Health claims and food labeling: The FDA Final Rule permitting health claims for barley

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On May 19, 2006, the FDA issued a final rule (the Rule) allowing foods containing whole-grain barley to carry a health claim on their labels that the whole-grain barley may help to reduce the risk of coronary heart disease (CHD). The most immediate implications of this rule will be felt in the cereals industry, an industry estimated to generate approximately $7.1 billion in domestic revenues a year. The FDA estimates that products representing significant segments of the hot and cold cereal industry will be carrying this claim, and that new barley-based cereal products will be brought to market for companies to take advantage of this rule and the marketing edge with customers that it provides.

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FDA qualified barley health claim background

The rule provides that barley products containing at least 0.75 grams of soluble fiber per serving\(^2\) may use the following claim:

> 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 necessary per day to have this effect.

The rule is based on an amendment to 21 CFR 101.81 that added barley as an eligible source of soluble fiber. As a result, foods containing certain required amounts of barley are permitted to make a health claim citing the beneficial effects of barley as a soluble fiber in lowering cholesterol levels and reducing the risk of CHD.

Barley products include dehulled and hull-less whole-grain barley, and dry-milled barley products such as barley bran, flakes, grits, flour, meal, pearl barley, and sieved barley meal. Eligible barley products must be produced from “clean, sound, dehulled or hull-less barley grain using standard dry-milling techniques, which may include steaming or tempering.”

Health claim requirements

Under the Dietary Supplement Health and Education Act (DSHEA), passed in 1994, and the Nutrition Labeling Act (NLEA), passed in 1990, food producers may, upon approval by the FDA, make a health claim about a food product that expressly or by implication “characterizes the relationship of a nutrient in a food [] to a disease or a health-related condition.”\(^3\) These health claims may communicate certain beneficial effects on the body or reduce certain disease risks without that product being regulated as a drug, provided the FDA approves the claim based on the presentation of “significant scientific agreement.” Because the FDA requires this high level of substantiation, the process to secure the FDA’s approval to a food health claim may be long and costly.

In 1997, the FDA finalized a rule permitting a health claim for whole-oat products that says the consumption of beta-glucan soluble fiber (soluble fiber) in whole oats may reduce the risk of CHD. On August 3, 2004, the National Barley Foods Council submitted a health claim petition to FDA, requesting an amendment to that rule to allow barley products to be cited as an additional source of soluble fiber eligible for a CHD health claim. In December 2005, FDA issued an interim final rule

\(^2\) The claim is based on eating a total of 3 grams of beta-glucan soluble fiber daily.

\(^3\) See 21 U.S.C. § 343(r)(6) (FDCA §403(r)(6) (DSHEA structure/function claims).
permitting that health claim on the label of barley products. The rule in its final version became effective May 22, 2006.

The health claim now permitted for certain food products containing barley was sought by the Whole Grain Council as part of an increased focus by the food producers on reaching health-conscious consumers. The Whole Grains Council also petitioned the FDA to enlist its help in defining the terms “excellent” source and “good” source of whole grains for use on its labeling stamps. In June 2006, the FDA rejected the petition, causing the Whole Grains Council to design and implement its own product stamps to indicate the whole-grain content of products by weight, such as “27g or more per serving.” To further clarify the daily recommended levels, the text directly below the weight stamp will read, “Eat 48g or more of whole grains daily.”

Conclusion

In light of the FDA estimate that one-half of the food products claiming the barley health claim will be new to the market, cereal and other food producers may want to examine existing products and products under development to determine if any are eligible to take advantage of the rule. Consumer interest in, and concern about, health and diet can be viewed as an opportunity for food producers to use new or extended new health claims on product packaging to increase sales and market share.

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