



The Quaker Oats Company, 617 Main Street, Barrington, Illinois 60010 (847) 381-1980

April 12, 2001

Lynn A. Larsen, Ph.D.
Director, Div. of Nutrition Science & Policy
Office of Nutrition Products, Labeling and
Dietary Supplements
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Dear Dr. Larsen:

As requested, The Quaker Oats Company and Rhodia Inc., are hereby submitting an additional copy of the Oatrim (BetaTrim™) petition to expand the original health claim concerning the relationship between the consumption of soluble fiber from certain foods and reduced coronary heart disease (CHD). The current petition requests that 21 CFR 101.81 be expanded to include Oatrim, with specific reference to the Quaker-Rhodia group of Oatrim, known as BetaTrim™.

The enclosed includes the following information:

- ◆ Overall evidence that demonstrates our fulfillment of the health claim requirements set forth in 21 CFR 101.14 to permit a health claim for the relationship between Oatrim (BetaTrim™) and CHD.
- ◆ A PAPER copy of the *original petition* dated April 05, 2001
This is a summary of scientific evidence demonstrating the cholesterol-lowering efficacy of Oatrim (BetaTrim™)
- ◆ A second set of scientific articles/references & appendices (2 binders)
- ◆ A third COPY of the petition, references and appendices 6 & 7 in electronic form (CD-rom).

Should the U.S. Food and Drug Administration (FDA) grant preliminary approval of this health claim petition, Quaker Oats and Rhodia also request that FDA grant an *Interim Final Rule* by which products containing Oatrim (BetaTrim™) could carry the "Oats/soluble fiber and CHD health claim" during the period after FDA's preliminary approval and prior to its publication of a Final Rule.

01Q-0313

HCN1

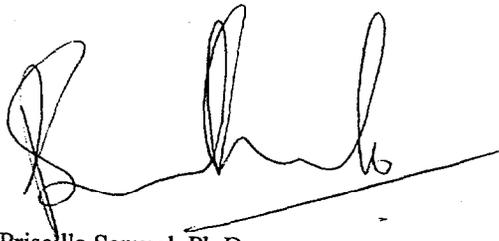


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Again, please do not hesitate to contact Quaker Oats or Rhodia if further discussion or information is required. For this reason, questions, phone calls, and communication may be addressed to the undersigned at the address provided.

Thank you.

Yours truly,



Priscilla Samuel, Ph.D.
Senior Scientist
Director, Clinical Research Programs
(847) 304 2230



Mark L. McGowan
Counsel
The Quaker Oats Company
(312) 222 7801



The Quaker Oats Company, 617 Main Street, Barrington, Illinois 60010 (847) 381-1980

April 5, 2001

Lynn A. Larsen, Ph.D.
Director, Div. of Nutrition Science & Policy
Office of Nutrition Products, Labeling and
Dietary Supplements
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Dear Dr. Larsen:

The Quaker Oats Company and Rhodia Inc., are hereby submitting a petition to expand the original health claim concerning the relationship between the consumption of soluble fiber from certain foods and reduced coronary heart disease (CHD). The current petition requests that 21 CFR 101.81 be expanded to include Oatrim, with specific reference to the Quaker-Rhodia group of Oatrim, known as BetaTrim™.

The enclosed petition and binders (2) contain the following information:

- ◆ Summary of scientific evidence demonstrating the cholesterol lowering efficacy of Oatrim (BetaTrim™)
- ◆ Evidence that demonstrates our fulfillment of the health claim requirements set forth in 21 CFR 101.14 to permit a health claim for the relationship between Oatrim (BetaTrim™) and CHD.

Should the U.S. Food and Drug Administration (FDA) grant preliminary approval of this health claim petition, Quaker Oats and Rhodia also request that FDA grant an *Interim Final Rule*, by which products containing Oatrim (BetaTrim) could carry the "Oats/soluble fiber and CHD health claim" during the period after FDA's preliminary approval and prior to its publication of a Final Rule.

Please do not hesitate to contact Quaker Oats or Rhodia if further discussion or information is required. For this reason, questions, phone calls and communication may be addressed to the undersigned at the address provided.

Yours truly,

Priscilla Samuel, Ph.D.
Senior Scientist
Director, Clinical Research Programs
(847) 304 2230

Mark L. McGowan
Counsel
The Quaker Oats Company
(312) 222 7801

Encl: Petition
Reference Binders (2)