

Twin Cities Campus

Department of Food Science and Nutrition
College of Agricultural, Food, and
Environmental Sciences
College of Human Ecology

Food Science and Nutrition 225
1334 Eckles Avenue
St. Paul, MN 55108-6099
U.S.A.

612-624-1290
Fax: 612-625-5272
<http://www.fsci.umn.edu/>

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Lynn A. Larsen, Ph.D.
Director, Div. of Nutrition Science & Policy
Office of Nutritional 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:

Quaker Oats Company is submitting a petition to expand the original health claim on oat consumption and coronary heart disease. In this petition, they cite unpublished work conducted in my laboratory describing the effect of BetaTrim™ consumption on liver cholesterol and intestinal contents supernatant viscosity in rats. I have reviewed the petition and found that their description of our study and its results is accurate. These results have been published in abstract form only¹. However, it is our intention to submit these results for publication in a peer-reviewed journal within the next few months.

The animal feeding protocol used in our rat study of BetaTrim™ consumption was essentially identical to that used in a study of the effect of Cheerios™ consumption on intestinal contents supernatant viscosity. This study was described in a letter dated August 6, 1996, submitted to FDA during the comment period in support of the extension of the oat and heart disease health claim to include whole oat flour. The work presented in this letter was cited as supporting evidence for the health claim. This work was subsequently published².

My laboratory has now done several studies investigating the link between intestinal contents supernatant viscosity and cholesterol lowering in animals^{3,4,5}. Based on our studies and other related studies in the scientific literature, I am convinced that viscosity is the major characteristic of dietary fiber responsible for its cholesterol lowering effect. I recently summarized the evidence supporting this view in a presentation to the National

¹ Freiburger, L.M. and Gallaher, D.D. (2000) Association between intestinal contents viscosity and cholesterol lowering in rats fed fermentable and non-fermentable dietary fibers. *FASEB J.* 14, A291.

² Gallaher, D.D., Schmidt, K.J., Gallaher, C. M., Marquart, L. F., and Engstrom, A. M. (1999) Intestinal contents viscosity of rats fed oat-based muffins and cereal products. *Cereal Chemistry* 76: 21-24.

³ Gallaher, D.D., Hassel, C.A., Lee, K-J, and Gallaher, C. (1993) Viscosity and fermentability as attributes of dietary fiber responsible for the hypocholesterolemic effect. *J. Nutr.* 123: 244-252.

⁴ Gallaher, D.D., Hassel, C.A. and Lee, K-J. (1993) Relationships between viscosity of hydroxypropyl methylcellulose and plasma cholesterol in hamsters. *J. Nutr.* 123: 1732-1738.

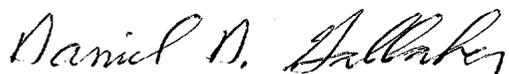
⁵ Carr, T.P., Gallaher, D.D., Yang, C-H., and Hassel, C.A. (1996) Intestinal contents viscosity and cholesterol absorption efficiency in hamsters fed hydroxypropyl methylcellulose. *J. Nutr.* 126: 1463-1469.

Academy of Science Food and Nutrition Board panel charged with proposing a definition of dietary fiber.

The results of our animal study demonstrating an increase in intestinal contents supernatant viscosity and reduction in liver cholesterol with BetaTrim™, combined with the results of the human feeding trials of BetaTrim™ (reviewed in the petition from Quaker Oats), indicates to me that BetaTrim™ is efficacious in reducing serum cholesterol in humans when consumed in appropriate amounts.

I would be happy to discuss our work with BetaTrim™ further to clarify any question that you may have.

Sincerely,



Daniel D. Gallaher, Ph.D.
Associate Professor
Director of Graduate Studies, Nutrition