



## GENERAL MILLS

April 23, 2007

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

Re: Docket No. 2006P-0069  
Food Labeling: Health Claims; Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease

General Mills, Inc. (GMI)<sup>1</sup> submits these comments in response to the Food and Drug Administration's (FDA) proposed rule amending the health claim on the relationship between soluble fiber from certain foods and risk of coronary heart disease. The amendment specifically proposes to exempt certain foods from the nutrient content requirement of "low fat" due to fat content derived from whole oat sources.

GMI recognizes that health claims, such as the soluble fiber and heart disease claim, are an important tool for communicating health messages to consumers. We support and encourage changes to health claim regulations, based on current science, that increase food options to help consumers reduce risk of heart disease while still communicating truthful and non-misleading information.

**We support an amendment to the low-fat criterion currently included as a requirement of the soluble fiber from certain foods and heart disease health claim.** The proposed rule is consistent with current science related to the effects of fat on heart health, and may promote the development and/or marketing of "heart healthy" products for consumers.

**Although GMI generally supports the amendment, we encourage FDA consider additional changes beyond those described by the petitioner** (Quaker Oats Company), and specific to reduced-sugar flavored oatmeal. For example, we believe it is important to consider implications for other food products made primarily of whole oat sources and consumed commonly by consumers (e.g., ready-to-eat cereals). Additionally, we believe it would be prudent for FDA to re-evaluate the necessity of the low-fat requirement for this health claim given scientific evidence and changing dietary recommendations for total fat intake.

Our comments pertaining to this proposed health claim focus on the following areas:

- A. The exemption from the "low-fat" requirement should be extended to other substances eligible for the claim

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<sup>1</sup> GMI is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. GMI is a major packaged-food manufacturer engaged for over 75 years in the development and marketing of food products including flour, ready-to-eat cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other food products.

We have been committed to nutrition labeling for over 30 years beginning with voluntary labeling in 1974. We currently have nutrition labeling on more than 1500 retail products. Over the years, we have added additional information and claims to our products in response to increased consumer interest in the relationship between diet and health. We support changes in food-labeling practices that will provide consumers with nutrition information more relevant to today's needs.

- B. Fat from fortificants should be exempt from the “low-fat” requirement when all other fat is derived from beta-glucan soluble fiber sources eligible for the claim
- C. FDA should consider whether the total fat (low-fat) requirement is a necessary requirement for the claim
- D. FDA should confirm nutrient composition values for whole oat sources cited in the proposed rule

**A. The exemption from the “low fat” requirement should extend beyond whole oat sources**

The amendment, as written, proposes to exempt foods from the nutrient content requirement of “low fat” when fat content is solely derived from whole oat sources listed in 101.81 (c)(2)(ii)(A). Whole oat sources listed in this part include oat bran, rolled oats, whole oat flour and oatrim. We believe that the exemption from the “low fat” requirement should be extended to products containing any source of beta-glucan soluble fiber eligible for the claim. That is, products containing fat solely from whole oat sources, as well as whole grain barley or dry milled barley, would be exempt from the “low-fat” requirement.

Barley substances, like whole oat sources, have fat profiles consistent with fat intake recommendations of the 2005 Dietary Guidelines for Americans. Although the exemption from the “low fat” requirement may not be necessary for foods containing solely barley sources due to their inherently low fat content (e.g., 2.3 g fat/100 g), it may be important for foods containing a blend of grains (e.g., oats and barley). FDA should not preclude, from making the soluble fiber and heart disease claim, products containing an assortment of grains, including, but not limited to: wheat, corn, barley and rice. By extending the amendment to include barley, manufacturers may be encouraged to develop different types of products, thereby providing more food options for consumers seeking to reduce heart disease risk. *[Note to Gayle and John: Our internal decision has been to allow a combination of oats & barley to contribute toward the 0.75 B-glucan soluble fiber content. In this section, are we indirectly asking for FDA’s interpretation of that?]*

**B. Fat from fortificants should be exempt from the “low-fat” requirement**

The proposed rule specifies that a food product that contains any fat from ingredients other than whole oat sources would not be exempt from the “low fat” requirement. In addition to extending the proposed rule to include barley sources, as described above, GMI strongly believes that it is appropriate to exclude the minimal amount of fat from fortificants.

The trace, and likely inconsequential, amount of fat contributed through fortification should not prevent foods from making this heart health claim. Such a requirement potentially could disincite the food industry from improving the overall nutritional quality of foods and in turn, consumers’ diets.

As an example, vitamin A palmitate is commonly added to some ready-to-eat cereals. The 2005 Dietary Guidelines for Americans recognize vitamin A as a nutrient of concern for Americans. The amount of fat provided to cereals through the addition of this vitamin is dietarily insignificant (e.g. <0.0005 g fat for 10% DV vitamin A in a 30 g serving for certain cereals).

**C. The necessity of the total fat (low-fat) requirement should be considered**

GMI recommends that FDA consider whether the total fat (low-fat) requirement is necessary for this heart health claim. Specifically, we encourage FDA to thoroughly review the scientific evidence, particularly clinical trials, and the latest public health recommendations pertaining to total dietary fat intake and heart health.

We believe that, as much as possible, FDA claims should be based on the latest science and be consistent with dietary recommendations from government agencies and leading health organizations. Additionally, updating the claim requirements to reflect current science, if warranted,

may also lessen the filing of petitions requesting individual exemptions for specific foods from the low-fat requirement. Requiring manufacturers to go through the process of individual exemption petitions, similar to the present petition, discourages and/or delays the use of relevant health communications/claims on foods that can contribute to a healthy diet and disease risk reduction.

At the time the soluble fiber from certain foods and risk of heart disease was published, “low fat” was among the standard dietary recommendations for reducing risk of heart disease. Since then, there have been numerous scientific advances, including a better understanding of the relationship between total fat and type of fat on heart disease risks. Specifically, higher intakes of saturated fat and trans fat, not total fat, have been shown to be associated with higher heart disease risk. FDA has recognized this shift in knowledge and dietary advice, moving away from low-fat requirements for more recent heart disease claims and including limits for saturated and trans fat.

In the current amendment, FDA describes their rationale for not relaxing the total fat (low-fat) requirement for fat from all sources. Under this scenario, FDA adopted the disqualifying level (13 g) for total fat, and noted that the total fat content of certain products could approach the disqualifying level and that consumers using such products could increase their fat intake to levels above those recommended by the 2005 Dietary Guidelines for Americans.

Rather than entirely relaxing the total fat requirement, we encourage FDA to consider adopting a “more moderate level” as a limit on total fat content for this health claim, similar to that accepted for the 2004 FDAMA notification for whole grain foods and heart disease ( $\leq 6.5$  g total fat/RACC). This level is based on dietary recommendations for total fat intake from the Institute of Medicine (Dietary Reference Intakes) and is also consistent with the 2005 Dietary Guidelines for Americans and recommendations from the American Heart Association. Minimally, FDA should determine whether there is any evidence to suggest that adopting a more moderate total fat level for the claim would have adverse effects on heart health and/or diminish the effect of B-glucan soluble fiber on total and LDL cholesterol.

As an initial screen of the scientific evidence, we reviewed the research that FDA considered in reaching their decision about this health claim (Federal Register Vol. 61, no. 3., January 4, 1996). As clearly summarized, the majority of clinical studies (10 of 17) upon which the claim is based were conducted with a diet characterized as a “typical” or “normal” American diet (approximately 37% of calories from fat). In fact, 4 of the 5 studies identified as the “strongest evidence” did not use a “low-fat” diet.

#### **D. Nutrient composition values for whole oat sources should be confirmed**

We recommend FDA confirm the values cited in the published rule for total fat content of whole oat sources and ensure they reflect fat content of current oat varieties. Of note, is that values from USDA Handbook 18 are cited, although Handbook 19 was published in 2006. FDA should also consider that fat content of oat varieties has tended to shift upwards recent years. We recommend including reference data for fat (and fatty acid profile), including the analytical method and moisture basis, in the subsequent rule.

Additionally, FDA should provide the calculation and pertinent reference data to support the contention that for products that do not meet the “low fat” requirement due to fat from whole oat sources, the amount of fat exceeding the “low fat” requirement will be “small.” An example of a product not exceeding 4 g/55 g RACC is used by the petitioner and in the proposed rule.

**Other considerations for whole oat sources - “low fat” nutrient content claim**

We urge FDA to consider an exemption to the 50 g requirement of the “low-fat” nutrient content claim for products made predominantly from whole oat sources with small serving sizes ( $\leq 30$  g). The requirement that products with small serving sizes meet the “low fat” criteria not only on a per RACC and labeled serving size basis, but also per 50 g, unfairly penalizes certain whole oat products (e.g., ready-to-eat cereals) that make a valuable nutrition contribution to American diets.

Lower-density, predominantly whole oat cereals easily meet the FDA requirements for the low-fat nutrient content claim ( $< 3$  g fat) per labeled serving and RACC (30 g). The inherent fat content of oats, coupled with the recent upward trend in fat content of whole oat sources, however, is resulting in significant formulation challenges to maintain “low-fat” status on a 50 g basis. It would be counterproductive to health objectives to decrease oat content (and thereby beta-glucan levels) in order to meet the somewhat arbitrary “and per 50 g” requirement, especially when the naturally occurring fat in grain is not a health concern.

As noted earlier, the fat composition of whole oat sources is consistent with current dietary recommendations. Furthermore, should the 50 g requirement for the “low fat” nutrient content claim remain, it may lead to the unintended consequence of manufacturers formulating lower-density, predominantly whole oat cereals with lesser amounts of beneficial oat ingredients and more sugar (to displace fat). Whole oat cereals make an important nutritional contribution to the diet, while not delivering a significant amount of fat per serving. The 50 g requirement should not prevent them from promoting their “low fat” content to consumers.

We appreciate the opportunity to provide comments on this proposed rule.

Respectfully submitted,

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