Issued in Washington, DC on Febuary 8, 2008.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

Effective Upon Publication

FDC date	State	City	Airport	FDC No.	Subject
01/31/08 ...	VA	DUBLIN	NEW RIVER VALLEY	8/3193	ILS RWY 6, AMDT 4
02/01/08 ...	NE	OMAHA	EPPLEY AIRFIELD	8/3311	ILS OR LOC RWY 32L, AMDT 1
02/01/08 ...	OH	DAYTON	DAYTON INTL	8/3324	ILS OR LOC RWY 24R, AMDT 7
02/06/08 ...	ME	MILLINOCKET	MILLINOCKET MUNI	8/3814	LOC RWY 29, ORIG-B
02/06/08 ...	ME	MILLINOCKET	MILLINOCKET MUNI	8/3815	VOR OR GPS-A, AMDT 10A
02/06/08 ...	ME	MILLINOCKET	MILLINOCKET MUNI	8/3816	NDB OR GPS RWY 29, AMDT 3A
02/05/08 ...	CO	DENVER	DENVER INTL	8/3609	ILS RWY 25, AMDT 2
02/01/08 ...	IL	CHICAGO	CHICAGO O'HARE INTL	8/3306	ILS OR LOC RWY 9R, AMDT 8
02/05/08 ...	IL	CHICAGO	CHICAGO O'HARE INTL	8/3591	ILS OR LOC RWY 4R, AMDT 6G
02/04/08 ...	FL	ORLANDO	EXECUTIVE	8/3524	VOR/DME RWY 25, AMDT 2A
02/04/08 ...	FL	ORLANDO	EXECUTIVE	8/3525	RNAV (GPS) RWY 25, ORIG-A
02/04/08 ...	FL	ORLANDO	EXECUTIVE	8/3526	LOC BC RWY 25, AMDT 21A

[FR Doc. E8–2862 Filed 2–22–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2008–P–0090] (formerly Docket No. 2006P–0393)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the health claim regulation entitled ''Soluble fiber from certain foods and risk of coronary heart disease (CHD)'' to add barley betafiber as an additional eligible source of beta-glucan soluble fiber. Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley flour. FDA is taking this action in response to a health claim petition submitted by Cargill, Inc. FDA previously concluded that there was significant scientific agreement that a claim characterizing the relationship between beta-glucan soluble fiber of certain whole oat and whole grain barley products and CHD risk is supported by the totality of publicly available scientific evidence. Based on the totality of publicly available scientific evidence, FDA now has concluded that in addition to certain whole oat and whole grain barley products, barley betafiber is also an appropriate source of beta-glucan soluble fiber. Therefore, FDA is amending the health claim regulation entitled ''Soluble fiber from certain foods and risk of CHD'' to include barley betafiber as another eligible source of beta-glucan soluble fiber.

DATES: This interim final rule is effective February 25, 2008. Submit written or electronic comments by May 12, 2008.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–P–0090 (formerly Docket No. 2006P–0393), by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

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, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

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.regulations.gov*, 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.regulations.gov* 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: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 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.

FDA (we) issued several new regulations in 1993 that implemented the health claim provisions of the 1990 amendments. Among these were 21 CFR 101.14, *Health claims: general requirements* (58 FR 2478, January 6, 1993) and § 101.70 (21 CFR 101.70), *Petitions for health claims* (58 FR 2478), which set out the general requirements for the authorization and use of health claims and established a process for petitioning the agency to authorize health claims about substance-disease relationships and set out the types of information that any such petition must include. These regulations became effective on May 8, 1993.

When implementing the 1990 amendments, FDA also conducted a review of evidence for a relationship between dietary fiber and cardiovascular disease (CVD). Based on this review, the agency 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) (1993 dietary fiber and CVD health claim final rule). However, FDA 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 CHD[1]. Therefore, FDA 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 1993 dietary fiber and CVD health claim 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 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 Risk of CHD Health Claim (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 and cholesterol (62 FR 3584 at 3597 and 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 1997 oat beta-glucan health claim final rule). 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 the 1997 oat beta-glucan health claim final rule, FDA anticipated the likelihood that other sources and types of soluble fibers could 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 because FDA had not reviewed the totality of evidence on other, non-whole oat sources of soluble fiber (62 FR 3584 at 3588).

The agency amended § 101.81 (21 CFR 101.81), in response to a health claim petition to add a health claim relating soluble fiber from psyllium seed husk and CHD risk (63 FR 8103, February 18, 1998). At this time, FDA 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)'' (63 FR 8103). FDA has also amended § 101.81, in response to health claim petitions, to include oatrim, whole grain barley, and certain dry milled barley grain products as eligible sources of beta-glucan soluble fiber. In 2002, FDA amended § 101.81 to add oatrim, which is the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, as an eligible source of beta-glucan soluble fiber (67 FR 61733, October 2, 2002), and finally, FDA amended § 101.81 to add whole grain barley and certain dry milled barley grain products as eligible sources of beta-glucan soluble fiber in 2005 (70 FR 76150, December 23, 2005).

II. Petition and Grounds

A. The Petition

Cargill, Inc. (petitioner), submitted a health claim petition to FDA on June 20, 2006, under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). The petition requested that the agency expand the ''Soluble fiber from certain foods and risk of coronary heart disease health claim'' (§ 101.81) to include ''barley betafiber'' (described in section II.B of this document) as an eligible food ingredient source of beta-glucan soluble fiber in addition to the oat and whole grain and dry milled barley ingredients now listed (Ref. 1). On September 28, 2006, the agency notified the petitioner that it had completed its initial review of the petition and that the petition was

[1] Cardiovascular disease 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.

being 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)). The petitioner and FDA subsequently mutually agreed to extend the deadline for the agency's decision on the petition to March 6, 2008. The petitioner also requested that FDA issue an interim final rule by which labeling of foods that contain ''barley betafiber'' in appropriate amounts could bear the health claim prior to publication of a final rule.

B. Nature of the Substance

The substance that is the subject of the oat/barley portion of current § 101.81 is beta-glucan soluble fiber from the specific oat and barley food products listed in § 101.81(c)(2)(ii)(A). Current § 101.81(c)(2)(ii)(A) has been amended twice previously to list additional oat or barley food products as eligible sources (67 FR 61773 and 70 FR 76150). Similar to these previous actions, FDA is now, in response to Cargill's health claim petition, amending § 101.81(c)(2)(ii)(A) to list barley betafiber as an eligible source of barley beta-glucan soluble fiber.

The petition states that barley betafiber is a concentrated barley beta-glucan soluble fiber product derived from whole barley flour. The petitioner's description of the barley betafiber manufacturing process reflects information contained in the petitioner's patent entitled ''*Improved Dietary Fiber Containing Materials Comprising Low Molecular Weight Glucan*'' (*World Intellectual Property Organization, International* Publication Number WO 2004/086878 A2) (Ref. 2) and a report of an expert panel on the generally recognized as safe (GRAS) status of barley betafiber commissioned by the petitioner (Ref. 3). The patent and the GRAS status report provide information on multiple variations of procedures for manufacturing concentrated barley beta-glucan soluble fiber products; these procedures differ from the manufacturing procedures for producing the unique barley betafiber substance that is the subject of the petition. Further, the clinical trial reported in the petition tested two different barley beta-glucan soluble fiber concentrates—a high molecular weight concentrate and a low molecular weight concentrate. The petitioner specified that the barley betafiber product, which is the subject of the petition, is only the low molecular weight concentrate studied in the clinical trial (Ref. 4). FDA was not satisfied that the information in the petition was sufficiently specific in describing the manufacturing process for the unique barley betafiber product for which there is scientific evidence to permit a showing that the product is comparable in cholesterol-lowering ability to the other oat and barley food products listed in current § 101.81(c)(2)(ii)(A). Discussion between the agency and the petitioner resulted in the description of the barley betafiber manufacturing process presented in the following paragraph and in final § 101.81(c)(2)(ii)(A)(*6*) (Refs. 2 through 5).

Barley betafiber is produced from an aqueous slurry of whole grain barley flour, starting with addition of an exogenous grain liquefying enzyme preparation with cellulase and alpha-amylase activity, derived from *Bacillus amyloliquefaciens*. The cellulase activity of the enzyme preparation acts on the beta-glucan soluble fiber in barley flour, since beta-glucan is a type of cellulose, and the alpha-amylase activity of the enzyme preparation acts on the starch in the barley flour. The temperature of the slurry is kept at or above the gelatinization temperature of the barley starch but below cellulase enzyme inactivation temperature; i.e., about 65° C, for about 30 to 60 minutes, to facilitate a partial hydrolysis of both the beta-glucan soluble fiber and starch. The pH of the slurry is kept in the range of about 5 to 7. When the cellulase enzymatic hydrolysis of barley flour has modified the beta-glucan soluble fiber to the desired extent, the cellulase activity of the enzyme preparation is heat inactivated. After the cellulase activity of the enzyme preparation has been deactivated, an exogenous thermo-stable amylolytic enzyme is added to the barley flour slurry for continued hydrolysis of starch molecules at the higher temperature. The slurry is held at the higher temperature until substantially all the starch has been hydrolyzed. A clear aqueous extract, which contains barley betafiber and the sugars and dextrins resulting from substantial hydrolysis of starch is then separated from insoluble material by centrifugation. Barley betafiber is precipitated from the aqueous extract supernatant with ethanol to separate it from other soluble components (i.e., substantially hydrolyzed starch, protein, lipids and other minor components) that remain suspended in the aqueous extract supernatant. The resultant barley betafiber precipitate is then dried and milled. The molecular weight range of barley betafiber produced by this procedure is 120 to 400 kilodaltons (Refs. 2, 3, and 5). The molecular weight range of barley betafiber is substantially reduced from that of native barley beta-glucan soluble fiber. The molecular weight range of native barley beta-glucan soluble fiber has been reported to range from about 500 to 3,330 kilodaltons depending upon the cultivars and applied extraction procedures, although lower molecular weight values of 80 to 300 kilodaltons have also been reported (Ref. 1). In final § 101.81(c)(2)(ii)(A)(*6*), FDA defines barley betafiber by its manufacturing process, as follows ''*Barley betafiber*. Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.''

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 beta-glucan soluble fiber 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. 6). Heart disease has been recognized as the leading cause of death in the United States for at least the last 50 years (Ref. 6). 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 of the health claim is beta-glucan soluble fiber from listed oat and barley sources. The petitioner requests an amendment to add barley betafiber to the list of eligible sources of beta-glucan soluble fiber. Barley betafiber is derived from whole barley flour. Barley flour 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 barley betafiber, a processed whole barley flour product, is a ''substance'' as defined in § 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)). The level necessary to justify the claim is 0.75 g beta-glucan soluble fiber per serving. The term ''nutritive value'' is defined in § 101.14(a)(3) as ''a value in sustaining human existence by such processes as promoting growth, replacing lost essential nutrients, or providing energy.'' The petitioner provided several examples of food categories (bars, beverages, bread, breakfast cereals, cookies, crackers, instant rice, pasta, muffins, salad dressings, snack chips, soups, tortillas and taco shells, vegetarian patties/crumbles, and reduced fat yogurt) in which barley betafiber could be used as an ingredient at a maximum level of 3 grams (g) beta-glucan soluble fiber per serving. Beta-glucan soluble fiber at 0.75 to 3 g per serving contributes nutritive value because it provides a source of calories and soluble fiber. In addition to its role as a source of beta-glucan soluble fiber, barley betafiber also has technical effects, including food applications as a thickener (e.g., soups), texturizer (e.g., snack foods), humectant (e.g., retain moisture of tortillas), or fat replacer (e.g., dressings for salads). Therefore, FDA concludes that the preliminary 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 petitioner asserts that the use of barley betafiber as a food ingredient is GRAS. The petitioner included in its health claim petition documentation of its 2003 GRAS self-determination for barley betafiber, which contains 70 percent or more pure barley beta-glucan soluble fiber as evidence that barley betafiber meets the safe and lawful requirement (Ref. 3). FDA also received a notice informing FDA that the petitioner determined, through scientific procedures, that the use of barley betafiber is GRAS. FDA issued a letter (Ref. 7) in response to this notice stating that the agency had no questions at the time regarding petitioner's conclusions that barley betafiber is GRAS under the intended conditions of use.

The 2003 Cargill GRAS self-determination stipulates that barley betafiber is obtained from food-grade whole grain barley flour by water extraction at elevated temperature, while starch is removed during the extraction process by treatment with enzymes that are GRAS for use in food manufacturing processes, specifically alpha-amylases from *Bacillus licheniformis* and *B. amyloliquefaciens*. The extracted barley betafiber is recovered by precipitation with denatured ethanol suitable for food production, and contains 70 percent or more beta-glucan, 2 to 12 percent protein, and less than 3 percent of each sugars, lipids, and inorganic salts. The basis of the safety determination relies on the fact that barley betafiber contains only native components of barley and is formed by the action of applied food-grade enzymes, residues, or processing aids.

In addition, barley is a traditional food with a long history of safe use, since at least 8,000 B.C. based on archeological discoveries (Ref. 3). In the Maghreb countries of Morocco, Algeria, Libya, and Tunisia, barley is used in a variety of traditional foods (bread, soup, porridge), resulting in an average intake of up to 172 g per person per day (Morocco). With this intake of barley, about 6 g per person per day of pure beta-glucan soluble fiber is consumed. The preparation of these traditional foods involves baking or boiling for longer periods of time, which ensures extraction of beta-glucan from its natural context (cell walls, complexes with proteoglycans). The physiological properties of beta-glucan as a dietary fiber may, therefore, be found in these traditional foods as is intended to be achieved with the addition to processed foods of barley beta-glucan concentrate.

The intended uses of barley betafiber listed as a food ingredient stated in the 2003 Cargill GRAS self-determination include the following food categories: Bars, beverages, bread (whole grain and specialty), breakfast cereals (ready to eat and cooked), cookies (lite), crackers (reduced fat), instant rice, macaroni products, muffins (reduced fat), salad dressings (lite), snack chips (reduced fat), soups, tortillas and taco shells, vegetarian patties/crumbles, and reduced fat yogurt. The maximum incorporation rate for each of these food applications is 3 g beta-glucan soluble fiber from barley betafiber per serving.

FDA concludes that the petitioners have satisfied the preliminary requirement of § 101.14(b)(3)(ii) to demonstrate, to FDA's satisfaction, that the use of beta-glucan soluble fiber from barley betafiber at levels necessary to justify the health claim is safe and lawful under the applicable food safety provisions of the act. The agency has not made its own determination regarding the GRAS status of barley betafiber or beta-glucan soluble fiber from barley betafiber. Furthermore, the agency notes that a regulation to authorize a health claim for a substance should not be interpreted as affirmation that the substance is GRAS.

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

A. Basis for Evaluating the Relationship Between Beta-Glucan Soluble Fiber from Barley Betafiber and CHD

The types of data that FDA has recognized in previous CHD health claim evaluations as useful for assessing CHD risk reduction are: Coronary events (myocardial infarction, ischemia), cardiovascular death, atherosclerosis, high blood pressure, serum total cholesterol, and serum LDL cholesterol. FDA considers high blood pressure, serum total cholesterol, and serum LDL cholesterol levels to be the only currently validated surrogate measures for CHD risk (Ref. 8). Elevated levels of serum total and LDL cholesterol, a prerequisite for atherosclerotic disease, is a major modifiable risk factor in the development of CHD (Ref. 8). For these reasons, the agency based its original evaluation of the relationship between oat beta-glucan soluble fiber and CHD risk (62 FR 3584) and subsequent evaluations to add oatrim (67 FR 61773) and barley as eligible sources of beta-glucan soluble fiber (70 FR 76150) in the health claim, primarily on evidence for serum total and LDL cholesterol-lowering effects of beta-glucan soluble fiber containing food ingredients. As such, our evaluation of the evidence

supporting the petitioned request to extend the eligible barley sources to include barley betafiber (as described in section II.B of this preamble), focused on evidence from human randomized controlled trials of the effects of consuming beta-glucan soluble fiber from barley betafiber on blood lipids. This focus is consistent with existing § 101.81 in which FDA concluded that there is significant scientific agreement that the relationship between CHD risk and consumption of beta-glucan soluble fiber from certain oat and barley food ingredients is mediated primarily by the effect of the beta-glucan soluble fiber on serum lipids.

FDA's determination of significant scientific agreement that the totality of publicly available scientific evidence supports the relationship between beta-glucan soluble fiber from certain oat and barley foods and CHD risk is documented in rulemaking for § 101.81. When issuing the 1997 oat beta-glucan health claim final rule, 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). In the 2002 and 2005 amendments to the health claim to add oatrim and whole grain and dry milled barley products, respectively, as eligible sources of beta-glucan soluble fiber, the agency considered evidence that beta-glucan soluble fiber from those sources had comparable cholesterol-lowering effects to that from the sources previously listed in § 101.81(c)(2)(ii)(A) as further support for FDA's previous determination that there is significant scientific agreement that a relationship exists between consumption of certain beta-glucan soluble fiber sources and reduced risk of CHD (67 FR 61773 at 61779 and 70 FR 76150 at 76155). Similarly, FDA considers that scientific evidence to establish that the cholesterol-lowering effects of beta-glucan soluble fiber from barley betafiber are comparable to the effects of beta-glucan soluble fiber from the oat/barley products in current § 101.81(c)(2)(ii)(A) builds on the substantial base of scientific evidence that already establishes significant scientific agreement for the association between consumption of the oat/barley products now listed and reduced risk of CHD. FDA's review of the evidence to support the petitioned amendment of the health claim regulation entitled ''Soluble fiber from certain foods and risk of CHD'' was conducted consistent with FDA published guidance on significant scientific agreement in the review of health claims (Ref. 9) and focused on evidence from intervention studies.

B. Assessment of Intervention Studies

This petition identified one relevant human randomized controlled trial of how consumption of beta-glucan soluble fiber from barley betafiber affects heart disease risk and serum lipid levels. A summary of this trial was included in the petition and subsequently published in a peer reviewed scientific journal (Ref. 4). FDA also evaluated reported results from randomized controlled trials of other types of beta-glucan concentrates, extracts, and gums (Refs. 10 through 19).

The study reported in Keenan et al. 2007 (Ref. 4) investigated the effects of consuming concentrated barley beta-glucan soluble fiber-enriched foods (fruit drink and corn flakes) on blood lipids in hypercholesterolemic men and women. The study was conducted as a randomized, double-blind, placebo-controlled, parallel arm study of five groups with 30 to 32 subjects per group. The study included a total of 155 hypercholesterolemic adult subjects, between 25 and 73 years of age, with baseline serum LDL cholesterol levels between 140 and 190 milligrams per deciliter (mg/dL). The subjects were instructed to follow a diet low in saturated and *trans* fatty acids (less than 10 percent kilocalories (kcals) per day) and to consume three servings of the concentrated barley beta-glucan soluble fiber-enriched test foods per day, one serving with each of three major meals. The concentrated barley beta-glucan soluble fiber-enriched test foods were formulated to provide either 3 or 5 g of beta-glucan soluble fiber per day; a placebo version of the test foods without added barley beta-glucan extracts was also used. Two concentrated barley beta-glucan soluble fiber products were used; one is the barley betafiber produced from the manufacturing process described in section II.B of this preamble, and was described in the study report as a low molecular weight (LMW) extract; the other concentrated barley beta-glucan soluble fiber product of the study was described as a high molecular weight (HMW) beta-glucan extract. The HMW barley beta-glucan extract was processed in a fashion similar to that for barley betafiber but omitted the cellulase enzymatic hydrolysis step, thus producing a concentrated source of barley beta-glucan soluble fiber with a molecular weight similar to that of the endogenous beta-glucan soluble fiber in barley grain from which it was derived.

Following a 4-week run-in period to adjust to the low saturated/*trans* fat diet, the subjects were randomly assigned to one of five treatment groups: placebo control, 3 g per day barley betafiber, 5 g per day barley betafiber, 3 g per day HMW beta-glucan extract, and 5 g per day HMW beta-glucan extract. Subjects consumed the test foods daily for 6 weeks. Consumption of 3 or 5 g beta-glucan per day from barley betafiber significantly lowered serum total cholesterol levels (6.0 percent and 9.9 percent, respectively) relative to the placebo control group. Consumption of 3 or 5 g beta-glucan per day from the HMW barley beta-glucan extract also significantly lowered serum total cholesterol (7.0 percent and 11.2 percent, respectively) relative to the placebo control group. Serum LDL cholesterol levels were significantly decreased in all active treatment groups. At the end of the 5-week intervention period, the mean serum LDL cholesterol level of the 3 g per day beta-glucan from barley betafiber group was 10 mg/dL lower than the mean serum LDL cholesterol level of the placebo control group, representing a 7.5 percent reduction in LDL cholesterol relative to the placebo control group. The reduction in mean serum LDL cholesterol for the 5 g per day beta-glucan from barley betafiber group relative to the placebo control group was 16 mg/dL or 12 percent. The reduction in mean serum LDL cholesterol for the 3 g per day HMW beta-glucan group was 12 mg/dL or 8 percent relative to the placebo control group. For the 5 g per day HMW beta-glucan group, the reduction in mean LDL cholesterol was 19 mg/dL or 13 percent relative to the placebo control group. There were no statistically significant differences between barley betafiber and the HMW barley beta-glucan extract groups, or between 3 g per day or 5 g per day beta-glucan groups, in the magnitude of the cholesterol lowering effects.

The magnitude of cholesterol-lowering reported by Keenan et al. (Ref. 4) for 3 and 5 g per day beta-glucan from barley betafiber is consistent with the magnitude of cholesterol-lowering observed with similar barley beta-glucan soluble fiber intake levels consumed as dry milled barley foods (70 FR 76150 at 76153). The randomized controlled trials with dry milled barley foods that FDA considered when previously

amending the health claim to add dry milled barley had reported mean serum LDL cholesterol reductions of between 10 and 19 mg/dL from barley beta-glucan intake levels of 3 to 8 g per day. Based on evidence from the randomized controlled trials of dry milled barley ingredients which FDA relied upon when adding barley products to the health claim, the data for barley betafiber from Keenan et al. are consistent with the expected magnitude of cholesterol-lowering from consumption of the barley products listed in current § 101.81(c)(2)(ii)(A)(*5*).

Clinical trial evidence of oat/barley beta-glucan extracts other than barley betafiber indicate that not all oat/barley beta-glucan extracts affect serum total and LDL cholesterol levels as consistently as does consumption of the intact oat and barley grain from which they have been extracted (Refs. 10 through 19). This indicates that some extraction processes negatively affect whatever characteristics of beta-glucan soluble fiber in whole grain oats and barley that are responsible for the cholesterol-lowering effect. Accordingly, data from trials of beta-glucan extracts and concentrates other than barley betafiber support FDA's previous position (62 FR 3584 at 3587) that oat and barley products will be added to the health claim as eligible sources of beta-glucan soluble fiber only on a case-by-case basis when FDA is presented with adequate supporting evidence.

Evidence from the randomized controlled trial reported by Keenan et al. (Ref. 4) indicates that beta-glucan soluble fiber from barley betafiber, prepared as described in section II of this preamble, is comparable to beta-glucan soluble fiber from the oat and barley sources now included in current § 101.81 in regard to cholesterol-lowering properties. Evidence from randomized controlled trials of other oat or barley beta-glucan extracts indicate that some forms of processing of oat and barley grain to extract or concentrate beta-glucan can negatively affect whatever properties of oat and barley beta-glucan are responsible for the cholesterol-lowering effect. Therefore, results from Keenan et al. can not be extrapolated to beta-glucan extracts other than the specific products tested in the trial. Results from the Keenan et al. trial also demonstrate that the serum cholesterol-lowering effects were comparable for beta-glucan soluble fiber from barley betafiber (i.e., the LMW product in the Keenan et al. trial) and for the barley beta-glucan extract that was not subjected to beta-glucan hydrolysis (the HMW product in the Keenan et al. trial) (Ref. 4). This evidence demonstrates that the cholesterol-lowering ability of beta-glucan soluble fiber in barley betafiber is not affected by the process used in the manufacture of barley betafiber to reduce the molecular weight of the barley betafiber product.

IV. Decision to Amend the Health Claim

Available evidence demonstrates that foods enriched with beta-glucan soluble fiber from barley betafiber at levels sufficient to provide at least 3 g beta-glucan soluble fiber per day are effective in lowering serum LDL-cholesterol levels, which may reduce the risk of CHD. As noted previously, when issuing the 1997 oat beta-glucan health claim final rule 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 clinical trial results reported by Keenan et al. (Ref. 4) demonstrating the cholesterol-lowering effect of consuming beta-glucan soluble fiber from barley betafiber are consistent in magnitude with what would be expected based on the oat beta-glucan soluble fiber/cholesterol-lowering dose-response evidence, which was cited in the 1997 oat beta-glucan health claim final rule, and cholesterol-lowering effect of consuming beta-glucan soluble fiber from dry milled barley grain ingredients (70 FR 76150 at 76155). Thus, FDA concludes that the cholesterol-lowering effect of beta-glucan soluble fiber from barley betafiber is comparable to that of beta-glucan soluble fiber from whole grain oat and dry milled barley sources currently listed in § 101.81(c)(2)(ii)(A). FDA also concludes that the scientific evidence supports a minimum daily effective intake of beta-glucan soluble fiber from barley betafiber the same as that which was previously found for whole oat and dry milled barley sources of beta-glucan soluble fiber, i.e., 3 g per day. Therefore, FDA is amending § 101.81, by adding § 101.81(c)(2)(ii)(A)(*6*) to list barley betafiber as an eligible source of beta-glucan soluble fiber. Consistent with current § 101.81(c)(2)(i)(G)(*1*), the source of the 3 g or more per day of beta-glucan soluble fiber may be from whole oats or barley, including the barley betafiber source, or a combination of oats and barley eligible sources. In addition, consistent with the description of other oat and barley products listed in current § 101.81, amended § 101.81 will specify barley betafiber by the method of production as described in section II.B of this preamble. The agency is satisfied that the description of the method for producing barley betafiber appropriately characterizes the barley product being added to the regulation. Further, barley beta-glucan can be measured by the same quantitative analytical method as is currently specified in § 101.81(c)(2)(ii)(A) for the determination of oat beta-glucan and barley beta-glucan from whole grain barley and dry milled barley products. 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, FDA is amending § 101.81(c)(2)(ii)(A) to include barley betafiber derived from whole barley flour, prepared as described in section II.B of this document, as an additional source of beta-glucan soluble fiber.

The requirement in § 101.81(c)(2)(iii)(A) states that a food bearing the claim on its label include one of the ingredients listed within § 101.81(c)(2)(ii)(A) and that the ingredient provide at least 0.75 gram of beta-glucan soluble fiber per reference amount customarily consumed (RACC) of the food product. This level is based on the minimum daily effective intake of beta-glucan soluble fiber from barley betafiber and is the same as that which was previously found for whole oat and dry milled barley sources of beta-glucan soluble fiber, i.e., 3 g per day. FDA arrived at a value of 0.75 gram beta-glucan soluble fiber per RACC based on a standard assumption that the daily dietary intake is divided over four eating occasions per day (three meals and a snack) (62 FR 3584 at 3592). Thus, adding barley betafiber as an additional eligible source of beta-glucan soluble fiber will further increase the type and number of qualifying food products and make it easier for consumers to select barley and oat products at four eating occasions per day. Thus, FDA is retaining under the ''Nature of the food eligible to bear the claim'' section of the codified text of this interim final rule, the criterion that foods eligible to bear the claim contain at least 0.75 gram of soluble fiber (§ 101.81(c)(2)(iii)(A)(*2*)).

There is strong 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. 8). 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 issuing the 1997 oat beta-glucan health claim final rule, 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 in the 1997 oat beta-glucan health claim final rule that the 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)). FDA reiterated this position and extended it to soluble fiber from listed barley products when the agency amended § 101.81 to add whole grain barley and certain dry milled barley products as eligible sources of beta-glucan soluble fiber in 2005 (70 FR 76150 at 76156).

Beta-glucan soluble fiber from barley betafiber functions comparably to beta-glucan soluble fiber from the listed oat and barley sources in current § 101.81(c)(2)(ii)(A) in its effect on reducing LDL and total cholesterol. Barley betafiber, as a source of beta-glucan soluble fiber, is a useful adjunct to selection of diets low in saturated fat and cholesterol to reduce CHD risk. Thus, the agency is requiring that the beta-glucan soluble fiber from barley betafiber health claim be subject to the requirements in § 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 Amendments to the Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease Health Claim Regulation

A. Nature of the Substance; Eligible Sources of Soluble Fiber

Section 101.81(c)(2)(ii) (nature of the substance) lists the types and sources of soluble fiber that have been demonstrated to FDA's satisfaction to have a relationship to a reduced risk of CHD. Section 101.81(c)(2)(ii)(A) lists beta-glucan soluble fiber from whole oat and barley sources, along with specifying an AOAC INTERNATIONAL method of analysis for beta-glucan soluble fibe, which will be used by FDA for verifying compliance. Section 101.81(c)(2)(ii)(A)(*1*) through (c)(2)(ii)(A)(*5*) identifies the whole oat and barley products that are eligible sources of beta-glucan, i.e., oat bran, rolled oats, whole oat flour, oatrim, whole grain barley, and dry milled barley.

FDA is amending § 101.81(c)(2)(ii)(A) by adding § 101.81(c)(2)(ii)(A)(*6*), which would specify barley betafiber as being the ethanol isolated, soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley flour, with a beta-glucan content of at least 70 percent on a dry weight basis (dwb). Thus, § 101.81(c)(2)(ii)(A)(*6*) will read as follows ''*Barley betafiber.* Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.''

B. Nature of the Food Eligible to Bear the Claim

Section 101.81(c)(2)(iii)(A)(*2*) (nature of the food) currently states ''The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product;''

Because FDA is amending § 101.81 to add barley betafiber, FDA is amending § 101.81(c)(2)(iii)(A)(*2*) as follows ''The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product;''

C. Other Requirements

All other requirements in § 101.81(c)(1) through (c)(2)(i) and the optional information in § 101.81(d) will apply to the use of the health claim authorized in § 101.81 for barley betafiber-containing products.

D. Model Health Claims

This interim final rule to amend existing § 101.81(c)(2) does not affect the model health claims specified in paragraph (e) of § 101.81. Thus, the model health claims in § 101.81(e) apply to a claim about beta-glucan soluble fiber from barley betafiber and a reduced risk of CHD.

VI. Analysis of Impacts

FDA has examined the impacts of this 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). 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). The agency believes that this interim final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this interim final rule concerns voluntary claims, the agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that

includes any 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 threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this interim final rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA has identified the following three options regarding this petition: (1) Deny the petition; (2) authorize the petition (add only barley betafiber to the ''Soluble fiber from certain foods and risk of coronary heart disease health claim'' in § 101.81 (the soluble fiber and CHD health claim)); or (3) add barley betafiber to the soluble fiber-CHD health claim and also expand the scope of the claim to include all sources of soluble fiber. FDA concludes that authorizing the petition by adding barley betafiber to the soluble fiber and CHD health claim is the best option of those identified.

Option One: Deny the Petition

FDA can only define costs and benefits relative to a baseline. FDA usually selects the option of taking no action as the baseline because it helps readers identify the costs and benefits of actions that change the status quo. In this case, denying the petition would correspond to taking no action because it would imply no change in the soluble fiber and CHD health claim and thus the continuation of the status quo. By definition, the baseline itself has no costs or benefits. This does not mean that we ignore the costs and benefits of the baseline. Instead, it means that FDA expresses the costs and benefits of the baseline in how it calculates the costs and benefits of the other regulatory options.

Option Two: Authorize the Petition (Add Only Barley Betafiber to the Soluble Fiber and CHD Health Claim)

This option would allow producers who use barley betafiber to use the soluble fiber and CHD health claim on their product labels under certain conditions. Producers would only choose to change product labels or reformulate products if they believe that the benefits that they will derive from doing so are at least as great as the costs of making those changes. FDA has reviewed the data supplied in the petition and concludes that the claim is truthful and not misleading. If this interim final rule is finalized without change, FDA can be sure that to whatever extent producers use the claim, consumers will be in a better position, assuming that more information that is truthful and not misleading is always better for consumers. Based on this, FDA can conclude that adding barley betafiber to the soluble fiber and CHD health claim is better for social welfare than denying the petition.

Option Three: Add Barley Betafiber to the Soluble Fiber and CHD Health Claim and Also Expand the Scope of the Claim to Include All Sources of Soluble Fiber

This option would allow producers who use barley betafiber and all other sources of soluble fiber to use the soluble fiber and CHD health claim on their product labels under certain conditions rather than just listing specific sources of soluble fiber. Similar to option two, producers would only choose to change product labels or reformulate products if they believed that the benefits that they will derive from doing so are at least as great as the costs of making those changes. In addition, this option would reduce the future burden on manufacturers of petitioning FDA to use the soluble fiber and CHD health claim for additional sources of soluble fiber, and it would also reduce the agency's burden of evaluating each petition for each individual source of soluble fiber. However, by expanding the use of the claim to all sources of soluble fiber without reviewing the scientific data on each source, FDA would not be able to verify that the claim was being used under circumstances where it is truthful and not misleading to consumers. If the expanded claim was used on a product that did not reduce the risk of CHD, then the expanded claim could actually result in an increase in CHD. This would happen if consumers were misled into thinking that they were reducing their risk of CHD by consuming a product that actually did not reduce the risk of CHD. As a result, they might not take other beneficial steps that would decrease their risk of CHD.

FDA cannot conclude that the cost savings of option three outweigh the increased risk of a false or misleading claim being made under the expanded claim. Therefore FDA cannot conclude that option three is better for social welfare than option two. Moreover, the agency believes that expanding the soluble fiber and CHD health claim to all sources of soluble fiber without reviewing the scientific data supporting such a claim of CHD risk reduction for each individual source of fiber would be a failure to carry out our statutory responsibility under section 403(r)(3)(B) of the act to issue health claim regulations only when the agency determines that there is significant scientific agreement that the claim is supported by the totality of publicly available scientific evidence.

VII. Environmental Impact

The agency 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.

VIII. Paperwork Reduction Act of 1995

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 betafiber 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)).

IX. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act provides that ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—* * * any requirement respecting any claim of the type described in section 403(r)(1) of the act made in the label or labeling of food that is not identical to the requirement of section 403(r). * * *''

Currently, this provision operates to preempt States from imposing health claim labeling requirements concerning beta-glucan soluble fiber from barley betafiber and reduced risk of CHD because no such requirement had been

imposed by FDA under section 403(r) of the act. This interim final rule, if finalized without change, would amend existing food labeling regulations to add barley betafiber as an eligible source of beta-glucan soluble fiber to the authorized health claim for soluble fiber from certain foods and risk of CHD. Although this rule would have a preemptive effect in that it would preclude States from issuing any health claim labeling requirements for beta-glucan soluble fiber from barley betafiber and a reduced risk of CHD that are not identical to those that would be required by this interim final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. (*Medtronic* v. *Lohr*, *518 U.S. 470, 503 (1996)* (Breyer, J., concurring in part and concurring in judgment); *id. at 510* (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id. at 548–49* (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the preemptive effect of this interim final rule, if finalized without change, is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA provided the States with an opportunity for appropriate participation in this rulemaking on December 12, 2007, when FDA's Division of Federal and State Relations provided notice via fax and email transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel of FDA's intent to amend the health claim regulation authorizing health claims for soluble fiber from certain foods and risk of CHD (§ 101.81). It advised the States of FDA's possible action and encouraged the States and local governments to review the petition and to provide any comments to the docket (Docket No. 2006P–0393), until January 12, 2008. FDA received no comments in response to the notice. FDA is also providing an opportunity for State and local officials to comment on this interim final rule.

In conclusion, the agency has determined that the preemptive effects of this interim final rule are consistent with Executive Order 13132.

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

FDA is 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 is necessary to: (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 all three of the criteria in section 403(r)(7)(A) of the act have been met for the amendment to the soluble fiber from certain foods and risk of CHD health claim to list barley betafiber as eligible source of beta-glucan soluble fiber. This health claim amendment will help enable consumers to develop and maintain healthy dietary practices. The health claim will also provide consumers with important knowledge regarding the effects of beta-glucan soluble fiber in reducing the risk of, and will provide consumers with scientifically sound information on the benefits of foods containing beta-glucan soluble fiber from barley betafiber. 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 for soluble fiber from barley betafiber and CHD, effective 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 the Division of Dockets Management, in any of the ways noted in the **ADDRESSES** section at the beginning of this document, comments regarding this interim final rule by (see **DATES**). 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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.

XI. 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 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

XII. 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. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Cargill, Inc., ''Petition for Health Claim—Barley Betafiber and Coronary Heart Disease,'' (Docket 2006P–0393 CP1), June 20, 2006.

2. Cargill, Inc., ''Petition for Health Claim—Barley Betafiber and Coronary Heart Disease,'' Appendix 4, (Docket 2006P–0393), June 20, 2006.

3. Cargill, Inc., ''Petition for Health Claim—Barley Betafiber and Coronary Heart Disease,'' Appendix 1, (Docket 2006P–0393), June 20, 2006.

4. Keenan, J.M., Goulson, M., Shamliyan, T., et al., ''The Effects of Concentrated Barley Beta-Glucan on Blood Lipids in a Population of Hypercholesterolaemic Men and Women,'' *British Journal of Nutrition*, 97:1162–1168, 2007.

5. E-mail from Lore Kolberg, Cargill, Inc., to Jillonne Kevala, FDA, August 28, 2006.

6. Cooper, R., Cutler, J., Desvigne-Nickens, P., et al., ''Trends and Disparities in Coronary Heart Disease, Stroke, and Other Cardiovascular Diseases in the United States: Findings of the National Conference on

Cardiovascular Disease Prevention,'' *Circulation*, 102:3137–3147, 2000.

7. Agency Response Letter to Generally Recognized as Safe Notice No. GRN 000207, FDA, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, December 19, 2006.

8. National Heart, Lung, and Blood Institute; National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Pressure in Adults (Adult Treatment Panel III), Third Report of the NCEP Adult Treatment Panel III, Executive Summary, Bethesda (MD): National Institutes of Health, National Heart, Lung and Blood Institute, (*www.nhlbi.nih.gov/guidelines/cholesterol/atp_iii.htm*), May 2001.

9. 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; December 1999, Available from: *http://www.cfsan.fda.gov/~dms/ssaguide.html*.

10. Biörklund, M., vanRees, A., Mensink, R.P., et al., ''Changes in Serum Lipids and Postprandial Glucose and Insulin Concentrations After Consumption of Beverages with β-Glucans from Oats or Barley: A Randomized Dose-Controlled Trial,'' *European Journal of Clinical Nutrition*, 59:1272–1281, 2005.

11. Keogh, G.F., Cooper, G.J.S., Mulvey, T.B., et al., ''Randomized Controlled Crossover Study of the Effect of a Highly β-Glucan-Enriched Barley on Cardiovascular Disease Risk Factors in Mildly Hypercholesterolemic Men,'' *American Journal of Clinical Nutrition*, 78:711–718, 2003.

12. Kerckhoffs, D.A.J.M., Hornstra, G., and R.P. Mensink, ''Cholesterol-Lowering Effect of β-Glucan from Oat Bran in Mildly Hypercholesterolemic Subjects May Decrease When β-Glucan is Incorporated Into Bread and Cookies,'' *American Journal of Clinical Nutrition*, 78:221–227, 2003.

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14. Naumann, E., vanRees, A.B., Önning, G., et al., ''β-Glucan Incorporated Into a Fruit Drink Effectively Lowers Serum LDL-Cholesterol Concentrations,'' *American Journal of Clinical Nutrition*, 83:601–605, 2006.

15. Pick, M.E., Hawrysh, Z.J., Gee, M.I., et al., ''Oat Bran Concentrate Bread Products Improve Long-Term Control of Diabetes: A Pilot Study,'' *Journal of the American Dietetic Association*, 96:1254–1261, 1996.

16. Beer, M.U., Arrigoni, E., and R. Amado, ''Effects of Oat Gum on Blood Cholesterol Levels in Healthy Young Men,'' *European Journal of Clinical Nutrition*, 49:517–522, 1995.

17. Braaten, J.T., Wood, P.J., Scott, F.W., et al., ''Oat β-Glucan Reduces Blood Cholesterol Concentration in Hypercholesterolemic Subjects,'' *European Journal of Clinical Nutrition*, 48:465–474, 1994.

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19. Törrönen, R., Kansanen, L., Uusitupa, M., et al., ''Effects of an Oat Bran Concentrate on Serum Lipids in Free-Living Men with Mild to Moderate Hypercholesterolemia,'' *European Journal of Clinical Nutrition*, 46:621–627, 1992.

List of Subjects in 21 CFR Part 101

Food labeling, 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 adding paragraph (c)(2)(ii)(A)(*6*) and by revising paragraph (c)(2)(iii)(A)(*2*) to read as follows:

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

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(A) * * *

(*6*) *Barley betafiber.* Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.

* * * * *

(iii) * * *

(A) * * *

(*2*) The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product; or

* * * * *

Dated: February 15, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3418 Filed 2–22–08; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No.: 001–2008]

Privacy Act of 1974; System of Records

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: Final rule.

SUMMARY: The Federal Bureau of Investigation (FBI), a component agency of the Department of Justice (DOJ), is issuing a final rule exempting a new Privacy Act system of records, the Law Enforcement National Data Exchange. The FBI published a system of records notice for N–DEx and a proposed rule implementing these exemptions on October 4, 2007. The listed exemptions are necessary to avoid interference with the law enforcement functions and responsibilities of the FBI. This document addresses public comments on the proposed rule.

DATES: This final rule is effective February 25, 2008.

FOR FURTHER INFORMATION CONTACT: Kirsten J. Moncada, Director, Office of Privacy and Civil Liberties, 950 Pennsylvania Avenue, NW., Washington, DC 20530, or facsimile 202–616–9627.

SUPPLEMENTARY INFORMATION:

On October 4, 2007, the FBI issued a system of records notice at 72 FR 56793, for a new Privacy Act records system, JUSTICE/FBI–020, the Law Enforcement National Data Exchange (N–DEx), and a notice of proposed rulemaking, at 72 FR 56704, to exempt it from subsections (c)(3) and (4); (d)(1), (2), (3), and (4); (e)(1), (2), (3), (5), and (8); and (g) of the Privacy Act. The FBI explained that the exemptions were necessary in order to avoid interference with the FBI's law enforcement functions and responsibilities.

Two thoughtful comments from individuals were received on the proposed exemptions. One commenter supported the claimed exemptions, observing that they were ''most