

Reference #2



JUL 20 2001

Mr. James T. Elfstrum
Manager, Regulator Affairs
Rhodia Inc.
CN 7500, 259 Prospect Plains Road
Cranbury, NJ 08512-7500

RE: Health Claim Petition - Petition to Expand the Oats Soluble Fiber and Coronary Heart Disease Health Claim, (21 CFR 101.81)

Dear Mr. Elfstrum:

This letter is in reference to the subject health claim petition that you submitted on April 12, 2001, and was received in the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration on April 13, 2001. We informed you on April 26, 2001, that the date by which FDA would either file or deny your petition is July 20, 2001. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act). We will either publish a proposal in response to the petition or deny the petition within 90 days of the filing date, i.e., within 90 days of July 20, 2001. Consistent with our strategy for implementation of the 1999 *Pearson* court decision (see 65 Fed. Reg. 59855, October 6, 2000) we will consider using our interim final rule authority under section 403(r)(7)(A)(iii) of the act to allow use of the health claim immediately upon publication of the proposal.

You need to be aware that the Center for Food Safety and Applied Nutrition is scheduled to move from Washington, D.C. to College Park, Maryland this fall. Due to the interruptions in our work anticipated from this move, we may need to discuss with you in the future an extension of the proposal date in accordance with section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(3)(iii).

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

cc: Priscilla Samuel, Ph.D.
Robert Murray, Ph.D.
The Quaker Oats Company



JUL 20 2001

Priscilla Samuel, Ph.D.
Director, Clinical Research Program

Robert Murray, Ph.D.
Director, Gatorade Sports Science Institute & Quaker Nutrition

The Quaker Oats Company
617 W. Main Street
Barrington, IL 60010

RE: Health Claim Petition - Petition to Expand the Oats Soluble Fiber and Coronary Heart Disease Health Claim, (21 CFR 101.81)

Dear Drs. Samuel and Murray:

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Sincerely yours,

Lynn A. Larsen, Ph.D.
Director

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cc: Mr. James T. Elfstrum
Rhodia Inc.