



THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
P05- 112
December 23, 2005

Media Inquiries: Kimberly Rawlings
301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Allows Barley Products to Claim Reduction in Risk of Coronary Heart Disease

As part of its continuing initiative to provide Americans with the information they need to make healthy nutritional choices about foods and dietary supplements, the Food and Drug Administration (FDA) today announced that whole grain barley and barley-containing products are allowed to claim that they reduce the risk of coronary heart disease (CHD).

Consumers can expect to see whole barley and dry milled barley products such as flakes, grits, flour, meal, and barley meal bearing the health claim. An example of the health claim that may be used is:

Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies x grams of the soluble fiber for necessary per day to have this effect.

CHD is the cause of almost 500,000 deaths annually. Risk factors for CHD include high total cholesterol levels and high levels of low density lipoprotein (LDL) cholesterol. Scientific evidence shows that adding barley to one's diet can contribute to lowering serum cholesterol.

"Promoting health by helping people get better nutrition information about the foods they eat is among FDA's top priorities, because the choices that Americans make about their diet have a great impact on their well-being," said FDA Deputy Commissioner for Medical and Scientific Affairs Scott Gottlieb, MD. "The FDA review process for making health claims, when combined with our strong enforcement work, rewards companies that make healthier products while we enforce the law against companies that appeal to consumers through false and misleading health claims."

FDA is authorizing food manufacturers to immediately use the health claim for barley and the reduced risk of coronary heart disease through the issuance of an interim final rule. To qualify for the health claim, the barley containing foods must provide at least 0.75 grams of soluble fiber per serving of the food.

FDA will accept public comments on the interim final rule, published in the *Federal Register*, for 75 days. Comments may be submitted to Docket No. 2004P-0512, by any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov
- Agency Web site: <http://www.fda.gov/dockets/ecomments>

- Mail/Hand delivery/Courier [for paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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