DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

APR 26 2001

2048 '01 JUL 20 P1:53

Priscilla Samuel, Ph.D.
Senior Scientist
Director, Clinical Research Program
The Quaker Oats Company
617 W. Main Street
Barrington, IL 60010

RE: Health Claim Petition for Oatrim (Betatrim™) – To Expand the "Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease" Health Claim" (21 CFR 101.81)

Dear Dr. Samuel:

This acknowledges receipt on April 13, 2001 by the Food and Drug Administration (FDA) of your petition submitted by both the Quaker Oats Company (Quaker Oats) and Rhodia Inc. pursuant to 21 U.S.C. 343(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You requested that the "Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease Health Claim" (21 CFR 101.81) be expanded to include Oatrim, with specific reference to the Quaker-Rhodia group of Oatrim, known as Oatrim (BetaTrim™).

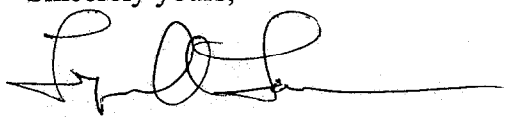
Your petition is undergoing initial FDA review. In accordance with 21 U.S.C. 343(r)(4)(A)(i) and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, the petition will either be filed for comprehensive review or denied. A denial may be by FDA action within the 100-day period, which ends on July 20, 2001, or by operation of law. FDA will notify you by letter of the disposition of your petition.

01Q-0313

ACK!

Please feel free to contact me at 202-205-5372 if you have questions concerning your petition.

Sincerely yours,



Lynn A. Larsen, Ph.D.
Director
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition