then send it to the Manager, Rotorcraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Certification Office.

(c) Special flight permits will not be issued.

(d) This amendment becomes effective on November 6, 2002.

Issued in Fort Worth, Texas, on September 18, 2002.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 02–24993 Filed 10–1–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 01Q–0313]

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 beta-glucan soluble fiber from whole oat sources and reduced risk of coronary heart disease (CHD). The amendment adds as an additional eligible source of whole oat beta-glucan soluble fiber, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent on a dry weight basis (dwb) and not less than that of the starting material (dwb). We (FDA) are taking this action in response to a petition jointly filed by the Quaker Oats Co. and Rhodia, Inc. (the petitioners). We concluded previously that there was significant scientific agreement that a relationship exists between the beta-glucan soluble fiber of certain whole oat sources and the reduction of risk of CHD by lowering blood cholesterol levels. We now have concluded, based on the publicly available scientific evidence that, in addition to rolled oats, oat bran, and whole oat flour, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan content up to 10 percent (dwb) and not less than that of the starting material (dwb) is an appropriate source of beta-glucan soluble fiber for the health claim. Therefore, we are amending the regulation that authorizes a health claim on the relationship between soluble fiber from whole oats and reduced risk of CHD to include this additional source of beta-glucan soluble fiber.

DATES: This interim final rule is effective October 2, 2002. Submit written or electronic comments by December 16, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, 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, including confirming 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) (58 FR 2478, January 6, 1993), which set out the rules for the authorization and use of health claims, and § 101.70 (21 CFR 101.70) (58 FR 2478, January 6, 1993), which established a process for petitioning the agency to authorize health claims about a substance-disease relationship and set out the types of information that any such petition must include. Each of these regulations became effective on May 8, 1993.

In addition, we conducted extensive reviews of the evidence on the 10 substance-disease relationships listed in the 1990 amendments, including dietary fiber and reduced risk of cardiovascular disease (CVD). As a result of our review, we have authorized claims that relate to 8 of these 10 relationships.

B. 1990 to 1993 Dietary Fiber and Cardiovascular Disease Health Claim Evaluation

During 1990 to 1993, we conducted an extensive review of the relationship between dietary fiber and CVD. We examined the then current state of scientific opinion regarding the role of total dietary fiber in general, without focusing on any particular dietary fiber. Although we denied the use of a health claim relating total dietary fiber to reduced risk of CVD (58 FR 2552, January 6, 1993), we authorized a health claim relating fruits, vegetables, and grain products that contain dietary fiber, particularly soluble dietary fiber, to reduced risk of CHD, one of the more common serious forms of CVD (58 FR 2552, January 6, 1993).

We concluded that, based on the totality of publicly available scientific evidence, there was significant scientific agreement that the evidence supported an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products (i.e., foods that are low in saturated fat and cholesterol and that are good sources of dietary fiber) and reduced risk of coronary heart disease (58 FR 2552 at 2572). We therefore authorized a health claim in part 101 (21 CFR part 101) in § 101.77 on the association 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.

In the 1993 dietary fiber and CVD final rule, in response to a comment regarding the apparent hypocholesterolemic properties of specific food fibers, e.g., oat bran, we agreed that the effectiveness of naturally occurring fibers in foods may be documented for specific food products (e.g., oat bran meeting specified parameters) (58 FR 2552 at 2567). We further stated that if a manufacturer could document, through appropriate studies, that dietary consumption of the soluble fiber in its particular food has the effect of lowering 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 a health claim for its particular product (58 FR 2552 at 2567).

C. 1997 Soluble Fiber From Whole Oats and Coronary Heart Disease Health Claim

We subsequently received a petition for, and authorized, a health claim on the relationship between soluble fiber from whole oats and reduced risk of CHD (the soluble fiber from whole oats final rule) (62 FR 3584, January 23, 1997; modified at 62 FR 15343, March 31, 1997). We initially proposed to authorize a health claim on the association between oat bran and oatmeal and reduced risk of CHD (the oats proposed rule) (61 FR 296, January

4, 1996). However, we concluded in the final rule 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 3585). We reached this conclusion based 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 blood total- and LDL-cholesterol, and that intakes of beta-glucan soluble fiber at or above 3 gram (g) per day were more effective in lowering serum lipids than lower intake levels (62 FR 3584 at 3585). As such, we concluded that, rather than oat bran and rolled oats, the appropriate substance for the subject of the authorized claim is beta-glucan soluble fiber from whole oats. We further determined that the relationship is scientifically valid in that there is significant scientific agreement, based on the totality of publicly available evidence, that beta-glucan soluble fiber from whole oats, as part of a diet low in saturated fat and cholesterol, may reduce the risk of CHD (62 FR 3584 at 3598).

Several comments to the oats proposed rule suggested that products containing whole oat flour made from 100 percent oat groats also should be eligible to bear the health claim (62 FR 3584 at 3585). The reasons given included: (1) Whole oat flour contains beta-glucan soluble fiber as does oat bran and rolled oats; (2) whole oat flour is derived from the same starting material as rolled oats (i.e., whole oat groats) and, other than the smaller particle size of whole oat flour, whole oat flour possesses a chemical and physical composition virtually identical to that of rolled oats; (3) intestinal content viscosity data from rodent studies demonstrate that whole oat flour beta-glucan soluble fiber retains viscosity similar to that of the beta-glucan soluble fiber from oat bran and rolled oats during processing and digestion; and (4) data from one human clinical study and several experimental animal studies demonstrate that whole oat flour has similar effects on blood cholesterol levels as oat bran and rolled oats (62 FR 3584 at 3585).

We were persuaded that the clinical data showing the positive effects of consuming whole oat flour foods on blood cholesterol, and comments showing compositional similarities between whole oat flour and rolled oats, provided sufficient evidence for us to conclude that whole oat flour has the same effects relative to reduced risk of CHD as do oat bran and rolled oats (62 FR 3584 at 3586). Further, this conclusion was corroborated by evidence from the rodent intestinal contents studies. These studies demonstrate that the beta-glucan soluble fiber from whole oat flour retains the same level of viscosity in the rodent digestive tract as does that from rolled oats (62 FR 3584 at 3586). The whole oats final rule concluded that beta-glucan soluble fiber was the appropriate substance for the subject of the health claim, and that the three eligible sources of this substance were oat bran, rolled oats, and whole oat flour.

D. 1998 Amendment to Broaden the Claim to ''Soluble Fiber From Certain Foods and CHD''

In the soluble fiber from whole oats final rule, we acknowledged the likelihood that consumption of other sources of beta-glucan soluble fiber, as well as other sources and types of soluble fibers, will affect blood lipid levels, and thus, the risk of heart disease (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 evidence on other, nonwhole oat sources of soluble fiber (62 FR 3584 at 3588). In 1998, FDA announced that, in response to a health claim petition and on the totality of the available scientific evidence, it had concluded that soluble fiber from 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 action, 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 To Amend § 101.81 by Adding an Additional Eligible Source of Beta-Glucan Soluble Fiber From Whole Oats

A. Background

The Quaker Oats Co. and Rhodia, Inc. (the petitioners), jointly submitted a health claim petition to FDA on April 21, 2001, under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (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 a fourth source of beta-glucan soluble fiber eligible for the claim. The petitioners requested that this amendment be made ''* * * with specific reference to the Quaker-Rhodia group Oatrim, known as Oatrim (BETATRIM).'' The petition notes that ''[n]ot all Oatrims have been tested for cholesterol-lowering efficacy; hence we are limiting our petition to the subgroup Oatrim (BETATRIM), Oatrims with demonstrated cholesterol-lowering efficacy'' (Ref. 1). FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on July 20, 2001 (Ref. 2).

The petitioners' description of the substance that is the subject of the health claim is broader than what the available evidence supports. We have determined that the evidence supports specifying the substance that is the subject of the claim as the beta-glucan-containing soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb), also known as oatrim (Ref. 3). This oatrim substance is produced by the methods described by Inglett and Newman, 1994 (Ref. 3). In brief, the manufacturing method consists of first preparing a 10 to 40 percent slurry of a milled oat product (specifically, oat bran or whole oat flour) in water containing 25 to 50 parts per million calcium to stabilize the subsequently added alpha-amylase enzyme, and with a pH adjusted between 5.5 and 7.5. Then the starch of the oat product is liquefied by adding a thermostable alpha-amylase enzyme and processing at a temperature (70 to 100 °C) and time (10 to 60 minutes) determined by the desired product properties. After completion of the enzymatic hydrolysis of the starch, the enzyme is inactivated and the water-soluble fraction consisting of soluble oat fiber and maltooligosaccharides is separated from the water-insoluble residue by centrifugation (Ref. 3). For brevity, we will refer to this substance as oatrim, which is the substance that is the subject of the claim in this interim final rule. Oatrim was developed by George Inglett, Agriculture Research Service, U.S. Department of Agriculture (USDA) (Ref. 3).

The petition describes the substance that is the subject of the health claim to

be ''oatrim (BETATRIM),'' a source of ''oat beta-glucan soluble fiber and oat starch obtained by enzymatic and/or acid-base hydrolysis of whole oat flour or oat bran.'' Thus, the substance as described by the petition includes, in addition to solubilized beta-glucan-containing oat products produced by the enzymatic hydrolysis method, solubilized beta-glucan-containing oat products produced by an acid-base chemical hydrolysis method. In addition, BETATRIM is the petitioners' brand-name for a group of beta-glucan-containing food ingredients. The petitioners have noted that the products they include under their brand-name are ''oatrims'' processed by either alpha-amylase enzymes or by acid/base hydrolysis, and having a beta-glucan soluble fiber content ranging between 4 and 25 percent. However, as discussed later in this preamble, we are limiting the substance that is the subject of the health claim to the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent (dwb) and not less than that of the starting material (dwb).

B. 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 from whole oats health claim (§ 101.81), FDA recognizes the CHD risk reduction benefit resulting from effects on blood total and LDL-cholesterol associated with certain foods that are sources of soluble dietary fiber. While 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. 4). CVD accounts for more than 900,000 U.S. deaths annually and has been recognized as the dominant cause of death in the United States for at least the last 50 years (Ref. 4). 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

Oatrim is to be consumed at ''other than decreased dietary levels,'' and contributes nutritive value when used at a level providing at least 0.75 g beta-glucan soluble fiber per serving, in a variety of food products. The term ''nutritive value'' is defined in § 101.14(a)(3) as ''value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.'' The petitioners provided three examples of food categories (bars, beverages and beverage mixes) in which oatrim could be used as an ingredient at a level providing 0.75 g beta-glucan soluble fiber per serving, the level necessary to justify the claim (Ref. 1, Table 3: Some Uses of Oatrim (BETATRIM)). At this level, oatrim provides nutritive value because it provides a consequential source of calories and soluble fiber. Therefore, the preliminary requirement of § 101.14(b)(3)(i) is satisfied.

3. The Substance Is Safe and Lawful

The petition states that oatrim has been used as a food ingredient in a variety of food products. The petition also notes that oatrim-containing foods including cereals, frozen foods, dairy products, beverages, baked products, mixes, and meat and poultry products have been consumed by the public for a number of years. The agency therefore is satisfied that the substance is a food, food ingredient, or a component of a food ingredient.

The petitioners assert that the basis for safe and lawful use of oatrim in food as a food ingredient, at levels necessary to justify the health claim, is that such food use of oatrim is GRAS (generally recognized as safe) by GRAS self-determination. In addition, the petitioners declare that BETATRIM derived from either oat bran or whole oat flour, and subjected to hydrolysis by treatment with safe and suitable food grade enzymes and/or GRAS listed food grade acids or bases, is GRAS through scientific procedures for use as a fat substitute in a variety of foods. The petitioners also declare that over the last several years, Quaker Oats and Rhodia have sold BETATRIM with a concentration of 4 to 6 percent beta-glucan soluble fiber, which has been incorporated by food manufacturers into a number of foods, including low-fat pancakes, muffins, biscuits, a low-fat, high-fiber nutrition bar, and fat-free frankfurters (Ref. 1). The petitioners submitted documentation of a 1992 GRAS self-determination for oatrim by The Quaker Oats Co. (Ref. 1, Appendix 3), a 1991 GRAS self-determination for oatrim by ConAgra (Ref. 1, Appendix 4), and an individual opinion regarding the GRAS status of purified forms of beta-glucan soluble fiber from oats (Ref. 1, Appendix 5) as evidence that oatrim meets the safe and lawful requirement.

The 1992 Quaker Oats Co. documentation of GRAS self-determination (Ref. 1, Appendix 3) characterized oatrim as the water soluble, partially enzymatically hydrolyzed starch fraction of whole oat flour. Oatrim was described as representing about 60 percent of the whole oat flour starting material, and containing 4 to 6 percent beta-glucan soluble fiber and 6.9 percent total dietary fiber. The Quaker Oats Co. determined that the use of oatrim as a fat replacer in fresh ground and processed meats and poultry products, salad dressings, baked goods, baking mixes, processed cheese, yogurt, ice cream and frozen desserts, snack foods, vegetable oil spreads, icings and frostings, frozen entrees, and confections was GRAS. The basis of the safety determination was the similarity of oatrim to oat starch and maltodextrin, two food ingredients that are generally recognized as safe for food use.

The 1991 ConAgra Specialty Grain Products Co. documentation of GRAS self-determination (Ref. 1, Appendix 4) characterized the processing of oatrim as ''oat flour or oat bran that is pre-gelatinized and enzyme thinned, by alpha-amylase, to facilitate separation and recovery of the soluble fraction.'' It noted that the basis of the safety determination was the similarity of oatrim to other existing cereal adjuncts, such as pre-cooked flours, pre-cooked bran, and starches.

The petitioners also submitted a letter from Joseph F. Borzelleca, Consultative Services, Medical College of Virginia & Toxicology and Pharmacology, Inc. (Ref. 1, Appendix 5), stating his opinion that beta-glucan soluble fiber extracted from oat bran or oat flour through enzymatic or by acid/base hydrolysis and containing a maximum concentration of beta-glucan of 25 percent is GRAS when used as a water-binder, humectant, or texture modifier. However, the substance that is the subject of this opinion letter is beta-glucan soluble fiber; the letter mentions neither oatrim nor BETATRIM, and does not describe a manufacturing process that would identify clearly the subject of the letter as oatrim.

The documentation of GRAS self-determination (Ref. 1, Appendices 3 and 4) includes oatrim produced by alpha-amylase hydrolysis and with a beta-glucan content of up to approximately 10 percent. The petition suggests that the Borzelleca Consultative Services' opinion on the GRAS status of beta-glucan soluble fiber extends to the petitioners' BETATRIM products that are manufactured by hydrolysis with

suitable acids or bases and that have a beta-glucan content of up to 25 percent.

FDA is not challenging the petitioners' determination that the beta-glucan-containing soluble fraction of hydrolyzed oat bran or whole oat flour produced by treatment with either alpha-amylase enzymes or with suitable acids or bases is GRAS. However, the scientific evidence submitted, as discussed in section III of this document, only supports a relationship between oatrim, i.e., the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb), and a reduced risk of CHD. The substance that is the subject of this health claim does not include the soluble fraction of hydrolyzed oat bran or whole oat flour solubilized by acids or bases or containing a beta-glucan content of over 10 percent or with less beta-glucan than that of the starting material. FDA has evaluated the petitioner's position that the use of oatrim at a level providing 0.75 g beta-glucan soluble fiber per serving is safe and lawful. Based on its review, 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 oatrim, as described previously, is safe and lawful as a food ingredient at levels necessary to justify a claim (Ref. 5).

The agency has not made its own determination regarding the GRAS status of either oatrim or other BETATRIM products. Moreover, an agency determination of the GRAS status of these other BETATRIM products would not be relevant to the substance that we are authorizing for this health claim, i.e., oatrim, because such BETATRIM is different from the oatrim that is the subject of this health claim and there is insufficient evidence before the agency to support a finding on the relationship between these other BETATRIM products and a reduced risk of CHD. The agency notes that authorization of 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 Oatrim and CHD

As previously noted, in the 1997 soluble fiber from whole oats final rule the agency was persuaded that whole oat flour has the same effects relative to reduced risk of CHD as do oat bran and rolled oats. The agency based its conclusion on: (1) Data from a clinical study and several experimental animal studies demonstrating that consumption of whole oat flour had similar effects on blood cholesterol levels as does consumption of oat bran or rolled oats and (2) compositional similarities between whole oat flour and rolled oats (62 FR 3584 at 3586). This conclusion was corroborated by evidence that the beta-glucan soluble fiber from whole oat flour retains the same level of viscosity in the digestive tract as does that from rolled oats. Accordingly, the soluble fiber from whole oats final rule included whole oat flour, along with oat bran and rolled oats, as eligible sources of beta-glucan soluble fiber for the health claim. We now are applying those same criteria to evaluate the petitioned request to add oatrim and other BETATRIM products to the sources of beta-glucan soluble fiber listed in § 101.81(c)(2)(ii)(A).

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

1. Scientific Evidence of Efficacy in Cholesterol Reduction

a. *Human serum lipid studies of oatrim.* The criteria that the agency used to identify studies pertinent to the current review were the same as those previously used when reviewing evidence supporting the relationship between reduced risk of CHD and consumption of soluble fiber from whole oat products (61 FR 296 at 298) and consumption of psyllium husk soluble fiber (62 FR 28234 at 28237, May 22, 1997). These criteria are: (1) Include an adequate presentation of data, study design, and methods; (2) be available in English; (3) include estimates, or enough information to estimate, soluble dietary fiber intakes; (4) include direct measurement of blood total cholesterol and other blood lipids related to CHD; and (5) be conducted in persons who represent the general U.S. population. Further, factors that exclude human studies from review are: (1) Reports published only in abstract form, (2) studies using special population groups, and (3) secondary prevention studies (i.e., subjects who already have had a myocardial infarction). In addition, in this current evaluation of the relationship between beta-glucan soluble fiber from oatrim and reduced risk of CHD, the agency has included only those studies in which the substance tested was identified to be oatrim or other BETATRIM products.

Reports of five human clinical studies with data on serum lipids were submitted with this petition (Refs. 6 to 10). The study of Braaten et al., 1994 (Ref. 7) and that of Beer et al., 1995 (Ref. 8) both investigated the effects of oat gum on serum cholesterol levels in humans. The study of Torronen et al., 1992 (Ref. 6) and that of Pick et al., 1996 (Ref. 9) both investigated the effects of oat bran concentrate products on serum cholesterol levels in humans. While oat gums and oat bran concentrate are sources of oat beta-glucan soluble fiber, the subject of the petition is oatrim and other BETATRIM products, the beta-glucan-containing soluble fraction from hydrolyzed oat bran or whole oat flour. Neither oat gum nor oat bran concentrates are produced through an extraction process analogous to the process for producing oatrim. As none of these four studies utilized the substance that is the subject of the petition, they were not relevant to the present consideration and were excluded from review.

The study reported in Behall et al., 1997 (Ref. 10) investigated the effects on blood lipids of adding an oat fiber extract, identified as the oatrim developed by George Inglett, Agriculture Research Service, USDA, to diets of mildly hypercholesterolemic subjects. The oat fiber extracts had either 1.6 percent or 10.2 percent by weight beta-glucan soluble fiber (low beta-glucan and high beta-glucan, respectively). Both oat fiber extracts (high and low) were provided by Quaker Oats Co. and by ConAgra, Inc. The petitioners comment in the petition that all of the oatrim that was used in this study had been processed by the enzymatic methods licensed from George Inglett. The oat fiber extracts were added to test diets, replacing 5 percent of the fat energy with a corresponding amount of carbohydrate energy, resulting in beta-glucan soluble fiber consumption of approximately 0.8 g/day (maintenance diet, no oat fiber extract addition), 1.6 to 2.0 g/day (low beta-glucan extract added), or 5.1 to 7.6 g/day (high beta-glucan extract added). The oat fiber extracts were added to the diet in several foods including fruit juice, applesauce, muffins, cookies, cake, brownies, waffles, gelatin, yogurt, spaghetti sauce and meat loaf. The study included 23 mildly hypercholesterolemic adult subjects (age 38 to 61 years) (mean serum total-cholesterol 212 ± 7 mmole/dL; mean LDL-cholesterol 141 ± 6 mmole/dL). The maintenance diet was fed for 1 week followed by diets containing one of the oat fiber extracts for two 5-week periods in a crossover pattern. In comparison to basal serum lipid levels measured following the initial maintenance diet week, serum total-cholesterol was statistically significantly lower ($p < 0.05$) by 9.5 percent (low beta-glucan

extract) and by 14.8 percent (high beta-glucan extract) following the oat fiber extract supplemented diet periods. The mean serum total-cholesterol levels were also statistically different ($p < 0.05$) between the two beta-glucan extract-supplemented diet periods. Likewise, for oat fiber extract-supplemented diets, statistically significant decreases ($p < 0.05$) of serum LDL-cholesterol levels of 14.8 percent (low beta-glucan extract) and by 20.8 percent (high beta-glucan extract) were observed, compared to the maintenance diet period. Serum LDL-cholesterol levels were not significantly different between the two oat fiber extract-supplemented diets. Serum HDL-cholesterol levels were not significantly different among the maintenance, low beta-glucan, or high beta-glucan diet periods.

The results of Behall et al., 1997 (Ref. 10), the only available study that evaluated the effects of oatrim on human serum lipid levels, demonstrate that consumption of a variety of foods containing oatrim produced by the enzymatic method, in amounts providing sufficient beta-glucan soluble fiber to qualify for the health claim, may contribute to statistically significant reductions in serum total- and LDL-cholesterol levels. Further, there appears to be a positive dose-response of the amount of beta-glucan soluble fiber from oatrim and the beneficial effect on serum total cholesterol.

b. *Animal serum lipid studies of oatrim.* The petition included reports from nine studies that investigated the effects of processed oat bran products on cholesterol metabolism in experimental animal models (Refs. 3, and 11 to 18). Among these were studies in which the oat products tested were oat gums (Refs. 11, 12, 14, and 15) or processed oat bran concentrate (Refs. 13 and 17). Results from these six studies were not directly relevant to the consideration of oatrim or other BETATRIM products as a source of beta-glucan soluble fiber eligible for the health claim, and were thus excluded from review. Three of the nine studies investigated effects of oatrim products on blood cholesterol level in experimental animals (Refs. 3, 16, and 18). Preliminary data from Inglett and Newman 1994 (Ref. 3) suggested reductions of plasma total- and LDL-cholesterol associated with the addition of oatrim containing 10-percent beta-glucan to the diet in a hypercholesterolemic chick model. These results were confirmed by Inglett et al., 1994 (Ref. 16) in a followup study with a larger sample of chicks and with an oatrim containing 8.6-percent beta-glucan. Oatrim did not affect plasma HDL-cholesterol levels in either of the above two studies (Refs. 3 and 16).

Yokoyama et al., 1998 (Ref. 18) reported on the effects of oatrim on cholesterol levels in a hypercholesterolemic hamster model. The hamster diets were supplemented with one of four oat flour products, or with cellulose. The oat flour products included a beta-glucan-enriched oat flour, a 5-percent beta-glucan oatrim, a 10-percent beta-glucan oatrim, and a beta-glucan-free hydrolyzed oatrim. All diets, except for the cellulose control and the beta-glucan-free hydrolyzed oatrim, contained equivalent amounts of beta-glucan. The two oatrim-containing diets and the beta-glucan-free oatrim hydrolyzate diet, were effective in showing statistically significant decreases ($p < 0.05$) in plasma total- and LDL-cholesterol levels relative to that of the cellulose-containing diet. The beta-glucan enriched oat flour-containing diet reduced neither plasma total- nor LDL-cholesterol levels. Statistically significant reductions ($p < 0.05$) in the plasma HDL-cholesterol level, relative to that of the cellulose-containing control diet, occurred with the two oatrim-containing diets and with the enriched oat flour-containing diet, but not with the oatrim hydrolyzate-containing diet.

Consistent with the clinical study, data from three animal models corroborate the finding that oatrim products containing beta-glucan soluble fiber lower blood total- and LDL-cholesterol levels. Furthermore, with the exception of the study employing a hamster model (Ref. 18), HDL-cholesterol levels were not significantly altered.

2. Composition of Oatrim Relative to Whole Oat Products

As discussed previously, a key factor in our decision to add whole oat flour to the food sources of beta-glucan soluble fiber eligible for the health claim was evidence that, other than being milled to a smaller particle size, the composition of whole oat flour and rolled oats is the same (62 FR 3584 at 3586). Oat bran differs from whole oat flour in that a portion of the starch-rich endosperm of whole oat flour has been removed whereas the outer soluble fiber-rich layers of the oat groat are retained. Although oatrim is derived from two of the same eligible food sources of beta-glucan soluble fiber currently authorized for the health claim, i.e., whole oat flour and oat bran, the composition of oatrim differs from each. Oatrim differs from oat bran and whole oat flour in that, in the manufacturing of oatrim, much of the starch present in the whole oat flour or remaining in the oat bran has been converted to soluble amylodextrins, and nonwater soluble components of the starting milled oat products are removed by centrifugation. However, like oat bran, the oatrim fraction produced from the manufacturing methods of Inglett and Newman, 1994 (Ref. 3) retains most of the beta-glucan soluble fiber and fiber-associated substances found in whole oat products.

3. Rat Intestinal Viscosity Studies

As explained in the soluble fiber from whole oats final rule, the viscosity of intestinal contents is known to be a critical factor in the ability of soluble dietary fiber to reduce the risk of CHD, and soluble dietary fiber viscosity is affected in unpredictable ways by food processing, or following ingestion, by the digestive system (62 FR 3584 at 3586). Therefore, evidence demonstrating that the level of viscosity in the digestive tract of the beta-glucan-containing oatrim is similar to the level of viscosity of rolled oats, oat bran, and whole oat flour is an important factor in our decision to add oatrim as an additional source of oat beta-glucan soluble fiber eligible for the health claim. As noted in the soluble fiber from whole oats final rule (62 FR 3584 at 3587), there are no generally accepted or validated criteria for predicting which sources or processed forms of beta-glucan soluble fiber beyond oat bran, rolled oats, and whole oat flour are capable of reducing blood total- and LDL-cholesterol levels. Therefore, FDA must evaluate data that are relevant to each source of beta-glucan soluble fiber and compare these data to other authorized sources. FDA considered evidence demonstrating that the processed sources of beta-glucan soluble fiber retain the same level of viscosity in the digestive tract as soluble fiber from rolled oats to determine whether the processed forms can provide the same benefits as rolled oats (62 FR 3584 at 3586).

The petitioners submitted results of animal tests to show that beta-glucan soluble fiber from oatrim or other BETATRIM products retains the viscosity characteristics of soluble fiber in whole oat products (rolled oats, oat bran, and whole oat flour) in the rodent digestive tract (Refs. 19 to 22). Gallaher et al., 1999 (Ref. 21) reported data on rat intestinal contents supernatant viscosity (ICSV) resulting from rats consuming an oat product meal. Rats that had been fasted overnight were meal-fed a whole oat-based cereal (Cheerios, cooked and uncooked oatmeal, or cooked oat bran).

Two hours later, the intestinal contents were collected, then centrifuged, and the viscosities of the resultant supernatants were determined. Differences in resultant mean ICSV values among the whole oat-based cereals tested were not statistically significant ($p > 0.05$). Gallaher et al., 1999 (Ref. 21) did not report data regarding the beta-glucan content of the whole oat-based cereals tested; however, based on information provided in the study report we have estimated that the whole oat-based cereal test meals contained approximately 0.12 g (Cheerios) to 0.22 g (oat bran) of beta-glucan per meal.

The ICSV data from Gallaher et al., 1999 (Ref. 21) were subsequently compared to ICSV data for the petitioners' enzymatically processed BETATRIM, also tested by Gallaher under the same test protocol (Ref. 22). The BETATRIM tested included a 4-percent beta-glucan BETATRIM, a 20-percent beta-glucan BETATRIM, and a blend of the two containing 12-percent beta-glucan. The petition identified the BETATRIM products used in this study as all having been produced with the alpha-amylase process. These test meals provided between 0.02 g and 0.10 g beta-glucan per meal. The blended 12-percent beta-glucan test meal (0.06 g beta-glucan/meal) yielded a mean ICSV value comparable to that of 0.12 to 0.22 g beta-glucan/meal from whole oat-based cereals. The mean ICSV value resulting from the high beta-glucan BETATRIM (0.10 g beta-glucan/meal) was approximately four times greater than that of 0.12 to 0.22 g beta-glucan/meal from whole oat-based cereals. These data indicate that the enzymatic processing of whole oat products into BETATRIM, and the subsequent digestion in the rat gastrointestinal tract, do not degrade the viscosity of oat beta-glucan soluble fiber relative to that of whole oat products.

The petitioners provided a report of a third viscosity study that was conducted to compare the viscosity of BETATRIM processed by the acid/base chemical method to that of BETATRIM enzymatically processed (Ref. 22). This viscosity study was conducted with the same test protocol as before, and using two sources of 20-percent beta-glucan content BETATRIM, one enzymatically processed and the other acid/base processed. The mean ICSV values for the two sources of 20-percent beta-glucan content BETATRIM were not statistically significantly different and were comparable to that of the previous study. No data were provided with respect to comparative ICSV values of enzymatic and acid/base processed BETATRIM products with beta-glucan content less than 20 percent.

The ICSV data demonstrate that the viscosity characteristics of beta-glucan soluble fiber in intact whole oat products is not degraded in the beta-glucan-containing soluble fraction of alpha-amylase hydrolyzed whole oat products. Further, the type of hydrolysis treatment, alpha-amylase enzymatic or acid/base, does not appear to have an effect on viscosity characteristics in products with beta-glucan content of 20 percent.

C. Physiochemical Properties

As noted previously, there are no generally accepted or validated criteria for predicting which sources or processed forms of beta-glucan soluble fiber are capable of reducing blood LDL-cholesterol, and therefore have an effect on CHD risk. Comments to the original soluble fiber from the whole oats proposed rule (62 FR 3584 at 3591) suggested that the effect on blood lipids from consumption of beta-glucan soluble fiber is related to both the molecular weight and the solution viscosity of the beta-glucan. The comments stated that processing methods can alter the molecular structure of the beta-glucan molecule and may cause it to lose its effect on blood cholesterol levels. The comments suggested that to ensure that the processed oat-containing food product will provide the effects associated with beta-glucan soluble fiber in the starting material, i.e., oat bran, rolled oats, and whole oat flour, the finished oat product should be tested to determine whether its beta-glucan soluble fiber has retained the physical properties, such as molecular weight, that it had in the starting material. FDA was not convinced, at the time of our initial soluble fiber from whole oats and CHD risk health claim rulemaking, that there was a need to require molecular weight or viscosity testing of foods containing oat bran, rolled oats, or whole oat flour. Although processing of whole oat substances could result in extensive depolymerization of the beta-glucan, there was clinical evidence demonstrating that most oat bran or rolled oats products processed as ready-to-eat cereals, muffins, breads, or other foods, whether they were consumed hot or cold, were effective in significantly lowering blood lipids when consumed as part of an appropriate diet.

Some studies failed to find blood lipid lowering effectiveness associated with consumption of highly processed oat gum extracts, but such studies were not relevant to FDA's analysis because FDA was authorizing the health claim for whole oat products only. As we are now proposing to extend eligible beta-glucan sources to include a processed extract of oat bran and whole oat flour, we also need to reconsider the utility of physiochemical measures of the beta-glucan soluble fiber sources that would be predictive of effectiveness in lowering blood lipids. However, we are unaware of clinical data that establish a direct correlation of any physiochemical measures (e.g., molecular weight, or viscosity) and of beta-glucan soluble fiber sources and effects on blood lipids.

Viscosity data from the ex vivo rat intestinal model of Gallaher et al. (Ref. 21) have been considered as corroborating evidence that the processing of whole oat flour or of oatrim does not significantly affect viscosity properties of the whole oat starting material from which it is made. However, we have no direct clinical evidence demonstrating the applicability of this model to predicting blood lipid-lowering effect in humans. Further, there are many methods of measuring the complex viscosity properties and the result is dependent upon the conditions of measurement. Although we do not recognize a standard method for measuring soluble viscosity applicable to a range of conditions, we do accept that soluble fiber viscosity is a major physiochemical property responsible for physiological effects of consuming soluble fiber, e.g., lowering blood lipids, and that viscosity is related to polymer size of the soluble fiber. For example, a study of viscosity as a variable in effectiveness of beta-glucan in altering blood glucose and insulin responses to an oral glucose load (Ref. 23) found a significant correlation between peak blood glucose and a combination of beta-glucan concentration and molecular weight. The agency is requesting comment and scientific data on the potential of using a molecular weight or other physiochemical properties as a predictive parameter of the ability of beta-glucan soluble fiber from highly processed sources to be effective in lowering blood lipids.

Lacking direct evidence correlating physicochemical properties of a substance with cholesterol-lowering efficacy in humans, we continue to rely on clinical intervention studies demonstrating effectiveness of a beta-glucan source in LDL-cholesterol reduction when we authorize additional eligible sources of beta-glucan soluble fiber. For this health claim, we were able to determine that a beta-glucan source from oat bran or whole oat flour (the starting materials), combined with limitations on the manufacturing

process (the alpha-amylase process used to manufacture the oatrim substance tested by Behall et al. (Ref. 10)) and on the beta-glucan content of the finished product, are sufficient to ensure an adequate description of the substance that is the subject of this claim. The substance that is the subject of the claim, i.e. oatrim, is that which was used in the Behall et al. study (Ref. 10) that demonstrated a reduction in risk of CHD. Parties considering variations of the processing method used to produce the oatrim used in the Behall et al. clinical trial (Ref. 10) would need to demonstrate the bioequivalence in cholesterol reduction of their products to those oat beta-glucan sources listed in § 101.81(c)(2)(ii)(A), and submit these data to FDA in a petition to amend the health claim regulation to include such processing variations in the definition of oatrim.

IV. Decision To Amend the Health Claim: Soluble Fiber From Whole Oats and Reduced Risk of CHD to Include Oatrim as an Eligible Source of Oat Beta-Glucan Soluble Fiber

Results from Behall et al., 1997 (Ref. 10) indicate that, like the effects of consuming rolled oats, oat bran, and whole oat flour, the beta-glucan-containing soluble fraction from alpha-amylase hydrolyzed oat bran and whole oat flour with a beta-glucan soluble fiber content up to 10 percent is effective in reducing blood total- and LDL-cholesterol levels, which in turn may reduce the risk of heart disease. Three studies employing various animal models also demonstrate a relationship between consumption of oatrim and a reduction in cholesterol levels. Furthermore, results from an experimental animal model of intestinal viscosity indicate that oatrim yields intestinal contents supernatant viscosity similar to that of beta-glucan soluble fiber in whole oat products. These data provide evidence of a physiological equivalence of beta-glucan soluble fiber from oatrim and beta-glucan soluble fiber from whole oat sources such as oat bran and rolled oats. Thus, these data support FDA's previous determination that, based on the totality of publicly available evidence, there is significant scientific agreement that a relationship exists between consumption of certain beta-glucan soluble fiber sources and reduced risk of CHD.

The petition requested that the amendment specifically reference Quaker-Rhodia BETATRIM brand-name products because they are the only sources with demonstrated blood cholesterol-lowering efficacy and retention of the whole oat product viscosity characteristics. We note, however, that the substance tested in the clinical cholesterol-lowering efficacy study, i.e., alpha-amylase hydrolyzed oat bran or whole oat flour, with not more than 10 percent beta-glucan content, was manufactured both by the Quaker Oats Co. and by ConAgra, Inc. Because the data upon which this health claim is based is not limited to petitioners' brand name products, FDA will not limit the health claim to these products. Instead, the health claim will be available to any substances that meet FDA's definition of oatrim, as specified previously.

Moreover, the substance tested in the clinical cholesterol-lowering efficacy study did not include acid-base hydrolyzed products or products with beta-glucan content exceeding 10 percent. Therefore, as previously discussed, the agency is not including substances other than oatrim, defined as the beta-glucan containing soluble fraction from alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb), as an eligible source of beta-glucan for this health claim. Based on the information before us, we are persuaded that the clinical evidence of positive effects on blood cholesterol of consuming this oatrim substance, provides sufficient evidence for the agency to conclude that oatrim has the same effects relative to reduced risk of CHD as do rolled oats, oat bran and whole oat flour. Further, this conclusion is corroborated by evidence from rat intestinal contents studies that demonstrate that processing of such oatrim does not degrade the viscosity characteristics of beta-glucan soluble fiber relative to the viscosity characteristics of the whole oat sources from which it is produced. The available clinical study demonstrated efficacy of oatrim on reducing serum cholesterol with oatrim added to the diet by incorporating it into a variety of foods including fruit juice, applesauce, muffins, cookies, cake, brownies, waffles, gelatin, yogurt, spaghetti sauce, and meat loaf. These foods cover a range of viscosities, densities, and textures (Ref. 10). The foods were functional, and the petitioners did not note any matrix effects on beta-glucan availability. Therefore, we conclude that the health claim for oatrim need not be restricted to any particular food category or type (Ref. 5).

In conclusion, we find that there is sufficient evidence to amend § 101.81(c)(2)(ii)(A) by adding the beta-glucan-containing soluble fraction from alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan content up to 10 percent (dwb) and not less than that of the starting material (dwb) as the fourth source of beta-glucan soluble fiber. We are not restricting the eligible substance to the Quaker-Rhodia BETATRIM brand-name, so that all foods that meet the eligibility requirements for oatrim under § 101.81 may use the claim. To this end, we are amending § 101.81, as discussed in section V of this document, to include beta-glucan soluble fiber from oatrim.

We have also concluded that there is insufficient evidence at this time to include beta-glucan-containing acid/base hydrolyzed oat products as a substance eligible for the health claim. Although there are direct clinical data and corroborating animal plasma lipids and viscosity data to support addition of oatrim with a beta-glucan content up to 10 percent, the only available data regarding hydrolyzed oat bran or whole oat flour with a beta-glucan content over 10 percent and that is manufactured using acid/base hydrolysis, are from a single experiment comparing viscosity of two oat products containing 20-percent beta-glucan. In one oat product, the hydrolysis treatment was alpha-amylase; in the other oat product, the hydrolysis treatment was acid/base (Ref. 22). In section II.B.3 of this document, we discussed whether oatrim used at levels necessary to justify a claim has been demonstrated to be a safe and lawful substance. FDA is not challenging the petitioners' contention that BETATRIM products produced from oat bran and whole oat flour treated with either alpha-amylase, or suitable acids or bases, and containing up to 25-percent beta-glucan, are GRAS. Hence, our decision not to include hydrolyzed oat products with a beta-glucan content of more than 10 percent and beta-glucan-containing acid/base hydrolyzed oat products, as substances which may be used in a food to make the food eligible to bear a claim about such sources of soluble fiber and reduced risk of CHD, rests on the lack of sufficient data to demonstrate such a relationship. We will evaluate any clinical data submitted in response to this interim final rule to demonstrate, by validated measures, that a relationship exists between consumption of hydrolyzed oat products with beta-glucan content over 10 percent and of acid/base hydrolyzed oat products and a reduced risk of CHD, to determine whether such data warrant a modification to this rule.

V. Description of Modifications to § 101.81

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

Section 101.81(c)(2)(ii) (nature of the substance; eligible sources of soluble fiber) lists the types and sources of soluble fiber that have been demonstrated to FDA's satisfaction to have a relationship to the reduced risk of CHD. Section 101.81(c)(2)(ii)(A) lists beta-glucan soluble fiber from whole oat sources, along with a method of analysis for beta-glucan soluble fiber by the Association of Official Analytical Chemists. Section 101.81(c)(2)(ii)(A)(*1*) through (c)(2)(ii)(A)(*3*) identifies the whole oat products that are eligible sources of beta-glucan, i.e., oat bran, rolled oats, and whole oat flour.

The nature of the substance for which we have concluded there is sufficient evidence to justify its addition to the list of eligible oat sources of beta-glucan is more narrowly circumscribed than that of the BETATRIM products requested by the petitioners. Oatrim, the substance to be added as an eligible oat source of beta-glucan soluble fiber is defined by the specific manufacturing process described by Newman and Inglett, 1994 (Ref. 3), by the limitations on the starting material from which the oatrim is extracted (i.e., oat bran or whole oat flour as defined in § 101.81(c)(2)(ii)(A)), and by the limitations on the beta-glucan content of the finished product (i.e., not less than that of the starting material and not more than 10 percent (dwb)).

In this interim final rule, we are amending § 101.81(c)(2)(ii)(A) by adding § 101.81(c)(2)(ii)(A)(4) which will specify the beta-glucan-containing soluble fraction of alpha-amylase hydrolyzed oat bran and whole oat flour, with a beta-glucan content up to 10 percent (dwb) and not less than that of the starting material (dwb), as a source of beta-glucan soluble fiber eligible to be the subject of this claim. Since the processing of oat bran and whole oat flour into oatrim involves only a liquefaction of starch and separation of insoluble components without alteration of the beta-glucan soluble fiber present in the starting material, we are specifying that the beta-glucan content of the oatrim product is not less than that of the starting material (dwb). New § 101.81(c)(2)(ii)(A)(4) specifies:

> Oatrim. The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section, or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

B. Nature of the Food Eligible to Bear the Claim

Section 101.81(c)(2)(iii)(A)(*1*) currently specifies that a food eligible to bear the health claim shall include one or more of the whole oat foods from paragraph (c)(2)(ii)(A) of this section (i.e., oat bran, rolled oats, whole oat flour), and that the whole oat food shall contain at least 0.75 g of soluble fiber per reference amount customarily consumed of the food product. We are concerned that expanding the eligible sources of beta-glucan soluble fiber from the current three whole oat sources to include oatrim, which is an extract of whole oat sources and has a character more as a food ingredient than as a whole oat food, may render current paragraph (c)(2)(iii)(A)(*1*) open to different interpretations as to the contribution of soluble fiber from oatrim-containing foods to meet the 0.75 g requirement. Oatrim-containing foods could contain sources of soluble dietary fiber other than oatrim. Although such foods may meet the criteria in § 101.81(c)(2)(iii)(A)(*1*) to bear the health claim (e.g., include a whole oat product listed in paragraph (c)(2)(ii)(A) and contain at least 0.75 g of soluble fiber), they would not necessarily contain sufficient beta-glucan soluble fiber from the oatrim ingredient to contribute in a meaningful way to the 3 g or more per day of beta-glucan fiber from whole oats necessary to reduce the risk of CHD.

The ''Nature of the Food'' section of the whole oats health claim originally was worded: ''The food shall contain at least 0.75 gram (g) per reference amount customarily consumed of whole oat soluble fiber from the eligible sources listed in paragraph (c)(2)(ii) of this section * * *''

However, when proposing to amend this regulation to broaden the health claim to the proposed rule on ''Soluble Fiber from Certain Foods and CHD'' and to add psyllium seed husk as an additional source of soluble dietary fiber eligible for the claim (62 FR 28234, May 22, 1997) the wording of § 101.81(c)(2)(iii)(A) was unintentionally changed to the present form that requires ''* * * 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product * * *'' The phrase used initially, ''whole oat soluble fiber,'' was intended to mean beta-glucan soluble fiber from whole oats (62 FR 3584 at 3588). This was based on information that the soluble fiber content of whole oats is predominantly (approximately 87 percent or more) beta-glucan. Thus, the total soluble fiber content of whole oats significantly reflects the beta-glucan present. Moreover, the agency thought the term ''soluble fiber'' would be more familiar to consumers than ''beta-glucan,'' because soluble fiber can be declared on the nutrition label; whereas, beta-glucan is a technical term that may not be widely understood. However, because of the possibility that oatrim-containing foods bearing the health claim could have insufficient amounts of beta-glucan, the specific type of soluble fiber that is the subject of this interim final rule, FDA is redesignating current § 101.81(c)(2)(iii)(A)(*2*), and adding new paragraph (c)(2)(iii)(A)(*2*) specifying that the oatrim-containing food bearing the health claim contain at least 0.75 g of beta-glucan per reference amount customarily consumed. FDA also is specifying that current paragraph (c)(2)(iii)(A)(*1*) refer to the three oat products previously authorized (i.e., oat bran, rolled oats, and whole oat flour).

In addition, FDA intends to consider in a future separate rulemaking the advisability of amending paragraph § 101.81(c)(2)(iii)(A)(*1*) to clarify that any food eligible for the health claim on the basis of containing a whole oat food must contain at least 0.75 g of beta-glucan soluble fiber from the whole oat source rather than 0.75 g of soluble fiber of unspecified type.

C. Other Requirements

All other requirements in § 101.81(c)(1) through (c)(2)(i) must be met before any health claim involving an oatrim-containing product can be utilized. FDA is providing that any or all of the optional information in § 101.81(d) may apply to oatrim.

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.

VI. 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. This authority enables us to act promptly on petitions that provide 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. Interim final 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)).

The petitioners have submitted requests for the agency to consider making any proposed regulation on the petitioned health claim effective upon publication of an interim final rule (Ref. 1). We acknowledge that all three of the eligible criteria in section 403(r)(7)(A) of the act have been met in the petition submitted by Quaker Oats and Rhodia, Inc. The health claim will provide consumers with important health information on the package label regarding the role of oatrim products in lowering cholesterol and reducing the risk of heart disease. The health claim also will provide consumers with scientifically sound information on the nutritional and health benefits of foods containing oatrim and will enable consumers to develop and maintain healthy dietary practices that include the incorporation of foods containing hydrolyzed oat products into their diets. Therefore, we are granting petitioners' requests for issuance of an interim final rule for this health claim.

VII. Analysis of Impacts

A. Regulatory Impact Analysis

We have examined the economic implications of this interim final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995. 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 of $100 million or more, or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation also is considered a significant regulatory action if it raises novel legal or policy issues. We have determined that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

This interim final rule will not generate any compliance costs relative to the status quo, because it does not require anyone to undertake any new activity. No firm will choose to use the claim allowed by this rule unless the firm believes that doing so will increase its profits. Because it specifies the manner in which a health claim can be made in product labeling, this rule imposes restrictions that may lead to social costs compared with alternative requirements for making the claim. The costs of making the claim under the specified requirements, however, would not differ significantly from the costs under plausible alternative requirements.

This interim final rule will generate social benefits because it provides for new information in the market regarding the relationship between soluble fiber and the risk of CHD. We have already authorized a health claim on beta-glucan soluble fiber from certain other whole oat sources and psyllium seed husk as sources of soluble fiber and the risk of CHD. Amending the existing health claim to include oatrim as an eligible source of beta-glucan soluble fiber will allow firms to inform consumers of the benefits of soluble fiber from oatrim. The provisions of this information in this format will signal to consumers that we have found the claim to be truthful, not misleading, and scientifically valid. Because it specifies the conditions under which a health claim can be made, this rule may lead to benefits that are greater or smaller than under alternative requirements for making the claim. The benefits of allowing the relevant claim, however, would not differ significantly from the benefits under plausible alternative requirements.

B. Regulatory Flexibility Analysis

We have 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 the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

As previously explained, this interim final rule will not generate any compliance costs for any small entities, because it does not require small entities to undertake any new activity. No small business will choose to use the soluble fiber from oatrim and CHD claim allowed by this rule unless it believes that doing so will increase its profits. Accordingly, we certify that this interim final rule will not have a significant economic impact on a substantial number of small entities. Under the Regulatory Flexibility Act, no further analysis is required.

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 rulemaking 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 1 year.'' We have determined that this interim final rule does not constitute a significant regulatory action under the Unfunded Mandates Reform Act.

VIII. 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.

IX. 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 oatrim and reduced risk of CHD is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

X. Federalism

We have 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, 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 Executive order and consequently, a federalism summary impact statement is not required.

XI. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this interim final rule by [see **DATES**]. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Submit one electronic 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 Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

XII. References

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

1. The Quaker Oats Co. and Rhodia, Inc., ''Oatrim (BetaTrim™) Health Petition,'' HCN1, vol. 1, Docket No. 01Q–0313, April 12, 2001.

2. Letter from Lynn Larsen, Center for Food Safety and Applied Nutrition, FDA, to Priscilla Samuel and Robert Murray, The Quakers Oats Co., Let 1, Docket No. 01Q–0313 and James T. Elfstrum, Rhodia, Inc., Let 2, Docket No. 01Q–0313, July 20, 2001.

3. Inglett, G.E., and R. K. Newman, ''Oat Beta-Glucan-Amylodextrins: Preliminary Preparations and Biological Properties,'' *Plant Foods for Human Nutrition*, 45:53–61, 1994.

4. Cooper, R., J. Cutler, P. Desvigne-Nickens, S. P. Fortmann, L. Friedman, R. Havlik, G. Hogelin, J. Marler, P. McGovern, G. Morosco, L. Mosca, T. Pearson, Jeremiah Stamler, D. Stryer, and T. Thom, ''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.

5. Memorandum to the record concerning oatrim beta-glucan health claim petition, prepared by Michael A. Adams, FDA, June 28, 2002.

6. Torronen, R., L. Kansanen, M. Uusitupa, O. Hanninen, O. Myllymaki, H. Harkonen, and Y. Malkki, ''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.

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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)(*4*), by revising paragraph (c)(2)(iii)(A)(*1*), by redesignating paragraph (c)(2)(iii)(A)(*2*) as paragraph (c)(2)(iii)(A)(*3*), and by adding new 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) * * *

(*4*) *Oatrim.* The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

* * * * *

(iii) * * *

(A) * * *

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

(2) 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; or

* * * * *

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25067 Filed 9–27–02; 4:39 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 02F–0042]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on meat carcasses, parts, trim, and organs. This action is in response to a petition filed by Ecolab, Inc.

DATES: This rule is effective October 2, 2002. Submit written or electronic objections and requests for a hearing by November 1, 2002.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3071.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 11, 2002 (67 FR 6265), FDA announced that a food additive petition (FAP 2A4731) had been filed by Ecolab Inc., Ecolab Center, 370 N. Wabasha St., St. Paul, MN 55102, proposing to amend the food additive regulations in Part 173 *Secondary Direct Food Additives Permitted in Food for Human Consumption* (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on meat parts, trim, and organs.

The agency has previously approved the use of the subject mixture on red meat carcasses (§ 173.370(b)(1)) in response to an earlier petition submitted by Ecolab, Inc. In the evaluation that led to that regulation, the agency considered ''red meat'' to include the species cattle, swine, sheep, goats, and equine. The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) uses the term ''meat'' to refer to these species (9 CFR 301.2). Thus, FDA is removing the term ''red'' as a descriptor for ''meat carcasses'' in § 173.370(b)(1) to make its terminology consistent with FSIS.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent on meat carcasses, parts, trim, and organs.

Therefore, FDA is approving the use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid as an antimicrobial agent on meat carcasses, parts, trim, and organs. Accordingly, § 173.370 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows: