



PEPSICO

Beverages & Foods

LAW DEPARTMENT

9495 '05 AUG 16 11:33

August 12, 2005

VIA AIRBORNE EXPRESS

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

Re: FDA Docket No. 2004P-0223

Dear Sir or Madam:

The Quaker Oats Company (Quaker) is filing these comments in response to General Mill's Citizen Petition requesting that the Food and Drug Administration (FDA) establish definitions for whole grain content claims such as "made with", "good source" and "excellent source." Quaker is headquartered in Chicago and is a division of PepsiCo, Inc. Quaker is well known as the manufacturer of many grain-based breakfast products including such hot cereals as Old-Fashioned *Quaker* Oats and *Quaker* Instant Oatmeals, ready-to-eat (RTE) cereals such as *Life* cereal, and *Aunt Jemima* pancake mixes. Quaker also makes *Quaker Chewy* granola bars, *Quaker* rice cakes, and *Rice-a-Roni* side dishes. Quaker's expansive portfolio of products provides consumers with many mealtime and snack time opportunities to include grains in their diet.

The importance of including whole grains in the diet is well-established. The Department of Health and Human Services and the US Department of Agriculture, as well as most health organizations have all recognized the considerable health benefits associated with whole grain consumption, such as reduction in the risk of heart disease and other chronic diseases. Moreover, the recently issued 2005 Dietary Guidelines for Americans note that the gap between the recommended levels of whole grain consumption and actual levels of consumption is significant. Clearly this is an opportune time for FDA to establish a labeling policy that regulates whole grain content claims in a manner that can help ameliorate this nutritional deficit.

Quaker is in wholehearted agreement with General Mills that FDA guidance on the use of whole grain claims is necessary. In general terms, Quaker agrees with the criteria set forth in the Petition. However, Quaker proposes the following modifications to more fully advance the dual objectives of (1) encouraging food manufacturers to increase the whole grain content of their products and (2) helping consumers actually increase their consumption of whole grain products.

Tropicana
2004P-0223



C26

First, in the interest of being consistent with FDA's policy rationale regarding nutrient content claims, Quaker proposes that the whole grain descriptor claims of "excellent source", and "good source" be based on the labeled food's reference amount customarily consumed (RACC) rather than the serving size. FDA has already made the determination that the RACC provides a more reliable basis for determining claim eligibility. In finalizing its rule governing general principles for nutrient content claims, the agency noted that basing claims on serving sizes could lead to identical products in different size containers having varying eligibility for a claim. The stated purpose of using the RACC was to reduce the likelihood that consumers would be misled. FDA explained: "[U]nder this approach the claim would reflect true characteristics of the product, not the container size, and may be less confusing to consumers." 58 Fed. Reg. 2302, 2314-15 (Jan. 6, 1993). Basing whole grain claims on the RACC would remove the incentive to manipulate serving sizes, would create an even playing field among food manufacturers, and would establish a practice that is consistent with consumer expectation.

Additionally, Quaker submits that a "made with whole grains" statement should be regarded simply as an ingredient claim. FDA has expressly identified categories of label statements that are not to be treated as nutrient content claims, implied or otherwise. Specifically, 21 CFR 101.65(b)(3) provides that a claim about the presence of an ingredient that is perceived to add value to the product, e.g., "made with whole fruit" is not an implied nutrient content claim. A factual statement of "made with whole grains" is similar, and should be available to manufacturers as a means of communicating the ingredient composition of their products. Determining the propriety of this statement should be left to the manufacturer in order to encourage product innovation and the development and marketing of more whole grain containing products. Quaker believes that this claim can properly be evaluated by FDA on a case by case basis.

Secondly, Quaker recommends that some allowance be made for grain-based products that have a very small RACC. Certain cereals (e.g., puffed RTE cereals) and certain crackers (e.g., puffed cereal-grain cakes, melba toast, hard bread sticks) have been assigned by regulation a RACC of only 15 grams (g). 21 CFR 101.12(b) (Table 2); FDA, Office of Food Labeling, List of Product Categories and Products (October 8, 1992), available at http://www.fda.gov/ora/inspect_ref/igs/nleaat26.html. Quaker believes that these products can make a significant contribution to increased daily whole grain consumption, especially (as is quite possible) if consumed at more than one eating occasion per day. However, under the General Mills' proposal these products would be unreasonably restricted in their eligibility to bear whole grain content claims.

Encouraging consumption of healthier whole grain products entails not only providing whole grain, but also a pleasing taste and texture. This is relatively easy to accomplish with a 30 g or greater RACC product when the whole grain content threshold is 8 g (per the General Mills "good source" claim proposal) since there are still 22 g or more which can be devoted to creating a palatable product. However, if the qualifying threshold does not change proportionally according to the size of the RACC, a product with a 15 g RACC would have only 7 g to devote to organoleptic attributes, which will make it

considerably more difficult to offer a wide selection of viable products that encourage healthier eating.

To address this shortcoming in the General Mills' proposal, we suggest that the FDA deem the "good source" claim appropriate for those 15 g RACC products that contain 4 or more grams of whole grain per RACC and "excellent source" appropriate for those that contain 8 or more grams. Under this approach a "good source" item would be delivering more than 25% of its content as whole grains, and would meet the 8 g threshold on a 30 g basis. Likewise, an "excellent source" item would exceed 50% of its content as whole grains and meet the 16 g threshold on a 30 g basis.

Quaker believes this approach is appropriate given the existing precedent for evaluating smaller RACC products differently from larger RACC products when determining eligibility for other nutrient content claims, including "low" and "very low" claims for calories, sodium and fat. 21 CFR 101.60, 101.61 and 101.62.

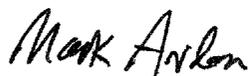
In the context of discussing such "low" claims, FDA has previously noted that:

"...foods with small serving sizes may be consumed frequently during the day and therefore may make substantial contributions to the diet..." 58 Fed Reg. 2302, at 2315 (Jan. 6, 1993).

There, FDA was concerned about the potential for over-consumption of nutrient dense foods, particularly if such foods were permitted to carry "low" and "very low" claims, and so required that products with a small RACC meet eligibility requirements on a 50 g basis, as well as a RACC basis. Conversely, certain grain based foods with small serving sizes, so long as they deliver meaningful amounts of whole grains (by meeting the claim eligibility criteria proposed above), may make a beneficial contribution to the diet and should be permitted to bear such claims. Through appropriate use of "good source" and "excellent source" whole grain claims, even these small serving size products can help to effectuate the goal of increasing consumption of whole grains by all Americans.

Quaker appreciates the opportunity to share its perspective on this timely topic and urges the FDA to act promptly to implement the recommendations in the General Mills' Petition, along with incorporating the modifications discussed above.

Sincerely,



Mark Andon, Ph.D.
Technical Director
QTG Nutrition



Mark L. McGowan, Esq.
Vice-President, Legal
Foods Division