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DEC 22 2005

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The Quaker Oats Company
Quaker Plaza
555 West Monroe Street
Chicago, Illinois 60661-3716

RE: Petition to amend health claim regulation (21 CFR §101.81) — soluble fiber from certain foods and risk of coronary heart disease

Dear Mr. McGowan:

The purpose of this letter is to confirm the steps the Food and Drug Administration (FDA) will take in responding to your health claim petition, as discussed with you by telephone on December 21, 2005. FDA's Dockets Management Branch received your health claim petition on November 7, 2005, and filed it on that date (Docket number 2005P-0449). As we discussed, Dockets Management Branch filed your health claim petition as a citizen petition and issued you a letter on November 7, 2005, stating that your petition had been filed. It was later learned that your petition was submitted pursuant to certain parts of section 403(r) in the Federal Food, Drug, and Cosmetic Act (FFD&C Act). The petition requests FDA to amend 21 CFR §101.81 to permit foods which exceed the nutrient content requirement in § 101.62 for "low fat" due to fat content deriving solely from oat sources (i.e., oat bran, rolled oats, whole oat flour, oatrim) to bear the health claim.

The provisions of section 403(r)(4)(A)(i) of the FFD&C Act require FDA to act within 100 days of the date of receipt of a health claim petition to either issue a decision denying the petition or to file the petition for further action. If FDA files the health claim petition, no later than 90 days from the date of filing FDA must either deny the petition or issue a proposed regulation to take the action requested in the petition. The statute also provides for an extension to this 90-day deadline when mutually agreed upon by FDA and the petitioner. In order to follow the statutory framework and preserve the time frames for health claim petitions specified in section 403(r)(4)(A)(i) of the FFD&C Act described above, we will be closing the original docket opened for your health claim petition. If we decide to file your health claim petition, we will open a new docket and assign a new docket number at that time. The petition receipt date remains November 7, 2005. The statutory deadline to issue a decision denying the petition or

2005P-0449

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Page 2 - Mark L. McGowan

filing the petition for further action is February 15, 2006 (i.e., 100 days from the date of receipt of the petition). Assuming your health claim petition is filed on this date, the deadline for FDA to issue either a proposed rule or a denial decision will be May 16, 2006 (90 days from the date the petition is filed) unless a mutually agreed upon extension is met.

Please contact me at (301) 436-1461 if you have questions regarding this petition.

Sincerely yours,



Tomoko Shimakawa, Sc.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition