

I support the definition of whole grain put forth by FDA in the draft guidance. This definition is consistent with that from the American Association of Cereal Chemists International. I agree with the list of grains included as cereal grains, but encourage FDA to clarify that this list is not all encompassing, and that the grains listed are only examples.

There are some issues here that need further consideration. Barley requires certain types of processing to be safely consumed by humans, and different types of barley, hull-less, naked, de-hulled will need to be considered as whole grain sources. With the low intake of whole grains in the US diet, it is critical to include a wide range of whole grains, especially those that are typically consumed throughout the day in main dishes and soups.

Label statements to help consumers identify significant sources of whole grain

One roadblock for consumers in reaching the recommended goals for whole grain consumption is confusion about how to identify foods that provide a significant amount of whole grain. At present, major food manufacturers are making claims about whole grain content of as little as 2 g per serving, to up to or more than 48 g per serving. This disparity in the levels of whole grain content being applied to claims has the potential to cause even more confusion among consumers.

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Although a statement about whole grain content (e.g., "10 grams of whole grain" or "½ ounce equivalent of whole grain") as described in FDA's draft guidance is factual, it will have little meaning to health professionals or consumers without any reference to the amount of whole grain that should be eaten daily. I recommend that if a product label makes a claim about the amount of whole grain (e.g., "X g whole grain"), that it be required to also include a phrase to put it in context of a daily recommended amount (e.g., at least X grams recommended daily).

I propose that the minimum recommended daily amount (g) of whole grain be set at 48 g. This is based on a review of several studies relating whole grain intake to reduced risk of disease, U.S. dietary patterns and consistency with manufacturers' practices.

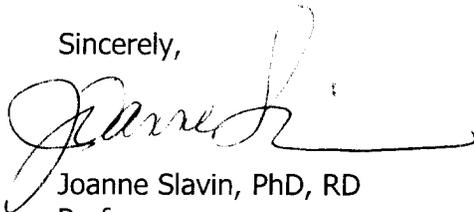
- Scientific studies suggest that intakes of whole grain between 43-50 g provide health benefits such as reduced risk of cardiovascular disease.
- Another approach to establishing a daily amount (g) for whole grain consumption is to base it on the amount of grain in three servings (or ounce-equivalents) of white bread since this is the most commonly consumed grain food in the American diet. USDA uses 16 g as the standard amount of grain in an ounce-equivalent of bread. Thus, three servings of whole grain bread would provide 48 g of whole grain.
- The 48 g level already has been adopted and used on label by some major food manufacturers as a minimum amount to be consumed daily.

I disagree with FDA's decision to not support the use of terms such as "good" and "excellent" source of whole grain, and encourage FDA to work to define these terms so that they describe amounts of whole grain that make a meaningful contribution to a person's daily diet. Consumers and health professionals, alike, are accustomed to the terms "good" and "excellent" source on food labels. FDA should work to extend this awareness to other food components, like whole grain, that confer health benefits. Uniform definitions of "good" and "excellent" source of whole grain, at levels that are of dietary significance, would provide consumers and health professionals with an important tool for identifying foods that contain a meaningful amount of whole grain.

If FDA does move forward in setting definitions for "good" and "excellent" source of whole grain, I recommend that the levels be set such that consumers' diets are consistent with those recommended by the Dietary Guidelines and MyPyramid. That is, consumers should be able to achieve 48 g of whole grain daily while staying within daily recommended calories and grain servings based on their age, sex and activity level.

Thank you for the opportunity to provide comments on the draft guidance on whole grain label statements. I am contacted frequently by the media about whole grain foods and the efforts of FDA to define and regulate whole grains and welcomed and appreciated.

Sincerely,



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Professor

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