

meet the recommendations put forth in the USDA/USDHHS's (2000) nutritional guidelines.

Thus, only positive health benefits are envisioned for the consumer upon approval of a health claim relating the consumption of barley and products derived from barley to the reduced risk of CHD.

V. MODEL HEALTH CLAIMS

Once barley β -glucan soluble fiber and barley products containing β -glucan soluble fiber are authorized to bear the heart health claim, the National Barley Foods Council intends to use statements similar to the following for use in describing the heart health benefits of barley β -glucan soluble fiber.

- A. Three grams of barley β -glucan soluble fiber, as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease. This _____ (product) contains _____ grams per serving.
- B. Three grams per day of β -glucan soluble fiber from barley as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease. This _____ (product) contains _____ grams per serving.
- C. β -glucan soluble fiber from barley as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease. This _____ (product) contains _____ grams per serving.
- D. Diets low in saturated fat and cholesterol that include 3 grams of β -glucan soluble fiber from barley may reduce the risk of coronary heart disease. This _____ (product) contains _____ grams per serving.

VI. ENVIRONMENTAL IMPACT

The National Barley Foods Council claims a categorical exclusion under 21 CFR 25.32(p) for an environmental assessment (EA) and an environmental impact statement (EIS). Under the environmental impact consideration regulations, actions involving the issuance of a health claim does not individually or cumulatively have a significant effect on the human environment, thus this process does not require the development of an EA or EIS.

VII. CONCLUSION

The information presented provides conclusive scientific evidence that the (1→3).(1→4)- β -D-glucan soluble fiber from barley products will reduce serum LDL and total cholesterol by clinically significant levels, thereby helping to reduce the risk of CHD in the U.S. population.

The initial health claim authorized by the FDA (1997a) identified oat β -glucan soluble fiber as the substance responsible for the cholesterol lowering properties of oats and approved a heart health claim for rolled oats, oat bran and oat flour. More recently the FDA (2003) extended the heart health claims for an oat β -glucan soluble fiber extract by approving certain Oatrim "Beta Trim™" products. The evidence presented in this petition clearly demonstrates the significant scientific agreement that barley β -glucan soluble fiber's cholesterol lowering properties are essentially indistinguishable from those exhibited by oat β -glucan soluble fiber. Key highlights are as follows:

- Human clinical trials clearly show that barley β -glucan soluble fiber reduces total and LDL cholesterol. The reductions in total cholesterol reported for 3g and 6g of barley β -glucan soluble fiber was equivalent or more effective than reductions predicted for oat β -glucan soluble fiber.
- Animal feeding studies directly comparing the cholesterol lowering properties of barley β -glucan soluble fiber to oat β -glucan soluble fiber reported either no significant difference or the animals consuming barley had significantly lower serum cholesterol levels. Additionally, over twenty studies comparing barley to a non-oat control reported significant reductions in total cholesterol when animals consumed barley products containing β -glucan soluble fiber.

- The chemical and physical properties of barley and oat β -glucan soluble fiber are essentially equivalent. Any existing differences do not appear to impact the cholesterol lowering properties of either barley or oat β -glucan soluble fiber.
- Barley is recommended as a food that contains viscous soluble fiber by the National Cholesterol Education Panel and as such, should be included as part of a therapeutic diet to lower LDL-cholesterol.
- On average barley has slightly higher β -glucan soluble fiber levels and has significantly lower fat levels than oats. This enhances the opportunities for food processors to incorporate barley β -glucan soluble fiber into heart healthy food products.

Increased consumption of barley products will provide significant heart health benefits to the U.S. consumer. Furthermore, a large increase in barley consumption does not have any negative health implications. Individuals who incorporate barley β -glucan soluble fiber into their diet will most likely choose to use barley to replace refined grains (white rice or pasta) or potato products. This dietary substitution is consistent with the USDAHHS recommendation for increased consumption of grain and whole grain products. Furthermore, a developing body of scientific evidence indicates that increased consumption of barley β -glucan soluble fiber should be beneficial for citizens with diabetes, high blood pressure and obesity related health issues.

Therefore the National Barley Foods Council requests that the Agency authorize dehulled and hullless barley and products derived from these materials as sources of barley β -glucan soluble fiber for inclusion in 21 CFR 101.81 as an eligible source of soluble fiber.

VIII. PROPOSED REGULATION AMENDMENT

The petitioners propose that 21 CFR 101.81 be amended to include the use of barley and products derived from barley, as sources of β -glucan soluble fiber eligible to bear the health claim.

It is suggested that 21 CFR 101.81 (c)(2)(i)(G)(1) be revised by adding modifying the sentence to read as follows:

(1) 3 g or more per day of β -glucan soluble fiber from whole oats or barley.

It is further suggested that 21 CFR 101.81 (c)(2)(ii)(A) be revised by adding modifying the first sentence in paragraph A to read as follows:

(A) Beta (β) glucan soluble fiber from the whole oat and barley sources listed below.

It is further suggested that 21 CFR 101.81 (c)(2)(ii)(A) be revised by adding subparagraph (5) as follows:

(A)(5) Barley. Barley products are produced from clean, sound barley grain that is either 1) dehulled, or 2) hullless and that provides at least 4% (dry weight basis (dwb)) of β -glucan soluble fiber. Products derived from barley, including but not limited to pearl, flakes, grits, meal, flour, β -glucan enriched meal or flour fractions, and bran are manufactured from the grain using standard milling techniques and must provide at least 4% (dwb) β -glucan soluble fiber.

It is further suggested that 21 CFR 101.81 (c)(2)(iii)(A) (1) be revised by adding modifying the sentence to read as follows:

(A)(1) One or more of the whole oat or barley foods from paragraphs (c)(2)(ii)(A)(1), (2), (3), and (5) of this section and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product; or

IX. CERTIFICATION

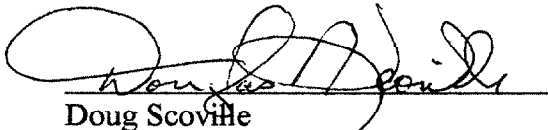
Attached herewith are copies of the scientific studies and other information referenced in, and constituting the basis for, this petition. To the best of the Petitioner's knowledge, all non-clinical studies relied upon in this petition were conducted in compliance with FDA's good laboratory practices regulations (21CFR Part 58) and all clinical investigations relied upon were either conducted in compliance with the requirements of institutional review set forth at 21CFR Part 56 or were not subject to such requirements by operation of 21CFR §§ 56.104 or 56.105. To the best of the Petitioner's knowledge, the clinical trials relied upon in the petition were conducted in compliance with the requirements for informed consent set forth in 21CFR Part 50.

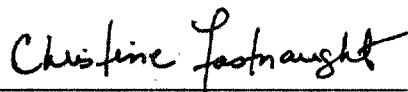
On behalf of the Petitioner, we, Doug Scoville, Chair, National Barley Foods Council; and, Christine Fastnaught, Ph.D., Barley Consulting; and, Francis Webster, Ph.D., Webster & Associates, hereby certify that, to the best of our knowledge, this petition is a representative and balanced submission that includes unfavorable information as well as favorable information, known by us to be pertinent to evaluation of the proposed health claim.


Respectfully submitted,

The National Barley Foods Council

AND,


Doug Scoville
Chair


Christine Fastnaught, Ph.D.
Barley Consulting


Francis Webster, Ph.D.
Webster & Associates

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