



OCT - 9 2003

Doug Scoville  
Chairman  
National Barley Foods Council  
W. 905 Riverside, Suite 501  
Spokane, Washington 99201

RE: Petition for barley and coronary heart disease health claim (amendment of 21 CFR 101.81)

Dear Mr. Scoville:

This letter acknowledges receipt on September 25, 2003, by the Food and Drug Administration (FDA) of the petition you submitted pursuant to Section 403(r)(4) of the Federal Food Drug and Cosmetic Act (FFD&C Act)(21 U.S.C. § 343(r)(4)). The petition requests amendment of the regulation that authorizes a health claim relating soluble fiber from certain foods with a decreased risk of coronary heart disease (21 CFR 101.81) to include  $\beta$ -glucan soluble fiber from barley and barley products.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 100-day period, which ends on January 3, 2004, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

In our preliminary review of your petition, we noticed that there are some minor deficiencies in your petition. Health claim petitions must comply with all the requirements in 21 CFR 101.70. First, you submitted only one copy of the references. Please note for future submissions that 21 CFR 101.70(a) specifies that an original and one copy of the petition (that includes references) must be submitted. Second, the following articles were either not legible, incomplete or had missing pages.

- (1) Aman, P. and Graham, H. (1987)—Not legible.
- (2) Burger, W. C. et al. (1982)—Not legible.
- (3) Kalra, S. and Jood, S. (2000)—Pages 142 and 144 are missing.
- (4) McIntosh, G. (1993)—Not legible.
- (5) Rooney Duke, T. (1996)—Pages 40 through 59 are missing.
- (6) Schwartz, P. B. and Lee, Y. T. (1995)—Left side of the text is cut off in page 102.

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- (7) Turnbull, W. H. and Leeds, A. R. (1987)—Not legible.
- (8) Van Horn, L. et al. (1986)—Not legible.
- (9) Webster, F. H. (2002)—Pages 96 through 113 are missing.
- (10) Wood, P. J. et al. (1983)—Left side of the text is cut off in pages 96 and 108 and right side of the text is cut off in pages 101, 103, and 105.

Please send us two complete legible copies of each of these articles. It is your responsibility to ensure that the petition is complete.

We also noticed that your petition contains several deviations from the petition format specified in 21 CFR 101.70(f). The regulation specifies attachment section headings labeled A. B. C., whereas your petition labeled all sections with roman numerals. In addition, 21 CFR 101.70(g) specifies that data under several letter headings (noted above) should be submitted on separate pages, suitably identified. Your section II through IV did not start on separate pages. Also, subsections 1-4 of Requirement B were not addressed completely. Complete submission and correct format facilitate the FDA review of petitions. We request that any future petitions you may submit follow all the requirements specified in 21 CFR 101.70, including format.

Please feel free to contact me at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,



Tomoko Shimakawa, Sc.D.  
Epidemiologist  
Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition