

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P-0512]

Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation authorizing a health claim on the relationship between oat beta-glucan soluble fiber and reduced risk of coronary heart disease (CHD). The amendment adds barley as an additional eligible source of beta-glucan soluble fiber. We (FDA) are taking this action in response to a petition that the National Barley Foods Council submitted. We have concluded, based on the totality of publicly available scientific evidence that, in addition to certain oat products, whole grain barley and certain dry milled barley grain products are appropriate sources of beta-glucan soluble fiber for the health claim.

DATES: This interim final rule is effective December 23, 2005. Submit written or electronic comments by March 8, 2006. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.81(c)(2)(ii)(A)(5) as of December 23, 2005.

ADDRESSES: You may submit comments, identified by the Docket Number 2004P-0512, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- 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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s), and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD, 20740-3835, telephone 301-436-1450.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101-535) amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One aspect of the 1990 amendments was that they clarified FDA's authority to regulate health claims on food labels and in food labeling. We issued several new regulations in 1993 that implemented the health claim provisions of the 1990 amendments. Among these were § 101.14 (21 CFR 101.14), Health Claims: General Requirements (58 FR 2478, January 6, 1993), which sets out the rules for the authorization and use of health claims, and § 101.70 (21 CFR 101.70), Petitions for Health Claims (58 FR 2478, January 6, 1993), which sets out a process for petitioning the agency to authorize health claims about substance-disease

relationships, and sets out the types of information that any such petition must include. Each of these regulations became effective on May 8, 1993.

When implementing the 1990 amendments, we also conducted a review of evidence for a relationship between dietary fiber and cardiovascular disease (CVD). Based on this review, we concluded that the available scientific evidence did not justify authorization of a health claim relating dietary fiber to reduced risk of CVD (58 FR 2552, January 6, 1993). However, we did conclude there was significant scientific agreement that the totality of publicly available scientific evidence supported an association between types of foods that are low in saturated fat and cholesterol and that naturally are good sources of soluble dietary fiber (i.e., fruits, vegetables, and grain products) and reduced risk of CHD¹. We therefore authorized a health claim about the relationship between diets low in saturated fat and cholesterol and high in vegetables, fruit, and grain products that contain soluble fiber and a reduced risk of CHD (21 CFR 101.77; 58 FR 2552 at 2572). In the preamble to the 1993 dietary fiber and CVD final rule, FDA commented that if a manufacturer could document with appropriate evidence that consumption of the type of soluble fiber in a particular food has the effect of lowering blood low density lipoprotein (LDL) cholesterol, and has no adverse effects on other heart disease risk factors (e.g., high density lipoprotein (HDL) cholesterol), it should petition for authorization of a health claim specific for that particular dietary fiber-containing food (58 FR 2552 at 2567).

B. Soluble Fiber From Certain Foods and Coronary Heart Disease Health Claim (§ 101.81 (21 CFR 101.81))

In 1995, FDA received a petition for a health claim on the relationship between oat bran and rolled oats and reduced risk of CHD. FDA concluded there was significant scientific agreement that the totality of publicly available scientific evidence supported the relationship between consumption of whole oat products and reduced risk of CHD. FDA further concluded that the type of soluble fiber found in whole oats, i.e., beta-glucan soluble fiber, is the component primarily responsible for the hypocholesterolemic effects associated with consumption of whole oat foods as part of a diet that is low in saturated fat

¹ CVD means diseases of the heart and circulatory system. Coronary heart disease, one form of cardiovascular disease, refers to diseases of the heart muscle and supporting blood vessels.

and cholesterol (62 FR 3584 at 3597–3598, January 23, 1997). As such, the final rule authorized a health claim relating the consumption of beta-glucan soluble fiber in whole oat foods, as part of a diet low in saturated fat and cholesterol, and reduced risk of CHD (the oat beta-glucan health claim). The source of beta-glucan soluble fiber in foods bearing this health claim had to be one of three eligible whole oat products; i.e., oat bran, rolled oats, or whole oat flour (see § 101.81(c)(2)(ii)(A)). In 2002, FDA amended this health claim regulation to add oatrim as a fourth eligible source of beta-glucan soluble fiber (67 FR 61733, October 2, 2002). Oatrim is the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour.

In the 1997 oat beta-glucan health claim final rule, we anticipated the likelihood that other sources and types of soluble fibers will also affect blood lipid levels, and thus, may reduce heart disease risk (62 FR 3584 at 3587). At that time, FDA considered structuring the final rule as an umbrella regulation authorizing the use of a claim for “soluble fiber from certain foods” and risk of CHD. Such action would have allowed flexibility in expanding the claim to other specific food sources of soluble fiber when consumption of those foods has been demonstrated to help reduce the risk of heart disease. However, the agency concluded that it was premature to do so inasmuch as FDA had not reviewed the totality of publicly available evidence on other, non-whole oat sources of soluble fiber (62 FR 3584 at 3588). In 1998, in response to a health claim petition, FDA concluded that soluble fiber of psyllium seed husk, similar to beta-glucan soluble fiber from whole oats, may reduce the risk of CHD by lowering blood cholesterol levels (63 FR 8103, February 18, 1998). In that final rule, FDA broadened § 101.81 to include soluble fiber from psyllium seed husk, and also modified the heading in § 101.81 from, “* * * Soluble fiber from whole oats and risk of coronary heart disease” to “* * * Soluble fiber from certain foods and risk of coronary heart disease (CHD).”

II. Petition and Grounds

A. The Petition

The National Barley Foods Council (petitioner), submitted a health claim petition to FDA on August 3, 2004, under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). The petition requested that the agency amend the “Soluble fiber from certain foods and coronary heart disease health claim” at § 101.81 to include barley and barley products as

an additional source of beta-glucan soluble fiber eligible for the health claim (Ref. 1). On November 10, 2004, we notified the petitioner that we had completed our initial review of the petition and that the petition had been filed for further action in accordance with section 403(r)(4) of the act. If the agency does not act, by either denying the petition or issuing a proposed regulation to authorize the health claim, within 90 days of the date of filing for further action, the petition is deemed to be denied unless an extension is mutually agreed upon by the agency and the petitioner (section 403(r)(4)(A)(i) of the act and § 101.70(j)(3)(iii)). On February 4, 2005, FDA and the petitioner mutually agreed to extend the deadline to publish the agency’s decision on the petition until August 9, 2005. On August 3, 2005, FDA and the petitioner agreed to further extend the deadline to December 31, 2005. The petitioner requested that FDA issue an interim final rule by which labeling of barley-containing foods could bear the health claim prior to publication of a final rule.

B. Nature of the Substance

The petitioner requests that § 101.81 be amended to include barley in addition to oats as a source of beta-glucan soluble fiber associated with reducing the risk of CHD. The petitioner further requests that whole grain barley (dehulled or hulless), and certain dry milled barley products, i.e., pearl, flakes, grits, meal, flour, beta-glucan enriched meal fractions, and bran, be determined as eligible barley sources of beta-glucan soluble fiber.

The substance which is the subject of the existing oat beta-glucan health claim is beta-glucan soluble fiber from oat sources listed in § 101.81(c)(2)(ii)(A). The requested amendment will expand the substance of the claim to include both oat and barley sources of beta-glucan soluble fiber. From an analytical perspective, beta-glucan soluble fiber from barley is the same substance as beta-glucan soluble fiber from oat sources. The method now specified in § 101.81(c)(2)(ii)(A) for the measurement of beta-glucan soluble fiber from oat sources, AOAC Official Method 992.28, is a method designated by AOAC INTERNATIONAL to be used for both oat and barley fractions and it is the same analytical method identified by the petition for measurement of beta-glucan soluble fiber from barley sources.

The petition characterizes the barley sources of beta-glucan soluble fiber as dehulled or hulless whole grain barley and barley products produced from dehulled or hulless clean, sound barley

grain by standard dry milling processes, which may include steaming or tempering, and that provide at least 4 percent (dry weight basis (dwb)) of beta-glucan soluble fiber and total dietary fiber content of at least 8 percent (dwb) (flour, grits, flakes, and meal), or at least 5.5 percent (dwb) of beta-glucan soluble fiber and at least 15 percent (dwb) total dietary fiber (bran and beta-glucan enriched barley fractions). For whole grain (dehulled and hulless) barley, the petition specified the minimum beta-glucan soluble fiber content as 4 percent (dwb) and the minimum total dietary fiber content as 10 percent (dwb).

Most barley varieties have a tough fibrous adherent hull covering the grain which must be removed for the grain to be edible. There are also hulless barley varieties in which, similar to wheat, the hull falls away during harvesting and the grain can be processed directly into food products without dehulling. The petition thus has specified the eligible sources of the barley beta-glucan soluble fiber to include both dehulled and hulless whole barley grain.

In addition to dehulled or hulless whole barley grain, the petition has specified that dry milled barley products that are eligible sources of the beta-glucan soluble fiber be produced from dehulled or hulless barley grain by standard dry milling processes. The petition includes dry milled barley products only and does not include beta-glucan extracts produced through “wet milling” processes. Wet milling processes used to extract or concentrate the beta-glucan soluble fiber component of barley are likely to alter physiochemical properties of fiber and other components of the grain. All but two of the dry milled barley products specified in the petition have been formally defined by the American Association of Cereal Chemists (AACC) in a “Barley Glossary” which is published in *AACC Approved Methods* (Ref. 2). Two additional dry milled barley products, which are not defined in the AACC Barley Glossary, i.e., barley meal and beta-glucan enriched barley fractions, are included in the petition as beta-glucan soluble fiber sources. The petition characterizes barley meal as differing from barley flour only in that it is unsifted and thus has a higher portion of bran and germ present than sifted barley flour. The petition has defined “beta-glucan enriched barley fractions” as fractions of dry milled barley that are enriched in endosperm cell walls by either mechanical sifting or air classification and that provide at least 5.5 percent (dwb) of beta-glucan soluble fiber and a total dietary fiber content of at least 15 percent (dwb). The

beta-glucan content of barley endosperm cell walls is greater than that of barley endosperm cell contents. During milling, endosperm cell walls break up into larger particles than do endosperm cell contents. Sieving or air classification milling steps can be used to separate milled barley flour or meal by particle size to produce endosperm cell wall-enriched fractions. Since barley endosperm cells walls have a greater beta-glucan content than do barley endosperm cell contents, these endosperm cell wall-enriched barley fractions have a greater beta-glucan content than of the starting flour or meal. For simplicity, in this document we will be referring to endosperm cell wall-enriched barley fractions as "sieved barley meal."

The petition specifies that the dry milled barley products which are the subject of this petition, with the exception of barley bran and sieved barley meal, have a minimum beta-glucan soluble fiber content of at least 4 percent (dwb), and a minimum total dietary fiber content of at least 8 percent (dwb). The petition specifies that eligible barley bran and sieved barley meal have a minimum beta glucan soluble fiber and total dietary fiber content of 5.5 percent (dwb) and 15 percent (dwb) respectively. The petition specifies that eligible whole grain barley (dehulled and hullless) have a minimum beta glucan soluble fiber and total dietary fiber content of 4 percent dwb and 10 percent dwb respectively. The petitioner selected the minimum beta-glucan soluble fiber and total dietary fiber content specifications for the whole grain barley and dry milled barley products that are eligible sources of beta-glucan soluble fiber to be inclusive of most all commercially available dry milled barley products, while excluding barley products such as barley brewers grain in which the soluble fiber has been depleted.

C. Review of Preliminary Requirements for a Health Claim

1. The Substance Is Associated With a Disease for Which the U.S. Population Is at Risk

CHD continues to be a disease that has a large impact on mortality and morbidity in the general adult U.S. population. As explained in the existing oat beta-glucan health claim (§ 101.81(b)), FDA recognizes the CHD risk reduction benefit of certain foods that are sources of soluble dietary fiber resulting from effects on lowering blood total and LDL-cholesterol. Although age-adjusted CHD mortality rates in the United States had been steadily

decreasing since approximately 1960, recent evidence has suggested that the decline in CHD mortality has slowed (Ref. 3). Heart disease has been recognized as the leading cause of death in the United States for at least the last 50 years (Ref. 3). Based on these facts, FDA concludes that, as required in § 101.14(b)(1), CHD is a disease for which the U.S. population is at risk.

2. The Substance Is a Food

The substance which is the subject of the existing oat beta-glucan health claim is beta-glucan soluble fiber from specified oat sources, i.e., oat bran, rolled oats, whole oat flour, and oatrim (§ 101.81(c)(2)(ii)(A)). The petitioner requests an amendment to extend the eligible sources of beta-glucan soluble fiber to include those from whole grain barley and certain dry milled barley products. Barley grain is a commonly consumed human food and beta-glucan soluble fiber is a nutrient component of this food, thus the beta-glucan soluble fiber from whole grain barley and dry milled barley products that include bran, flakes, grits, pearl, flour, meal, and sieved barley meal is a "substance" as defined by § 101.14(a)(2). Health claim general requirements provide that where a substance is to be consumed at "other than decreased dietary levels" the substance must contribute taste, aroma, nutritive value, or any other technical effect as listed in 21 CFR 170.3(o), and must retain that attribute when consumed at levels necessary to justify the claim (§ 101.14(b)(3)(i)). Whole grain barley and dry milled barley products are consumed by humans for their nutritive value, and retain that attribute when consumed at levels necessary to justify the claim. Thus the agency concludes that the requirement of § 101.14(b)(3)(i) is satisfied.

3. The Substance Is Safe and Lawful

Section 101.14(b)(3)(ii) requires that the substance be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act. The petition states that dry milled barley grain is a human food of natural biological origin that has been widely consumed in the United States for its nutrient properties prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists. The petitioner's description of the use of dry milled barley grain as a

food ingredient and the use of whole grain barley, as sources of barley beta-glucan soluble fiber, are consistent with FDA's definition of food ingredients ordinarily regarded as "generally recognized as safe" (GRAS) (21 CFR 170.30(d)). FDA is satisfied that the petitioner has demonstrated the use of barley beta-glucan soluble fiber, from whole grain barley and dry milled barley grain product sources that are included in this rule, is safe and lawful under the applicable food safety provision of the act.

III. Review of Scientific Evidence of the Substance-Disease Relationship

A. Basis for Evaluating the Relationship Between Barley and CHD

FDA has identified the following endpoints to use in identifying CHD risk reduction for purposes of a health claim evaluation: Coronary events (myocardial infarction, ischemia), cardiovascular death, atherosclerosis, high blood pressure, elevated serum total cholesterol, and elevated serum LDL-cholesterol. FDA considers high blood pressure, elevated serum total cholesterol, and elevated serum LDL-cholesterol levels as surrogate endpoints for CHD (Ref. 4). FDA considers low HDL-cholesterol levels a risk factor for CHD (National Institutes of Health Consensus Conference, 1993). Elevated levels of serum total and LDL cholesterol, a prerequisite for atherosclerotic disease, is a major cause of CHD (Ref. 4). To evaluate the potential effects of beta-glucan soluble fiber from whole grain barley and dry milled barley products on CHD risk, FDA focused on serum total and LDL cholesterol levels to evaluate the relationship between barley beta-glucan and CHD risk. This focus is consistent with existing § 101.81, in which FDA concluded that there was significant scientific agreement that the relationship between consumption of whole grain oats and CHD risk is mediated primarily by the effect of dietary beta-glucan soluble fiber on serum lipids.

FDA previously concluded that there is significant scientific agreement regarding the relationship between consumption of soluble fiber-containing whole oat foods and reduced risk of CHD (62 FR 3584 at 3598). FDA concluded that the type of soluble fiber found in whole oat foods, i.e., beta-glucan soluble fiber, is primarily responsible for the observed association between consumption of whole oat foods and the lowering of blood cholesterol. As such, to evaluate the evidence supporting the petitioned

request to extend the beta-glucan soluble fiber from whole oat health claim to include beta-glucan soluble fiber from whole grain barley and dry milled barley products, FDA focused on evidence from human clinical studies of the effects of consuming beta-glucan soluble fiber from whole grain barley and dry milled barley products on blood lipids.

B. Review of Scientific Evidence of the Substance-Disease Relationship

A health claim characterizes the relationship between a substance and a disease or health-related condition (21 CFR 101.14(a)(1)). The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup, is at risk (§ 101.14(b)(1)). Health claims characterize the relationship between the substance and a reduction in risk of contracting a particular disease.²

FDA's review of the evidence to support the petitioned amendment of the oat beta-glucan health claim was conducted consistent with FDA published guidance on significant scientific agreement in the review of health claims (Ref. 5) and focused on evidence from intervention studies.

1. Assessment of Intervention Studies

This petition identified reports of 11 human clinical studies with data on barley consumption and serum lipids (Refs. 6 to 16). We excluded six of these reports from our review because no scientific conclusions relative to effects of barley beta-glucan soluble fiber on CHD risk could be drawn from them. One of these excluded reports (Ref. 6) was available only as an abstract and therefore did not provide sufficient information about the study for FDA to determine critical elements, such as the study population characteristics and the composition of the products used. In addition, the lack of a detailed study description prevents FDA from determining whether the study is flawed in critical elements such as design, conduct, and data analysis. FDA must be able to review the critical elements of a study to determine whether any scientific conclusions relevant to the health claim can be drawn from it. These problems are not limited to abstracts, but include other similar publications, such as meta-analyses³

² See *Whitaker v. Thompson*, 353 F.3d 947, 950-51 (D.C. Cir.) (upholding FDA's interpretation of what constitutes a health claim), *cert. denied*, 125 S.Ct. 310 (2004).

³ A meta-analysis is the process of systematically combining and evaluating the results of clinical trials that have been completed or terminated.

and review articles,⁴ book chapters, letters to the editor, and committee reports.

A second excluded report, Lupton et al., 1994 (Ref. 7), tested potential cholesterol-lowering effects of spent brewer's grain barley and of barley oil, neither of which contains beta-glucan soluble fiber. Because this report did not provide information about the substance that is the subject of the health claim, it was excluded from further review. Another excluded report, Keogh et al., 2003 (Ref. 8), tested potential cholesterol-lowering effects of a beta-glucan concentrate product extracted from barley bran. The whole grain barley and dry milled barley products which are the sources of beta-glucan soluble fiber in the petition do not include wet milled barley products such as the beta-glucan concentrate used in Keogh et al., 2003. Beta-glucan extraction processes (e.g., hot water or alcohol washes, and extreme pH conditions), unlike dry milling processes, are likely to alter physiochemical properties of soluble fiber and other components of grain and will alter the relative proportions of beta-glucan soluble fiber and other components of the grain. The composition of wet milled barley beta-glucan products may be substantially different from that of dry milled barley products and thus the results of Keogh et al., 2003 do not assist our evaluation of evidence supporting a health claim for dry milled barley products. The three other excluded reports (Refs. 9, 10, and 11) did not contain enough information to estimate the barley beta-glucan soluble fiber in the test diets. Without knowing the amount of barley beta-glucan soluble fiber added to these studies' diets, FDA was unable to draw any conclusions as to the effect of barley beta-glucan soluble fiber on CHD risk from this evidence. The remaining 5 of the 11 reports of human clinical studies (Refs. 12 to 16) were of a sufficient quality for us to consider in our review of the evidence supporting the relationship between reduced risk of CHD and consumption of beta-glucan soluble fiber from whole grain barley and dry milled barley products included as sources of beta-glucan soluble fiber in this petition.

The study reported in Behall et al., 2004a (Ref. 12) investigated the effects of dry milled barley products (barley flour, barley flakes, and pearled barley) incorporated into a controlled whole-grain diet on blood lipids of mildly hypercholesterolemic men. The study

⁴ Review articles summarize the findings of individual studies.

included 18 mildly hypercholesterolemic adult males (mean age 46 years; mean baseline total cholesterol 238 milligrams/deciliter (mg/dL); mean baseline LDL-cholesterol 155 mg/dL). The test diet was a Step I diet (total fat 31 percent of energy, saturated fat 7.6 percent of energy, total dietary fiber 27 grams (g)/day) that included whole grain test foods (pancakes, spice cake, no-bake cookies, hot cereal, toasted flakes, steamed pilaf, and muffins). The test personnel prepared three versions of the whole grain test diet differing in levels of dry milled barley products. One version of the test diet, made with whole wheat flour, wheat flakes, and brown rice, but no barley, contained only trace amounts of beta-glucan soluble fiber. Another version of the test diet made with barley flour, barley flakes, and pearled barley replacing the wheat and rice in test foods, provided 6 g barley soluble fiber per day. The third version of the test diet was made with half whole wheat/brown rice and half barley to provide 3 g barley soluble fiber per day. The three whole grain test diets were designed to provide approximately the same amount of total dietary fiber per day, and vary only in the amount of barley beta-glucan soluble fiber. Following a 2-week run-in period consuming the test diet without barley to allow subjects to adjust to the dietary fiber level, the study administered each the three test diets (0, 3, or 6 g per day barley soluble fiber) to each participant in random order over three consecutive 5-week periods. In comparison to the 0 g per day barley soluble fiber diet period, there was a statistically significant ($p < 0.05$) 7.5 percent reduction of serum total cholesterol following the 6 g per day barley soluble fiber diet. Similarly, there was a statistically significant 8.5 percent reduction in serum LDL-cholesterol level following the 6 g per day barley soluble fiber period compared to the 0 g per day period. Reductions in serum total and LDL-cholesterol following the 3 g per day soluble barley fiber period were not statistically significant. Serum HDL cholesterol levels were not significantly different among the three diet periods.

Another study by Behall et al., (Ref. 13) investigated the effects of dry milled barley products (barley flour, barley flakes, and pearled barley) in a controlled whole-grain diet on blood lipids of mildly hypercholesterolemic adults. The study included 25 mildly hypercholesterolemic adult men and women (average baseline total cholesterol 223 mg/dL; average baseline LDL-cholesterol 145 mg/dL). The test

diet was the same as in the previous Behall et al. study (Ref. 12), i.e., a STEP I diet including whole grain test foods and with barley ingredients substituted for whole wheat/brown rice ingredients to produce three versions of test diet providing 0 g, 3 g, or 6 g per day of barley beta-glucan, but each with approximately the same amount of total dietary fiber. As in the previous study, the 17-week experimental period consisted of a 2-week run-in period followed by three consecutive 5-week periods during which each participant was administered each of the three versions of test diet in random order. In comparison to the 0 g per day barley beta-glucan diet period, there were statistically significant ($p < 0.05$) reductions of serum total cholesterol following both the 3 g and 6 g per day barley beta-glucan diets (5 percent and 6 percent reductions, respectively). Similarly, there were statistically significant reductions of serum LDL-cholesterol following both the 3 g and 6 g per day barley beta-glucan diets compared to the 0 g per day diet (10 percent and 13 percent reductions, respectively). Serum HDL cholesterol levels were not different among the three diet periods.

The study reported in McIntosh et al., 1991 (Ref. 14) investigated the effects of dry milled barley products (barley bran and barley flakes), as compared to wheat, on blood lipids of mildly hypercholesterolemic men. The study included 21 mildly hypercholesterolemic adult males (mean age 43 years; mean baseline total cholesterol 240 mg/dL; mean baseline LDL-cholesterol 177 mg/dL). Throughout the study, participants consumed their customary diets but replaced their customary grain-based foods with similar test foods (bread, muesli, pasta, and biscuits) provided by study personnel. The test foods were made with either whole wheat flour, or with barley bran and barley flakes replacing portions of the whole wheat flour. The grain-based test foods provided about 50 percent of total caloric intake and about 65 percent of total dietary fiber intake. The whole wheat test foods and the barley test foods were equivalent in content of energy, total fat, saturated fat, total dietary fiber, and soluble dietary fiber content. The diet with whole wheat test foods provided 1.5 g beta-glucan per day, whereas the diet with barley test foods provided 8 g beta-glucan per day. Following a 3-week run-in period with the usual diets, the participants consumed the diets supplemented with either whole wheat test foods or barley

test foods in random order during two consecutive 4-week periods. In comparison to the whole wheat test food period, there were statistically significant ($p < 0.05$) reductions of serum total cholesterol (6 percent reduction) and of serum LDL-cholesterol (7 percent reduction) following the barley test food period. Serum HDL cholesterol levels were not different between the two diet periods.

The study reported in Newman et al., 1989 (Ref. 15) investigated the effects of dry milled barley (barley flour), in comparison to wheat, on blood lipids of adult men. The study included 14 adult males (age greater than 35 years; total cholesterol range 140-247 mg/dL; LDL-cholesterol range 71-187 mg/dL). During the study, the participants consumed their customary diets but with three servings per day of test foods (muffins, applesauce bars, breads, muffins, cookies, and cereal) made with either whole wheat flour and wheat bran or with barley flour replacing similar foods of the customary diet. Both the wheat and barley grain-based test foods provided about 42 g total dietary fiber per day. The barley test foods provided approximately 3 g soluble beta-glucan per day. The 4-week study was a randomized, blinded study with one half of the participants consuming the wheat flour/bran test foods for 4 weeks, and the other half receiving the barley test foods for 4 weeks. At the end of the test period, mean serum total and LDL-cholesterol levels were significantly ($p < 0.05$) lower in the barley group than in the wheat group.

The study reported in Li et al., 2003 (Ref. 16) investigated the effects of whole grain barley on blood lipids of young healthy female Japanese. The study included 10 healthy Japanese medical students (average age 20 years; average baseline total cholesterol 140 mg/dL; average baseline LDL-cholesterol 53 mg/dL). During the study, participants consumed a typical Japanese diet (approximately 2,000 kcal/day, 35 percent fat) that the investigators provided. During the barley diet period, barley replaced 30 percent of the daily rice intake. The barley provided approximately 5 g per day of soluble dietary fiber. Each participant consumed the control diet (rice only) and barley diet (70 percent rice, 30 percent barley) in random order during two 4-week periods separated by a 4-week interval. In comparison to the control diet period, there were statistically significant ($p < 0.05$) reductions of blood total cholesterol (14.5 percent reduction) and of blood LDL-cholesterol (21 percent reduction) following the barley diet period. Blood

HDL cholesterol levels were not different between the two diet periods.

In summary, the five clinical trials included in our review which tested the impact of consuming whole grain barley and dry milled barley products (bran, flakes, flour and pearled barley) on serum lipids (Refs. 12 through 16), consistently reported statistically significant lower serum total and LDL-cholesterol levels following 4 to 5 weeks of consuming diets in which whole grain barley or dry milled barley product ingredients replaced wheat and rice ingredients. Serum HDL cholesterol levels were not affected by consuming the barley foods. The lowest daily dietary intake of barley beta-glucan fiber effective in significantly lowering serum total and LDL-cholesterol reported in these studies was 3 g per day.

2. Eligible Barley Sources of Beta-Glucan Soluble Fiber

The oat beta-glucan health claim, at § 101.81(c)(2)(ii)(A), lists four eligible oat sources of beta-glucan soluble fiber; i.e., oat bran, rolled oats, whole oat flour, and oatrim. FDA is amending § 101.81(c)(2)(ii)(A) to add dehulled and hullless whole grain barley and certain dry milled barley products to this list of eligible sources of beta-glucan soluble fiber.

Below, the agency describes the eligible sources of barley beta-glucan soluble fiber from dry milled barley products and the specifications for all eligible sources.

The five clinical trials with barley cited previously used the following barley sources in their test foods: Whole grain barley, barley bran, barley flour, barley flakes, and pearled barley. Each dry milled product used in the clinical studies is processed only to the extent that milling has altered the particle size of the intact grain, and in some cases the product is also subjected to a particle size separation process (e.g., sifting). The barley sources of beta-glucan soluble fiber in this rule, i.e., dehulled or hullless whole grain barley, barley bran, flakes, grits, pearl, flour, meal, and sieved barley meal, are produced from dry milling processes only. Wet milling, as opposed to dry milling, involves slurring the grain under pH, temperature, chemical, or enzyme conditions that cause changes other than just particle size. The one barley clinical trial that was excluded from our review because the product tested was a wet milled barley beta-glucan extract (Ref. 8) reported finding no effect of the barley beta-glucan extract on serum lipids.

There are many variations in dry milling processes for barley, most of the

resulting dry milled barley products are defined in the AACC "Barley Glossary" (Ref. 2), including barley bran, flakes, grits, pearl, and flour. The petition describes two additional dry milled barley products: Barley meal and sieved barley meal. Barley meal is unsifted, ground, whole grain barley. The petition described sieved barley meal as endosperm cell wall-enriched fractions of barley meal or barley flour resulting from including a particle size separation step (either sieving or air classification) in the dry milling process. Although the petitioner's term for this barley product was "beta-glucan enriched barley fractions," we are using the term "sieved barley meal" in this rulemaking as that is descriptive of the how this dry milled barley product is produced and to clarify that a barley "beta-glucan enriched" product produced by any other process is not included as an eligible source of barley beta-glucan soluble fiber.

The petition requests that the eligible barley sources of beta-glucan soluble fiber added to § 101.81 include, in addition to the whole grain barley and dry milled barley products used in the clinical studies FDA included in its review (i.e., barley bran, flakes, flour, and pearl barley), three dry milled barley products that were not used in the reviewed clinical studies (i.e., barley grits, meal, and sieved barley meal). FDA agrees with the petitioner that the additional barley products represent variations of the extent of dry milling and as such involve more textural difference and not compositional differences that would result in an outcome that is different from that in clinical trials. FDA is amending § 101.81(c)(2)(ii)(A) to add as eligible barley sources of beta-glucan soluble fiber, whole grain barley, barley bran, barley flakes, barley grits, barley flour, barley meal, sieved barley meal, and pearl barley. The petition has specified the minimum beta-glucan soluble fiber content of eligible dry milled barley products, with the exception of sieved barley meal and barley bran, to be at least 4 percent (dwb), and the minimum total dietary fiber content to be at least 8 percent (dwb). The minimum beta-glucan soluble fiber and total fiber content specified in the petition for eligible barley bran and sieved barley meal is at least 5.5 percent (dwb) and 15 percent (dwb), respectively. The minimum beta-glucan soluble fiber and total fiber content specified in the petition for eligible whole grain barley is at least 4 percent (dwb) and 10 percent (dwb), respectively. The petition states that these dietary fiber

content specifications were selected based on typical analyses of commercially available dry milled barley products in the United States. FDA is adopting the dietary fiber content specifications recommended by the petitioner that must be met in order for the listed sources of beta-glucan soluble fiber to be considered eligible sources.

IV. Decision to Amend the Health Claim

Evidence from five clinical trials (Refs. 12 through 16) consistently demonstrate that consuming whole grain barley and dry milled barley products, such as barley bran, flakes, flour and pearled barley that provide at least 3 g beta-glucan fiber per day, is effective in lowering serum total and LDL-cholesterol levels, which in turn may reduce the risk of CHD. The cholesterol-lowering effects of beta-glucan soluble fiber in dry milled barley products is comparable to that of the oat sources of beta-glucan now listed in § 101.81(c)(2)(ii)(A). When issuing the oat beta-glucan health claim the agency concluded that the beta-glucan soluble fiber component of oat products plays a significant role in the relationship between whole grain oats and the risk of CHD based, in part, on evidence that there is a dose response between the level of beta-glucan soluble fiber from whole oats and the level of reduction in serum LDL cholesterol, and evidence that intakes at or above 3 g per day were more effective in lowering serum lipids than lower intake levels (62 FR 3584 at 3585). The petition notes that a comparison of the serum cholesterol lowering evidence for barley beta-glucan soluble fiber, which has been submitted with the petition, and the oat beta-glucan soluble fiber/cholesterol-lowering dose-response evidence, which was cited in the oat beta-glucan health claim rulemaking, shows that the cholesterol lowering efficacy of the oat and the barley sources of beta-glucan soluble fiber are very similar. FDA agrees that the effect, on serum cholesterol, of consuming whole grain oat and dry milled barley sources of beta-glucan soluble fiber appears equivalent. FDA also agrees that the scientific evidence supports a minimum daily effective intake of beta-glucan soluble fiber from dry milled barley products the same as that which was previously found for beta-glucan soluble fiber from whole oat sources, i.e., 3 g per day. Therefore, FDA is amending § 101.81(c)(2)(i)(G)(1) to include 3 g or more per day of barley sources of beta-glucan soluble fiber, alone or in combination with whole oat sources of such fiber.

Barley beta-glucan can be measured by the same quantitative analytical method as is currently specified in § 101.81 for the determination of oat beta-glucan. Based on the totality of the publicly available scientific evidence, FDA concludes there is significant scientific agreement, among experts qualified by scientific training and experience, for a claim about the relationship between certain beta-glucan soluble fiber sources and reduced risk of CHD. Thus, we are amending § 101.81(c)(2)(ii)(A) to include dehulled or hullless whole grain barley and certain dry milled barley products as additional sources of beta-glucan soluble fiber. We also find that the serum cholesterol-lowering efficacy of barley beta-glucan soluble fiber and of oat beta-glucan are comparable and, like oat beta-glucan, 3 g per day of barley beta-glucan is a sufficient daily dietary intake to achieve a reduction in serum total and LDL cholesterol.

The barley products that are to be included in this amendment as eligible sources of beta-glucan soluble fiber include dehulled and hullless whole grain barley, and certain dry milled barley products including barley bran, barley flakes, barley flour, barley grits, and pearl barley as they are defined in the AACC Barley Glossary (Ref. 2), barley meal which is an unsifted ground barley grain, and sieved barley meal which is an endosperm cell-wall enriched fraction resulting from sieving or air classification of barley flour or barley meal to separate fractions based on particle size. The sieved barley meal fraction retains the coarser particles that originate from endosperm cell wall. Minimum dietary fiber content specifications for these barley products, recommended in the petition as representative of commercially available barley products in the United States are a minimum of 4 percent beta-glucan soluble fiber and 10 percent total dietary fiber for dehulled and hullless whole grain barley; a minimum of 5.5 percent beta-glucan soluble fiber and 15 percent total dietary fiber for barley bran and sieved barley meal; and a minimum of 4 percent beta-glucan soluble fiber and 8 percent total dietary fiber for all other dry milled barley products. All dietary fiber values are on a dwb.

The oat beta-glucan health claim requires that a food bearing the claim on its label include one of the whole grain ingredients listed within § 101.81(c)(2)(ii)(A), and that the whole oat ingredient provide at least 0.75 gram of beta-glucan soluble fiber per reference amount customarily consumed of the food product (§ 101.81(c)(2)(iii)(A)). FDA arrived at

this value based on a standard assumption that the daily dietary intake is divided over four eating occasions (three meals and a snack). FDA concluded that in adding whole oat flour to the eligible whole oat sources of beta-glucan soluble fiber that were included in the final rule there would be sufficient numbers and types of whole oat-containing food products available to increase the likelihood that whole oat food products will be consumed at four eating occasions per day (62 FR 3584 at 3592). Adding whole grain barley and dry milled barley products as additional eligible sources of beta-glucan soluble fiber will further increase the type and number of qualifying food products and make it easier for consumers to select whole grain barley, dry milled barley or whole oat containing food products at four eating occasions per day. Thus, FDA is retaining under the "Nature of the food eligible to bear the claim" section of this regulation the criterion that foods eligible to bear the claim contain at least 0.75 gram of soluble fiber (§ 101.81(c)(2)(iii)(A)(1)).

FDA authorized use of the oat beta-glucan health claim in 1997, in part, on the basis of clinical evidence demonstrating that consumption of whole oat foods such as oat bran, oatmeal, and whole oat flour lowers serum cholesterol. FDA also considered scientific evidence for a dose-response between the amount of beta-glucan consumed and the cholesterol-lowering effect (Ref. 17), and evidence that at least 3 grams of soluble fiber consumed per day in whole oat foods is sufficient for effective cholesterol lowering (Ref. 18). Information provided in the oat beta-glucan health claim petition indicated that the soluble fiber content of whole oats is predominantly beta-glucan. Therefore, FDA concluded that the total soluble fiber content of whole oats significantly reflects the beta-glucan present in whole oats (62 FR 3584 at 3588).

Although FDA had concluded that oat beta-glucan soluble fiber plays a significant role in the relationship between whole grain oats and reduced risk of CHD (62 FR 3584 at 3585), FDA had considered the term "beta-glucan" a technical term that presumably would not be widely understood, and that the term "soluble fiber" is more familiar to consumers because soluble fiber can be used on the nutrition label under 21 CFR 101.9(c)(6)(i)(A). As such, this health claim statement must identify the substance using the term "soluble fiber" (62 FR 3584 at 3588).

The standard method for measurement of beta-glucan in oat and

barley (AOAC Official Method 992.28) measures total beta-glucan content of the grain product without differentiating soluble and insoluble fractions. There is no standard method, nor a single definition for, soluble beta-glucan. Typically a grain product is analyzed for either soluble fiber or for total beta-glucan. Information in the original oat beta-glucan health claim petition convinced FDA that the total soluble fiber content of whole oats significantly reflects the beta-glucan content (62 FR 3584 at 3588). Information and data provided in the current petition demonstrate that the solubility of beta-glucan in oats and barley are similar and that the test for total beta-glucan is an adequate marker for the cholesterol-lowering functionality of whole oat, whole grain barley, and dry milled barley in foods. Therefore, FDA is requiring that the barley beta-glucan health claim identify the substance with the term "soluble fiber," although the substance is to be measured as total beta-glucan.

There is strong and consistent scientific evidence that diets high in saturated fat and cholesterol are associated with elevated serum total and LDL cholesterol, and that elevated serum cholesterol levels are a major modifiable risk factor for CHD. Expert groups recommend lowering dietary saturated fat and cholesterol as a primary lifestyle change for reducing heart disease risk (Ref. 4). Comments to the 1997 oat beta-glucan health claim final rule expressed concern that a CHD risk claim that does not include a reference to a low saturated fat, low cholesterol diet may mislead consumers into thinking that the single food, e.g., oat products, would appear to be a "magic bullet" (62 FR 3584 at 3594). Further, based on the scientific evidence, the role of soluble fiber from whole oats in the diet is generally recognized as being of smaller magnitude in reducing CHD risk compared to consumption of a low saturated fat, low cholesterol diet. When authorizing the oat beta-glucan health claim FDA concluded that although selection of foods with soluble fiber from whole oats is a useful adjunct to selection of diets low in saturated fat and cholesterol in reducing CHD risk, it would not be in the best interest of public health nor consistent with the scientific evidence to imply that selecting diets with soluble fiber from whole oats is a substitute for consuming diets low in saturated fat and cholesterol (id.). Therefore, FDA required that the oat beta-glucan health claim statement include the phrase

"diets that are low in saturated fat and cholesterol and that include soluble fiber from * * *" (§ 101.81(c)(2)(i)(A)).

Barley beta-glucan soluble fiber functions comparably to oat beta-glucan soluble fiber in its effect on reducing LDL and total cholesterol. Barley beta-glucan soluble fiber sources are a useful adjunct to selection of diets low in saturated fat and cholesterol to reduce CHD risk. Thus, the agency is requiring the barley beta-glucan health claim to include the information that selection of barley foods containing beta-glucan soluble fiber should "be part of a diet low in saturated fat and cholesterol," consistent with § 101.81(c)(2)(i)(A). Including a reference to a low saturated fat, low cholesterol diet in the health claim will enable the public to understand the relative significance of the information in the context of a total daily diet (21 U.S.C. 343(r)(3)(A)(iii)).

V. Description of Modifications to § 101.81

A. Requirements of the Health Claim

Specific requirements of the "nature of the claim" paragraph in § 101.81(c)(2)(i) of the soluble fiber from certain foods and risk of CHD health claim include, in part, that the claim specify the daily dietary intake of the soluble fiber source associated with coronary heart disease risk reduction. FDA is amending § 101.81(c)(2)(i)(G)(1) to indicate that the source of the 3 g or more per day of beta-glucan soluble fiber may be from whole oats or barley or a combination of oats and barley. FDA is amending § 101.81(c)(2)(ii)(A) to add barley sources of beta-glucan soluble fiber in addition to whole oat sources. In addition, FDA is amending § 101.81(c)(2)(ii)(A) by adding § 101.81(c)(2)(ii)(A)(5) to list dehulled and hullless whole grain barley and specific dry milled barley products as eligible sources of beta-glucan soluble fiber. The specific dry milled barley products include, barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal produced from clean, sound dehulled or hullless barley grain using standard dry milling techniques, which may include steaming or tempering. Eligible dehulled and hullless whole grain barley has a beta-glucan soluble fiber content of at least 4 percent (dwb) and a total dietary fiber content of at least 10 percent (dwb). Eligible barley flakes, barley grits, pearl barley, barley flour, and barley meal have a beta-glucan soluble fiber content of at least 4 percent (dwb) and total dietary fiber content of at least 8 percent (dwb). Eligible barley bran and sieved barley

meal have a beta-glucan soluble fiber content of at least 5.5 percent (dwb) and total dietary fiber content of at least 15 percent (dwb). FDA is incorporating by reference in new § 101.81(c)(2)(ii)(A)(5) the Barley Glossary (AACCC Method 55–99), published in Approved Methods of the American Association of Cereal Chemists, that contains definitions for barley bran, barley flakes, barley flour, barley grits, pearl barley, dehulled barley, and hullless barley. FDA is amending the “nature of the food eligible to bear the claim” paragraph at § 101.81(c)(2)(iii)(A)(1) to indicate that the eligible sources of beta-glucan fiber will include both whole oat and barley foods.

B. Optional Information

FDA is amending the “optional information” paragraph of this section (at § 101.81(d)(5)) to indicate that the eligible sources of beta-glucan fiber will include both whole oat and barley foods.

VII. Issuance of an Interim Final Rule and Immediate Effective Date

We are issuing this rule as an interim final rule, effective immediately, with an opportunity for public comment. Section 403(r)(7) of the act authorizes us to make proposed regulations issued under section 403(r) of the act effective upon publication pending consideration of public comment and publication of a final regulation, if the agency determines that such action is necessary for public health reasons. This authority enables us to act promptly on petitions that provide for information that will help: (1) Enable consumers to develop and maintain healthy dietary practices, (2) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food, or (3) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible. Proposed regulations made effective upon publication under this authority are deemed to be final agency action for purposes of judicial review. The legislative history indicates that such regulations should be issued as interim final rules (H. Conf. Rept. No. 105–399, at 98 (1997)).

We are satisfied that each of the three criteria in section 403(r)(7)(A) of the act have been met in the petition submitted by the National Barley Foods Council. This health claim will enable consumers to develop and maintain healthy dietary practices, such as increasing consumption of foods containing types of soluble dietary fiber shown to help reduce CHD risk. The health claim also

will provide consumers with important new knowledge regarding the effects of consuming whole grain barley and dry milled barley products on blood cholesterol, and will provide consumers with scientifically sound information about an additional dietary choice which may help reduce the risk of CHD. Therefore, we are using the authority given to us in section 403(r)(7)(A) of the act to issue an interim final rule authorizing a health claim relating consumption of barley beta-glucan soluble fiber and CHD risk, effectively immediately.

FDA invites public comment on this interim final rule. The agency will consider modifications to this interim final rule based on comments made during the comment period. Interested persons may submit to Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this interim final rule. This regulation is effective upon publication in the **Federal Register**. The agency will address comments and confirm or amend the interim final rule in a final rule.

VIII. Analysis of Impacts

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

A. Regulatory Impact Analysis

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

1. Need for Regulation

Current labeling regulations do not permit foods containing threshold amounts of beta-glucan soluble fiber from the whole grain barley or dry milled barley to claim health benefits that link their intake with a reduction in

the risk of CHD. Such claims are authorized for foods containing threshold amounts of beta-glucan soluble fiber-containing whole oat foods, and scientific evidence links consumption of foods with the same amount of beta-glucan soluble fiber from barley with the same health benefits. Allowing foods containing beta-glucan soluble fiber from barley to claim the same health benefits as those containing beta-glucan soluble fiber from whole oats will improve diet-related information available on food labels. Making this information available to consumers may facilitate disease risk-reducing dietary choices.

2. Regulatory Options

The regulatory options include: (1) No regulatory action and (2) the interim final rule.

3. Benefits and Costs From No Regulatory Action

The absence of any regulatory action is considered the baseline option for comparison with the regulatory option. There would be no compliance costs and no benefits in the absence of regulatory action.

4. Benefits and Costs From the Interim Final Rule

a. *Benefits from the interim final rule*—The benefit from the interim final rule is the reduced CHD risk that may result from consumers’ substituting barley foods containing beta-glucan soluble fiber for currently consumed, less healthful alternatives. Heart disease is the leading cause of death and permanent disability in the United States (Ref. 19). The National Center for Health Statistics in the Centers for Disease Control and Prevention (CDC) reports that in 2002 there were approximately 23 million non-institutionalized adults diagnosed with heart disease, resulting in approximately 700,000 deaths. According to the same source, heart disease patients made approximately 20.8 million office-based physician visits and approximately 1.1 million hospital outpatient visits in that year. In addition, there were approximately 4.4 million hospital discharges of heart disease patients, with average lengths of stay of approximately 4.4 days. As an indication of the extent to which this disease is disabling, the CDC reports that approximately 66 percent of heart patients fail to fully recover (Ref. 20). *Overview of Benefits Analysis*

This interim final rule may result in a reduction in the risk of heart disease by enabling at-risk consumers to make healthier food choices. We first describe

the theoretical framework for estimating the increase in the market shares and healthful consumption as a result of this interim final rule. We use results from FDA's 2001 Food Label and Packaging Survey (FLAPS) to compute the total sales of products with health claims from soluble fiber from whole oats to estimate a potential market share of foods containing beta-glucan soluble fiber from barley (Ref. 21). We describe the FLAPS data set, and use the estimated market share of foods claiming health benefits from beta-glucan soluble fiber from barley as the upper bound for the increase in healthful consumption from this interim final rule. We account for existing consumption of foods that are equally as healthful as the new foods containing beta-glucan soluble fiber from barley to adjust the upper bound in order to estimate the increase in healthful food consumption. We then suggest a link between any estimated increase in healthful food consumption and a reduction in the incidence of CHD. Finally, we suggest further adjustments to any estimated reductions in health risks from more healthful food consumption based on an assumed uneven distribution of diet-related health risks across the population.

Theoretical Framework

We assume that prices, taste, and health attributes determine consumer demand for food products within a food group, and that an increase in the consumer demand for an item within a food group results in an offsetting decrease in demand for other items within that group. In addition, we assume that an increase in the consumption of healthful products in the aggregate may result if there is a decrease in the relative price of healthful products compared with products in general. However, a decrease in the relative price of one healthful product may also result in a decrease in the demand for other healthful products.

We assume that the total sales of products within a general product group remain constant, so any increase in consumption of healthful products as a result of this interim final rule would be offset by a decrease in consumption of other products within the same product group; these other products may be more, less, or equally healthful. To the extent that aggregate consumption of products from an entire product group increases, aggregate consumption of products from other groups will decrease. In this analysis, however, we do not consider the effects of changes in aggregate consumption of product

groups that do not contain products with health claims.

Using FLAPS to Estimate the Market Share of Foods Claiming Health Benefits From Soluble Fiber From Whole Oats

We use results from FDA's 2001 FLAPS to estimate the increase in market shares of foods containing beta-glucan soluble fiber from barley (Ref. 21). The 2001 FLAPS survey contains label information on 1,281 products selected from 238 food types from 57 food groups. The information includes detailed descriptions of the labels including any health claims, structure-and-function claims, and nutrient content claims. We combine the label information with total sales information obtained from the Information Resources Incorporated (IRI) data used to design the sampling methodology for the FLAPS survey to estimate that products with health claims that link fiber from whole oats to reduced risk from CHD account for approximately 0.6 percent of all product sales. Moreover, products with these health claims are concentrated in the hot and cold cereals product groups: 5.1 percent of sales of cold cereals and 75.5 percent of sales of hot cereals claim these health benefits.

We acknowledge the potential sampling bias in the FLAPS survey, which selects brand name products with the largest sales within a product group. This sampling method likely overestimates the prevalence of health claims on labels (because large brand names may be more likely to make claims than their smaller, less-known competitors). However, FLAPS sampled these products because they represent an overwhelming share of total sales within their product groups. Consequently, the effect of the overestimation bias on the estimated consumption (and resulting health benefits) of healthier products may be small.

We characterize the uncertainty in the FLAPS estimates by assuming that the true percentages of sales of cold and hot and cereal products that currently make fiber from oats health claims are distributed lognormally with means of 75.5 percent and 5.1 percent (i.e., the estimates reported from the FLAPS data), both with variances of 10 percent relative to their means. The lognormal distribution is appropriate to use since it incorporates the idea that the true market shares of cold and hot cereal products that currently make health claims about fiber from oats is not too different from the mean estimate computed using FLAPS as would be implied by the use of a normal distribution. The parameters that describe the lognormal distribution are

the natural logarithms of the mean and variance of a normal distribution.

The Potential Market Shares of Foods Claiming Health Benefits From Soluble Fiber From Barley

Manufacturers may formulate new products to use barley as a principal ingredient if the ability to claim health benefits makes this option profitable. In addition, we assume current products with threshold amounts of beta-glucan soluble fiber from barley would be able to make the health claim if they incur the cost of changing labels. We do not know how many current products would use the health claim, and we do not know how many new products would be formulated to use the claim. We assume that the current market shares of products that claim health benefits from soluble fiber from oats can be used to estimate of the potential market share for products likely to claim health benefits from soluble fiber from barley.

We first assume that the potential market share from newly formulated cold cereals and hot cereals that claim health benefits from soluble fiber from barley would result from sales that would have otherwise been for less-healthful alternatives. We also assume that the potential market shares of newly formulated hot cereals and cold cereals claiming health benefits from soluble fiber from barley would be no larger than those for hot cereals and cold cereals currently claiming health benefits from soluble fiber from oats. Consequently, we estimate that the potential market share of hot cereals that claim health benefits from soluble fiber from barley would be 24.5 percent of the market for all hot cereals, and that the potential market share of cold cereals that claim benefits from soluble fiber from barley would be 5.1 percent of the market for all cold cereals.

The Increase in Healthful Consumption

The increases in market shares of more healthful food products may be less than that reflected in the potential market shares estimated previously if consumers of newly formulated and labeled hot and cold cereals claiming health benefits from soluble fiber from barley would have otherwise selected hot and cold cereals currently claiming health benefits from soluble fiber from oats. Increases in market shares of healthful food products may also be less than those reflected by the potential market shares estimated previously if consumers of newly formulated and labeled hot and cold cereals claiming health benefits from soluble fiber from barley would have otherwise selected existing hot and cold cereals that contain the threshold level of beta-

glucan soluble fiber from barley but are currently not allowed to make a health claim. We assume that half of the estimated potential market shares of newly formulated and labeled hot and cold cereals claiming health benefits from soluble fiber from barley would reflect purchases by consumers who otherwise would have selected hot and cold cereals currently claiming health benefits from soluble fiber from oats. We further assume that half of the remaining sales of newly formulated and labeled barley products would reflect purchases of existing products that contain the threshold level of beta-glucan soluble fiber from barley but are not currently allowed to make a health claim. Consequently, we estimate that one-quarter (i.e., one-half times one-half) of the potential market shares of newly formulated barley products would reflect purchases by consumers who otherwise would have selected less-healthy hot and cold cereal alternatives, or 1.3 percent of the cold cereal market (i.e., 0.25 times 5.1 percent), and 6.1 percent of the hot cereal market (i.e., 0.25 times 24.5 percent) would reflect increases in healthy food purchases as a result of this interim final rule.

To characterize the uncertainty in our methods, we assume that the estimates of the percent increases in market shares of healthy hot and cold cereal products due to this interim final rule are uniformly distributed with minimums equal to one-half of the previously estimated increases in healthy sales, and maximums of one and one-half times the previously estimated increases in healthy sales. Consequently, we estimate a range of between 0.5 to 2 percent with a mean of 1 percent (rounded to the nearest half-percent) increase in market share of more healthy cold cereal products, and between 3 and 9 percent with a mean of 6 percent (rounded to the nearest half-percent) increase in the market share of more healthy hot cereal products as a result of this interim final rule. We assume that increases in market shares of more healthy food products containing threshold levels of beta-glucan soluble fiber from barley would reflect more healthy food consumption which may decrease the risk of diet-related disease, including CHD.

The increase in healthy consumption by those consumers not at risk for diet-related diseases, including CHD, may mitigate the health benefits from the estimated increase in healthy consumption. As suggested earlier, healthy characteristics are just one of several considerations, including taste

and price, consumers use when making food purchases. Consumers who choose newly formulated barley products over less healthy alternatives may include both those at risk of these diseases as well as those who are not at risk. We assume that those who are at risk of CHD will contribute to half of the increase in the healthy consumption of hot and cold cereal products.

Consequently, we estimate an increase in healthy consumption of cold cereals by consumers who are at risk for CHD to be between 0.25 and 1 percent, with a mean of 0.5 percent of that market, and an increase in healthy consumption of hot cereals by consumers who are at risk for CHD to be between 1.5 and 4.5 percent with a mean of 3 percent of that market due to this interim final rule.

Finally, the incremental expansion of the health claim for foods that contain psyllium seed husk and beta-glucan soluble fiber from oats to include beta-glucan soluble fiber from barley raises the possibility that soluble fiber from other grains may also result in the same health benefits. In this analysis we have assumed that hot and cold cereal products that currently do not claim health benefits from soluble fiber from oats are less healthy than those that do make that claim. To the extent that hot and cold cereals contain threshold quantities of soluble fiber from other grains that reduce the risk for CHD, in addition to barley, yet are not permitted to make health claims, the changes in healthy consumption estimated for this interim final rule may be overstated. In the extreme case, if all current hot and cold cereal products were manufactured with grains having identical health benefits as those from beta-glucan soluble fiber from oats and barley, then the health benefits from allowing soluble fiber from barley to claim health benefits estimated for the interim final rule would be zero, because consumers would switch among equally healthy alternatives.

b. *Costs*—The costs incurred by manufacturers of foods that are newly developed or relabeled to claim health benefits from soluble fiber from barley would be voluntarily incurred. No manufacturer would incur these costs if it were not profitable to do so and, consequently they are not considered mandatory compliance costs.

Nevertheless, we do anticipate a voluntarily incurred allocation of resources devoted to re-labeling and new product development as a result of this interim final rule, and that the magnitude of this resource allocation is important for characterizing the broader economic impact on society. We refer to

these voluntarily incurred costs as change-over costs.

Although the mandatory compliance costs of this interim final rule are zero, the voluntarily incurred change-over costs that would result include costs of re-labeling products that contain threshold levels of beta-glucan soluble fiber from barley but are currently not allowed to claim health benefits, as well as the costs for developing products specifically to make the soluble fiber from barley health claim. The new product development change-over costs include the costs of idea generation, laboratory testing of new recipes that meet the threshold levels of beta-glucan soluble fiber from barley, process testing, shelf life studies, production related market research, production testing in increasingly large batch sizes, and consumer testing and marketing evaluations. At any stage in the development process a product may be dropped from consideration. Products that undergo a portion of the process but that are eventually dropped from consideration also constitute a new product development cost. Re-labeling change-over costs for products that contain threshold amounts of beta-glucan soluble fiber from barley but are currently not allowed to claim health benefits, include the costs of testing food products to verify that the levels of beta-glucan soluble fiber are consistent with that required for the health claim, the fixed and variable printing costs for the new label, and the storage costs associated with disposing old labels.

We use the FDA Reformulation Cost Model (Ref. 22) and the FDA Labeling Cost Model (Ref. 23) to estimate the new product development and labeling change-over costs from making health claims for beta-glucan soluble fiber from barley. Data on industry categories that are available to use in these models include from the North American Industry Classification System (NAICS) code 311230, Breakfast Cereals Manufacturing which includes both hot and cold cereals. Based on the earlier results, we estimate that the potential market shares for breakfast cereals that claim health benefits from soluble fiber from barley would be 24.5 percent of the market for all hot cereals, and 5.1 percent of the market for all cold cereals.

In order to separate the broad NAICS category into hot and cold cereals, we use estimates obtained from the FLAPS and IRI data sets indicating cold cereal sales of approximately \$6.5 billion, and hot cereals sales of approximately \$0.6 billion (Ref. 21). Consequently, the hot cereal market is approximately 8 percent (i.e., $100 \times \$0.6 \text{ billion} / \7.1

billion) of the size of the breakfast cereals market, and the cold cereal market is approximately 92 percent (i.e., 100 x \$6.5 billion / \$7.1 billion) of the breakfast cereals market. In addition, we estimate that approximately 5 percent (i.e., 5.1 percent x 92 percent rounded to the nearest percent) of the sales from NAICS 311230 reflects the market share of cold cereals that would claim health benefits from barley, and that 2 percent (i.e., 24.5 percent x 8 percent rounded to the nearest percent) of the sales from NAICS 311230 reflects that market share of hot cereals that would claim health benefits from barley. Consequently, we estimate that 7 percent of NAICS 311230 (i.e., 5 percent plus 2 percent) would either develop new products or re-label existing products in order to claim health benefits from beta-glucan soluble fiber from barley.

Based on the earlier discussion, we expect that one-half of all hot and cold cereals that would claim health benefits from soluble fiber from barley would be newly developed products (i.e., 3.5 percent of NAICS 311230), while one-half would be re-labeled existing products (i.e., 3.5 percent of NAICS 311230) that currently meet the soluble fiber from barley content requirements for making a health claim. To incorporate uncertainty surrounding our methodology, we estimate a uniform distribution between 2 and 5 percent of NAICS 311230 would re-label and between 2 and 5 percent of NAICS 311230 would be from new products developed in order to claim health benefits from soluble fiber from barley.

We ran the Reformulation Cost Model for the case when major production process changes are necessary to

approximate the change-over costs for new product development. These costs were estimated assuming a 12-month voluntary compliance period. We assume that product lines would become discontinued as a result of this interim final rule due to insufficient consumer demand, reflecting the assumption that growth in total breakfast cereal consumption will not change. However, we do not estimate the costs of discontinued product lines. High, low and medium estimates are generated from the model based on experts opinions, and are reported in table 1 for assumed market shares of 2 percent 3.5 percent, and 5 percent of the sales of breakfast cereals from new products developed to claim health benefits from soluble fiber from barley.

TABLE 1.

Assumed Market Share	Voluntarily Incurred New Product Development Change-Over Costs		
	Low	Medium	high
Low market share	\$8,128,000	\$16,768,000	\$33,813,000
3.5 percent market share	\$14,224,000	\$29,343,000	\$59,172,000
High market share	\$20,320,000	\$41,919,000	\$84,532,000

We ran the Labeling Cost Model assuming a 12-month voluntary compliance period to estimate the change-over costs for re-labeling existing products that meet the soluble

fiber from barley requirements but are currently unable to claim health benefits. High, low and medium estimates of the change-over costs are generated from the model based on

experts opinions, and are reported in table 2 for assumed market shares of 2 percent 3.5 percent, and 5 percent of the sales of breakfast cereals from re-labeled products.

TABLE 2.

Assumed Market Share	Voluntarily Incurred Re-labeling Changeover Costs		
	Low	Medium	High
Low market share	\$200,000	\$287,000	\$479,000
3.5 percent market share	\$353,000	\$502,000	\$837,000
High market share	\$504,000	\$717,000	\$1,198,000

In table 3 we report the annualized voluntarily incurred change-over costs for the interim final rule computed assuming discount rates of 3 percent and 7 percent over a 10-year horizon. All costs are assumed to be incurred in the beginning of the second year following promulgation of the interim final rule and there would be no recurring annual change-over costs after

the second year. The low, medium, and high estimates for the voluntarily incurred re-labeling and new product development change-over costs were added together, and the appropriate discount rate applied. This total cost was then divided by 10 to get the annualized costs. Because producers choose the time period for the development and re-labeling of new

products, the actual time periods for the changes can be different from the assumed 12 months assumed in the models and reported in the tables. We expect that the time periods chosen would be shorter and the voluntarily incurred costs higher, the greater the perceived consumer response to the health claims from soluble fiber from barley.

TABLE 3.

Discount Rate	Annualized Voluntarily Incurred Change-Over Costs for Interim Final Rule		
	Low	Medium	High
7 percent	\$1,932,000	\$3,965,000	\$7,979,000
3 percent	\$2,007,000	\$4,119,000	\$8,288,000

B. Regulatory Flexibility Analysis

FDA has examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Small businesses will incur costs only if they choose to take advantage of the marketing opportunity presented by this rule. No small entity, however, will choose to bear the cost of adding the health claim to its product labels unless it believes that the health claim will lead to increased sales of its product sufficient to justify the costs. No small business would be required to incur costs. FDA certifies that this interim final rule would not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current inflation-adjusted statutory threshold is about \$115 million. FDA has determined that this interim final rule would not constitute a significant rule under the Unfunded Mandates Reform Act.

IX. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act

FDA concludes that the labeling provisions of this interim final rule are not subject to review by the Office of Management and Budget because they

do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claim on the association between consumption of barley beta-glucan soluble fiber and CHD risk is a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.” (see 5 CFR 1320.3(c)(2)).

XI. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the states or on the relationship between the National Government and the States, or on the distribution of power and responsibility among the various levels of government. Accordingly, we have concluded that the interim final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

XII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9:00 a.m. and 4:00 p.m., Monday through Friday.

XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Barley Foods Council, “Petition for Health Claim—Barley Beta-Glucan Soluble Fiber and Barley Foods Containing

Beta-Glucan Soluble Fiber and Coronary Heart Disease,” (Docket 2004P–0512, CP1), August 2, 2004.

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5. “Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements,” Rockville, MD: U.S. Food and Drug Administration (<http://www.cfsan.fda.gov/~dms/ssaguide.html>), December 1999.

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Hypercholesterolemic Men," *Journal of the American College of Nutrition*, 23:55-62, 2004.

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21. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, "Food Label and Package Survey 2000-2001," (<http://www.cfsan.fda.gov/~dms/lab-flap.html>), August 2004.

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23. RTI International, "FDA Labeling Cost Model, Final Report," prepared for Amber Jessup, DHHS/PHS/FDA/CFSAN, prepared by Muth, M., E. Gledhill, and S. Karns, RTI Project Number 06673.010, January 2003.

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.81 is amended by revising paragraphs (c)(2)(i)(G)(1), (c)(2)(ii)(A) introductory text, (c)(2)(iii)(A)(1) and (d)(5), and by adding new paragraph (c)(2)(ii)(A)(5) to read as follows:

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

* * * * *

(c) * * *

(2) * * *

(i) * * *

(G) * * *

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

* * * * *

(ii) * * *

(A) Beta (β) glucan soluble fiber from the whole oat and barley sources listed below. β -glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the AOAC INTERNATIONAL," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html;

* * * * *

(5) *Whole grain barley and dry milled barley.* Dehulled and hull-less whole grain barley with a β -glucan soluble fiber content of at least 4 percent (dwb) and a total dietary fiber content of at least 10 percent (dwb). Dry milled barley grain products include barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal that are produced from clean, sound dehulled or hull-less barley grain using standard dry milling techniques, which may include steaming or tempering, and that contain at least 4 percent (dwb) of β -glucan

soluble fiber and at least 8 percent (dwb) of total dietary fiber, except barley bran and sieved barley meal for which the minimum β -glucan soluble fiber content is 5.5 percent (dwb) and minimum total dietary fiber content is 15 percent (dwb). Dehulled barley, hull-less barley, barley bran, barley flakes, barley grits, pearl barley, and barley flour are as defined in the Barley Glossary (AACC Method 55-99), published in *Approved Methods of the American Association of Cereal Chemists*, 10th ed. (2000), pp. 1 and 2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Association of Cereal Chemists, Inc., 3340 Pilot Knob Rd., St. Paul, Minnesota, 55121, or may be examined at the Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Barley meal is unsifted, ground barley grain not subjected to any processing to separate the bran, germ, and endosperm. Sieved barley meal is an endosperm cell wall-enriched fraction of ground barley separated from meal by sieving or by air classification.

* * * * *

(iii) * * *

(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

* * * * *

(d) * * *

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats or barley is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

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Dated: December 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-24387 Filed 12-22-05; 8:45 am]

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