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January 27, 2006

Food and Drug Administration
Office of Nutritional Products, Labeling and
Dietary Supplements (HFS-800)
5100 Paint Branch Parkway
College Park, MD 20740

Re: Petition for Health Claim for Barley Betafiber and Coronary Heart Disease

The undersigned, Cargill, Incorporated, a Delaware corporation with a principal place of business in Wayzata, Minnesota, submits this petition pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act with respect to barley betafiber (Cargill's concentrated barley beta-glucan soluble fiber) and reduced risk of coronary heart disease (CHD).

The data submitted with this petition are intended for consideration in light of, and in addition to, data submitted previously by the National Barley Foods Council in a health claim petition regarding whole grain barley and certain dry milled barley grain products and reduced risk of CHD. The Food and Drug Administration (FDA) recently authorized this health claim (*Fed Reg.* 70:76150). The totality of the data establish that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims regarding the relationship between barley betafiber (barley beta-glucan soluble fiber) and a reduced risk of CHD.

Attached hereto, and constituting a part of this petition, are the following:

- A. Preliminary requirements: A description of barley betafiber as a food ingredient that provides nutritive value and technical function. Data is also presented to establish that barley betafiber is safe and lawful and that it is associated with reduced risk of CHD.

Barley betafiber is generally recognized as safe (GRAS) based on scientific procedures and supported by evidence of safe use of barley in food prior to 1958. Cargill has completed a GRAS self-determination; the expert panel statement is attached as an Appendix to this petition. A GRAS notification will be filed with FDA subsequent to this petition.

- B. Summary of scientific data: Data establishing that, based on the totality of publicly available scientific evidence, including evidence from well-designed

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studies conducted in a manner which is consistent with generally recognized scientific procedures and principles, significant scientific agreement exists among experts qualified by scientific training and experience that a strong association exists between consumption of barley betafiber (barley beta-glucan soluble fiber) and a reduced risk of CHD.

- C. Analytical data: Information as to the analytical methods used to assay the presence of barley beta-glucan in foods.
- D. Model health claim: The proposed claim contains the recommended text for possible model health claims.
- E. Attachments: Copies of computer literature (Medline) search results and articles cited.
- F. Environmental impact: Cargill claims a categorical exclusion from the environmental assessment and environmental impact statements.

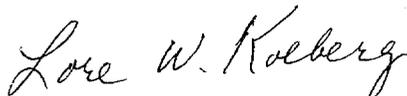
We respectfully request that upon determination of significant scientific agreement in support of this health claim, FDA issue an interim final rule under Section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act, which authorizes the Secretary to make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation. Such action would provide information necessary to enable consumers to develop and maintain healthy dietary practices, inform consumers promptly and effectively of important new knowledge regarding nutritional and health benefits of foods, and ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible.

Any questions regarding this petition should be directed to Lore Kolberg, Cargill, Incorporated at 952-742-1047. Correspondence may be sent to Lore Kolberg at the address below.

Yours very truly,

Cargill, Incorporated

By:



Lore Kolberg
Manager, Regulatory and Scientific Affairs

cc: Ted Ziemann, President, Health and Food Technologies
Barbara Bentson, Director, Regulatory and Scientific Affairs