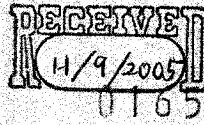




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Beverages & Foods

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LAW DEPARTMENT

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VIA OVERNIGHT MAIL

November 4, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Petition for Amendment

Dear Sir/Madam:

Enclosed please find a Petition filed by The Quaker Oats Company requesting amendment to 21 C.F.R §101.81.

We appreciate your attention to this matter.

Very truly yours,

Mark L. McGowan, Esq.
Vice President Law
The Quaker Oaks Company

2006P-0069

Tropicana



November 4, 2005

Petitioner: The Quaker Oats Company

Address: 555 West Monroe
Suite 11-11
Chicago, IL 60661

Tel. No. (312) 821-1801

Subject: Petition for Amendment of Health Claim Regulation (21 C.F.R. §101.81)—
Beta-Glucan Soluble Fiber from Whole Oat Sources and Risk of Coronary
Heart Disease

PETITION

The undersigned (The Quaker Oats Company ("Quaker Oats")) submits this petition under sections 403(r)(1)(B), 403(r)(3)(A)-(B), 403(r)(4)(A)(i), 403(r)(5)(D), 403(r)(7), and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA" or "the Act")¹ to request the Commissioner of Food and Drugs to amend the existing regulation authorizing health claims relating beta-glucan soluble fiber from specific whole oat sources to reduced risk of coronary heart disease (CHD), 21 C.F.R. §101.81, to permit foods which exceed the nutrient content requirement in 101.62 for "low fat" due to fat content deriving solely from these whole oat sources (i.e., oat bran, rolled oats, whole oat flour, oatrim) to bear the health claim.

A. Action Requested

Existing 21 C.F.R. §101.81(c)(2)(iii)(C) provides:

(C) The food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

Quaker Oats requests that this provision be amended, and that a new subparagraph (D) be added, to provide:

(C) The food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat" and "low cholesterol" food; and

(D) The food shall meet the nutrient content requirement in § 101.62 for a "low fat" food, unless it exceeds this requirement due to fat content solely derived from whole oat sources listed in paragraph (c)(2)(ii)(A).

B. Statement of Grounds

1. Overview

Quaker Oats requests that the Food and Drug Administration (FDA) amend the health claim regulation relating soluble fiber from specific whole oat sources to a reduced risk of CHD with regard to the total fat level permitted in certain foods eligible to bear the claim. Specifically, Quaker Oats requests that the FDA regulation, 21 C.F.R. § 101.81(c)(2)(iii), be amended such that the "low fat" eligibility standard, while remaining generally applicable, would not be applicable to foods exceeding the standard only because of total fat inherent in whole oat sources in the food. The "low saturated fat" and "low cholesterol" eligibility standards would be retained for all foods, regardless of the source of total fat.

¹ 21 U.S.C. §§ 343(r)(1)(B), (r)(3)(A)-(B), (r)(4)(A)(i), (r)(5)(D), (r)(7); 371(a).

In the event that FDA deems preliminary approval of this petition merited, in order to promptly further enable consumers to develop and maintain healthy dietary practices and to ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible, Quaker Oats requests that FDA make its proposed regulation effective upon publication (e.g., interim final rule) pending consideration of public comments and publication of a final regulation. Such action would permit certain foods consisting of or containing whole oat sources that currently are ineligible for the health claim to bear the claim during the period after FDA's preliminary approval and prior to publication and effectiveness of a final rule.²

2. Background

The Nutrition Labeling and Education Act of 1990 ("NLEA")³ authorized FDA to allow food products to bear label statements characterizing the relationship between a dietary substance and a disease or health-related condition. These statements are known as "health claims." The stated purpose of health claims is to assist the consumer in maintaining healthful dietary practices.⁴

In 1993, FDA promulgated regulations implementing the health claim provisions of the NLEA, including 21 C.F.R. §§ 101.14 and 101.70, which set forth the general rules for authorization and use of health claims. FDA also authorized a health claim relating consumption of fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, to a reduced risk of CHD.⁵

In response to a 1995 petition submitted by Quaker Oats, FDA in 1997 authorized the first food-specific health claim related to CHD risk reduction. The health claim associates diets low in saturated fat and cholesterol that include soluble fiber from specific whole oat sources with a reduced risk of CHD.⁶

In authorizing the health claim, FDA determined that the beta-glucan soluble fiber of whole oats is the primary component responsible for the serum total and LDL cholesterol-lowering effects of diets incorporating whole oat-containing foods at efficacious levels. Under the current regulation, foods eligible to bear the health claim must consist of or contain specific whole oat foods, i.e., oat bran, rolled oats (e.g., standard oatmeal and instant oatmeal), whole oat flour, or oatrim.

To be eligible to bear the health claim a food containing a specified whole oat source must provide at least 0.75 grams (g) of soluble fiber per reference amount customarily consumed (RACC). This level derives from the amount of soluble fiber scientifically shown beneficially to effect cholesterol levels, about 3 g per day, and is calculated by dividing this amount by four daily eating

² See generally 21 U.S.C. §343(r)(7)(A).

³ Pub. L. No. 101-553, 104 Stat. 2353 (Nov. 8, 1990).

⁴ FDA, Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, Dec. 1999, available at <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

⁵ 21 C.F.R. § 101.77.

⁶ 21 C.F.R. §101.81.

occasions. Eligible foods also must qualify under §101.62 as “low saturated fat,” “low cholesterol,” and “low fat.”⁷ The nutrient content claim, “low fat,” generally describes foods that contain 3 g or less total fat per RACC.⁸

3. Health Claim Eligibility Problem

Quaker Oats, beginning recently, produces flavor varieties of both reduced sugar instant oatmeal and unmodified (with respect to sugars content) instant oatmeal. Packets of Quaker Oats’ unmodified instant oatmeal are eligible to bear the health claim relating whole oat sources to a reduced risk of CHD. The RACC for flavored instant oatmeal is 55 g.⁹ Thus, in order to be “low fat” so as to be eligible for the health claim, instant oatmeal may contain no more than 3 g of total fat (including rounded values) per 55 g RACC. Quaker Oats’ unmodified instant oatmeal products that are not reduced in sugar meet this standard, and these products currently bear the health claim.

In response to consumer interest in reducing the amount of added sugars in the diet, Quaker Oats recently formulated flavor varieties of instant oatmeal that contain a reduced amount of sugar. These products comply with FDA regulations governing sugar content claims, which require that a “reduced sugar” product contain at least 25% less sugar per RACC than an appropriate reference food (e.g., unmodified instant oatmeal).¹⁰

Unfortunately, an unintended and unfair consequence of Quaker Oats formulation of reduced sugar instant oatmeal products was to make them technically ineligible under 21 C.F.R. § 101.81(c)(2)(iii)(C) to bear the whole oat sources and CHD health claim. Despite the fact that the new formulation of reduced sugar instant oatmeal has the same rolled oats content and total fat content (per serving, but not per RACC) as the unmodified instant oatmeal formulations, the reduced sugar varieties do not qualify for the claim under the existing total fat (i.e., “low fat”) eligibility standard.

An example of the problem with the existing “low fat” eligibility standard may be seen by comparing an illustrative reduced sugar product to its counterpart unmodified instant oatmeal product, as follows:

	Unmodified Instant Oatmeal	Reduced Sugar Instant Oatmeal
Packet weight	43 g	31 g
Rolled oats	28 g	28 g
Sugar	15 g	3 g
Fat content per packet	2 g	2 g
Fat content per 55 g RACC	3 g	3.5 g

⁷ 21 C.F.R. §101.81(c)(2)(iii)(C)..

⁸ 21 C.F.R. §101.62(b)(2).

⁹ 21 CFR §101.12(b) Table 2 (Product category: Cereal and Other Grain Products: Breakfast cereal (hot cereal type), hominy grits).

¹⁰ 21 C.F.R. §101.60(c)(5).

While the reduced sugar instant oatmeal product contains the same amount of rolled oats and of total fat per serving as the unmodified product, it does not qualify as "low fat."¹¹ The 2 g of total fat in the 31 g serving calculates to 3.548 g of total fat per 55 g RACC, which exceeds (even considering permissible rounding) the 3 g of total fat per 55 g RACC necessary to qualify as "low fat" to be eligible for the health claim.¹²

4. Proposed Solution

To address this unintended and unfair health claim eligibility consequence, Quaker Oats requests that FDA amend 21 C.F.R. §101.81(c)(2)(iii) such that the "low fat" eligibility standard, while remaining generally applicable, would not be applicable to foods exceeding the standard solely because of total fat inherent in the whole oat source(s) in the food. Such amendment is appropriate from both scientific and regulatory perspectives.

a. Scientific Basis

The Dietary Guidelines for Americans (2000) first modified prior recommendations regarding total fat intake, as reflected in the 4th edition of the U.S. Dietary Guidelines, from a recommendation to choose a diet low in total fat to a recommendation to choose a diet moderate in total fat.¹³

The total fat content and fatty acid composition of oats remains consistent with the current authoritative understanding of dietary patterns likely to promote health and reduce the risk of CHD. The Executive Summary in the Dietary Guidelines for Americans (2005) recommends saturated fat consumption equivalent to less than 10% of total calories and total fat consumption equivalent to 30-35%, 25-35%, and 20-35% of total calories, with most fats supplied from sources of polyunsaturated and monounsaturated fatty acids, for individuals age 2-3 years, 4-18 years, and 19 years or greater,

¹¹ In contrast, the unmodified instant oatmeal qualifies as "low fat." The 2 g of total fat in the 43 g serving calculates to 2.558 g of total fat per 55 g RACC.

¹² Permissible rounding (*see generally* 58 *Fed. Reg.* 44020, 44023-24 (Aug. 18, 1993)) of total fat content addresses the "low fat" health claim eligibility problem for some flavor varieties of Quaker Oats' reduced sugar instant oatmeal products, but does not solve it for all.

¹³ *See generally* "Re - Evaluation of Low Fat Criterion for Heart Disease Health Claims," available at

http://www.fda.gov/ohrms/dockets/ac/04/briefing/4035b1_02_low%20fat%20criterion.pdf. The document was a briefing paper for an April 27-28, 2004 meeting of the Nutrition Subcommittee of FDA's Food Advisory Committee. *See generally*

http://www.fda.gov/ohrms/dockets/ac/04/agenda/4035a1_draft%20Agenda.pdf;

http://www.fda.gov/ohrms/dockets/ac/04/questions/4035q1_01_questions.pdf; and

http://www.fda.gov/ohrms/dockets/ac/04/briefing/4035b1_01_toc.pdf. It specifies that a "low fat" eligibility criterion was not made a part of the regulation governing health claims about plant sterol and stanol esters and risk of CHD because of this change in the total fat intake recommendation.

respectively.¹⁴ Based on USDA Food Composition Database, the percent of calories from saturated fat and total fat in oats is 3% and 16%, respectively.¹⁵ The ratio of saturated fatty acids to polyunsaturated plus monounsaturated fatty acids in oats is approximately 1 : 5. Thus, amending the existing regulation regarding whole oat sources and CHD to make products eligible which, due solely to their oat content on a RACC basis, exceed the requirement of "low fat" would have no impact on the benefit described in the whole oat sources/CHD health claim.

b. Regulatory Basis

There exists precedent for the amendment Quaker Oats seeks in the FDA-authorized health claim regarding soy protein and a reduced risk of CHD. That claim requires eligible products to be low in saturated fat and cholesterol, but it does not require that the product always be "low fat."¹⁶ Where the food consists of, or is derived from, whole soybeans and contains only the fat inherently present in whole soybeans, it need not meet the nutrient content requirement of "low fat." This is particularly relevant to this petition from a regulatory perspective because, like oats, soy contains a significant amount of inherent fat.¹⁷

In the preamble to the final rule authorizing soy protein/CHD health claims,¹⁸ FDA discussed the requirement that an eligible food meet the criterion for "low fat." Several comments submitted in response to the proposed rule pointed out that, due to the inherent ratio of protein to fat, all foods made from whole soybeans would be disqualified due to fat content if a "low fat" eligibility standard was included in the final rule. In response, FDA allowed that products derived from whole soybeans "would not lead to an increase in the intake of saturated fat or cholesterol and, thus, negate the health benefits of soy protein."¹⁹ The preamble goes on to provide:

The amount by which foods made from whole soybeans that are otherwise eligible to bear the soy protein health claim would exceed the "low fat" criterion due to the inherent fat content of soybeans is small and well below the disqualifying level for total fat [i.e., 13 g per RACC] that a food bearing any health claim must meet (Sec. 101.14 (a)(4)). FDA is persuaded that products derived from whole soybeans are useful sources of soy protein and that they, like fish and game meats that are "extra

¹⁴ Executive Summary, Dietary Guidelines for Americans 2005, available at <http://www.health.gov/dietaryguidelines/dga2005/document/html/executivesummary.htm>.

¹⁵ U.S. Department of Agriculture, Agricultural Research Service, 2004, USDA Nutrient Database for Standard Reference, Release 17, Nutrient Data Laboratory Homepage, available at <http://www.nal.usda.gov/fnic/foodcomp/Bulletins/keyfoods.htm>

¹⁶ 21 C.F.R. § 101.82(c)(2)(iii)(B)-(C).

¹⁷ The amount of fat in oats, of course, while significant in terms of health claim eligibility, is far less than that inherent in soybeans. For comparison, according to the USDA food composition database (*see* footnote 15 *supra*), the percent of total calories supplied as fat in oats and raw mature soybeans is 16% and 43%, respectively. Saturated fat as a percent of calories for oats and raw mature soybeans is 3% and 6%, respectively.

¹⁸ Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease, 64 Fed. Reg. 57,700 (Oct. 26, 1999).

¹⁹ *Id.* at 57,717.

lean," can be appropriately incorporated in a diet that is low in fat, saturated fat, and cholesterol. Thus, FDA is modifying Sec. 101.82(c)(2)(iii)(B) to require that all products meet the criteria for "low saturated fat" and "low cholesterol" and adding Sec. 101.82(c)(2)(iii)(C) to require that a food meet the criterion for "low fat" in order to bear the soy protein health claim, except for products consisting of or derived from whole soybeans without additional fat.²⁰

In like fashion, products consisting of, or derived from, whole oat sources can be appropriately incorporated into a diet that is low in fat, saturated fat, and cholesterol, while serving as important sources of beta-glucan soluble fiber.²¹ Amending the whole oat sources/CHD health claim regulation to allow for products with greater fat content due to a greater proportion of whole oat sources would enable food manufacturers to create products that are lower in added sugar while still retaining the heart-protective qualities of these whole oat-based foods. Furthermore, such a change would enhance consumers' ability to incorporate beta-glucan soluble fiber into their diets while reducing their sugar consumption. The additional level of inherent fat in whole oats would not have a negative impact on the benefit described in the whole oat sources/CHD health claim.

C. Environmental Impact

Quaker Oats claims categorical exclusion from environmental assessment and environmental impact statement requirements because the action it requests is of the type excluded pursuant to 21 C.F.R. §§ 25.30(i), 25.30(k), and/or 25.32(p).

D. Economic Impact

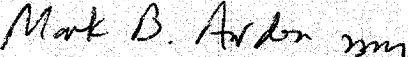
[Reserved in the event that FDA requests information.]

²⁰ *Id.*


²¹ Quaker Oats notes that the trend in CHD health claim authorizations appears to be moving away from a generally applicable "low fat" eligibility standard. FDA has authorized, pursuant to the "authoritative statement" notification procedure under the FDA Modernization Act (FDAMA), health claims relating whole grain foods with moderate fat content -- containing less than 6.5 g total fat and 0.5 g or less *trans* fat per RACC -- to reduced risk of CHD. See generally CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, Health Claim Notification for Whole Grain Foods with Moderate Fat Content (Dec. 9, 2003). Additionally, as noted above (footnote 13 *supra*), in the plant sterol/stanol esters and CHD health claim authorizing regulation FDA required that eligible foods be "low saturated fat" and "low cholesterol," but not "low fat"; rather, FDA required that eligible foods generally not exceed the total fat disqualifying level set forth in the general requirements for health claims, and a fat disclosure statement for salad dressings and spreads that exceed this level (on a per 50 g basis). 21 CFR §101.83(c)(2)(iii)(B)-(C). Similarly, there have been other health claims where FDA has required a fat disclosure statement, rather than imposing a "low fat" or other total fat disqualifying level; these include the agency's exercise of enforcement discretion relative to health claims relating walnuts and a reduced risk of CHD and relating nuts and a reduced risk of CHD. Qualified Health Claims: Letter of Enforcement Discretion - Walnuts and Coronary Heart Disease (Docket No 02P-0292); Qualified Health Claims: Letter of Enforcement Discretion - Nuts and Coronary Heart Disease (Docket No 02P-0505).

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.



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The Quaker Oats Company