

Appendix B

APPENDIX B

**Letter from Dr. Kay Behall Clarifying
β-glucan Content of Clinical Trial Diets 7/19/04**



United States Department of Agriculture

**Research, Education, and Economics
Agricultural Research Service**

June 19, 2004

**Dr. James Hoadley
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling and Dietary Supplements
Division of Nutrition Programs and Labeling (HFS-832)
5100 Paint Branch Pkwy.
College Park, MD 20740**

**Subject: β -glucan Content of Barley Diets Utilized in Human Clinical Trials
Conducted at USDA Diet and Human Performance Laboratory**

Dear Dr. Hoadley,

I have recently conducted two human clinical trials monitoring the lipid response of hypercholesterolemic men and women consuming barley (Behall et al 2004a, b). These trials have been included as evidence of the lipid lowering property of barley foods in the health claim petition submitted to you by the National Barley Foods Council. It is my understanding, that you have requested the β -glucan content of the diets consumed in the trials. The soluble fiber content of the diets was reported in the publications.

Analysis of β -glucan was performed by Chemists at the USDA Western Regional Research Center in Albany, CA on the raw barley materials. β -glucan analysis was determined enzymatically by AACC Method 32-23 (very similar to AOAC Method 992.16). Fiber content was performed at Covance Laboratories in Madison, WI. by AOAC Method 991.43 (AACC Method 32-07). The results are reported below.



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Clinical Trial	Nutrients from Barley		
	Soluble Fiber	β -glucan	β -glucan
	Analyzed - as fed	Calculated - Average grain	Analyzed - as fed
Behall et al 2004a			
Barley - (average as-is basis)		5%	
Diet - Barley Medium	5.4 g	3 g	3.3 g
- Barley High	8.4 g	6 g	6.7 g
Behall et al 2004b			
Barley - (average as-is basis)		5%	
Diet - Barley Medium	5.6 g	3 g	3.3 g
- Barley High	8.8 g	6 g	6.6 g

The first paper (2002a) utilized the terms 'added soluble fiber' and 'added β -glucan' interchangeably when discussing the amount of β -glucan in the diets. The second paper (2002b) uses only 'added β -glucan', rather than both soluble fiber and β -glucan, when discussing the diets containing barley. This was done to highlight barley as a β -glucan source and to recognize that some soluble fiber was in the diet from sources other than barley. The term 'soluble fiber' is used to discuss other research when the amount of β -glucan is not reported but the total soluble fiber is given.

Behall, K. M., Scholfield, D. J. & Hallfrisch, J. G. (2004a). Lipids significantly reduced by diets containing barley in moderately hypercholesterolemic men. *J Am Coll Nutr*, **23**, 55-62.

Behall, K. M., Scholfield, D. & Hallfrisch, J. (2004b). Diets containing barley reduce lipids significantly in mildly hypercholesterolemic men and women. *Am J Clinical Nutrition (Manuscript Accepted for publication June, 2004)*.



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