Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.

- *Fax:* 1–202–493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For more information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document and the NPRM.

Privacy: We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. For more information, see the Privacy Act discussion in the **SUPPLEMENTARY INFORMATION** section of the NPRM.

Docket: To read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Timothy W. Shaver, Avionics Systems Branch, Aircraft Certification Service, AIR–130, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 385–4686; facsimile (202) 385–4651; e-mail *tim.shaver@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA continues to invite interested persons to take part in this rulemaking by submitting written comments, data, or views about the NPRM. We also invite comments about the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in the NPRM. The most helpful comments reference a specific portion of the NPRM, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

Background

On November 15, 2006, the Federal Aviation Administration (FAA) published Notice No. 06–16 in the **Federal Register** (Filtered Flight Data, 71 FR 66634) (the NPRM). The comment period for this NPRM ends on February 13, 2007.

By letter dated January 12, 2007, The Boeing Company (Boeing) asked the FAA to extend the NPRM's comment period for sixty days. Boeing intends to submit comments that will include an assessment of those parameters that fall within the proposed definition of filtered data for each of its affected airplanes. Boeing also intends to provide cost data related to the proposed requirements to analyze in-service airplanes. Boeing states that it needs an additional sixty days to complete these assessments.

The FAA agrees with Boeing's request for an extension of the comment period. We recognize the assessments being performed by Boeing are time-consuming, but are expected to produce valuable information.

We have determined that an additional sixty days will be enough for potential commenters to collect the cost and operational data necessary to provide meaningful comments to the NPRM. Absent unusual circumstances, the FAA does not anticipate any further extension of the comment period for this NPRM.

Extension of Comment Period

In accordance with 14 CFR 11.47(c), the FAA has reviewed the petition submitted by Boeing for an extension of the comment period to the NPRM. The FAA finds that an extension of the comment period for Notice No. 06–16 is consistent with the public interest, and that good cause exists for taking this action. The FAA also has determined that Boeing has a substantive interest in the proposed rule and has shown good cause for the extension.

Accordingly, the comment period for Notice No. 06–16 is extended until April 16, 2007.

Issued in Washington, DC, on January 29, 2007.

John J. Hickey,

Director, Aircraft Certification Service.

[FR Doc. E7–1834 Filed 2–5–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2006P–0069]

RIN 0910–AF94

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation authorizing a health claim on the relationship between soluble fiber from certain foods and risk of coronary heart disease (CHD). The amendment proposes to exempt certain foods from the nutrient content requirement of ''low fat.'' The exemption would apply if the food exceeds this requirement due to fat content derived from whole oat sources. FDA is taking this action in response to a petition submitted by the Quaker Oats Company (the petitioner). The amendment would expand the use of this health claim to some whole oat products that are currently ineligible for the health claim.

DATES: Submit written or electronic comments by April 23, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2006P–0069, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or

comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, 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: Vincent de Jesus, 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. Among other changes, the 1990 amendments clarified FDA's authority to regulate health claims on food labels and in food labeling. FDA issued several new regulations in 1993 to implement the health claim provisions of the 1990 amendments. Among these were § 101.14 (21 CFR 101.14), *Health claims: general requirements* (58 FR 2478, January 6, 1993), which sets out the rules for the authorization and use of health claims, and § 101.70 (21 CFR 101.70), *Petitions for health claims* (58 FR 2478, January 6, 1993), which sets out a process for petitioning the agency to authorize health claims about substance-disease relationships, and sets out the types of information that any such petition must include. Each of these regulations became effective on May 8, 1993.

When implementing the 1990 amendments, FDA also conducted a review of evidence for a relationship between dietary fiber and cardiovascular disease (CVD). Based on this review, FDA 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 at 2572, January 6, 1993). However, the agency did conclude that there was significant scientific agreement that the totality of publicly available scientific evidence supported an association between diets relatively high in 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 coronary heart disease (CHD)[1] (id.). 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 (§ 101.77 (21 CFR 101.77)) (58 FR 2552 at 2572). In the preamble to the 1993 dietary fiber and CVD final rule, FDA commented that if a manufacturer could document with appropriate evidence that consumption of the type of soluble fiber in a particular food has the effect of lowering blood (serum or plasma) low density lipoprotein (LDL) cholesterol, and has no adverse effects on other heart disease risk factors (e.g., high density lipoprotein (HDL) cholesterol), the manufacturer should petition for authorization of a health claim specific for that particular dietary fiber-containing food (58 FR 2552 at 2567).

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

In 1995, FDA received a petition for a health claim on the relationship between oat bran and rolled oats and reduced risk of CHD. FDA concluded there was significant scientific agreement that the totality of publicly available scientific evidence supported the relationship between consumption of whole oat products and reduced risk of CHD. FDA further concluded that the type of soluble fiber found in whole oats, i.e., beta-glucan soluble fiber, is the component primarily responsible for the hypocholesterolemic effects associated with consumption of whole oat foods as part of a diet that is low in saturated fat and cholesterol (62 FR 3584 at 3597 through 3598, January 23, 1997). As such, the final rule authorized a health claim relating the consumption of beta-glucan soluble fiber in whole oat foods, as part of a diet low in saturated fat and cholesterol, and reduced risk of CHD (the oat beta-glucan health claim). The source of beta-glucan soluble fiber in foods bearing this health claim had to be one of three eligible whole oat products, i.e., oat bran, rolled oats, or whole oat flour (see § 101.81(c)(2)(ii)(A)). In 2002, FDA amended § 101.81 to add oatrim as a fourth source of beta-glucan soluble fiber eligible for the oat beta-glucan health claim (67 FR 61773, October 2, 2002). Oatrim is the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour.

[1] Cardiovascular disease means diseases of the heart and circulatory system. Coronory heart disease, one form of cardiovascular disease, refers to diseases of the heart muscle and supporting blood vessels.

In order to bear the oat beta-glucan health claim, a food must, among other requirements, provide at least 0.75 grams (g) of soluble fiber per reference amount customarily consumed (RACC) and meet the nutrient content requirements in § 101.62 (21 CFR 101.62) for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food (§ 101.81(c)(2)(iii)(C)).

II. Petition and Grounds

The Quaker Oats Company (the petitioner), submitted a petition to FDA on November 7, 2005, under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) (Ref. 1). The petition requested that FDA amend the soluble fiber from certain foods and CHD health claim at § 101.81 so that foods that exceed the nutrient content requirement in § 101.62 for ''low fat'' due to fat content derived from whole oat sources (i.e., oat bran, rolled oats, whole oat flour, and oatrim) listed in § 101.81(c)(2)(ii)(A) would be eligible to bear the health claim. On February 15, 2006, FDA notified the petitioner that the agency had completed its initial review of the petition and that the petition had been filed for further action in accordance with section 403(r)(4) of the act. If the agency does not act, by either denying the petition or issuing a proposed regulation to authorize the health claim, within 90 days of the date of filing for further action, the petition is deemed to be denied unless an extension is mutually agreed upon by the agency and the petitioner (section 403(r)(4)(A)(i) of the act and § 101.70(j)(3)(iii)). On April 28, 2006, FDA and the petitioner mutually agreed to extend the deadline to September 30, 2006. On September 25, 2006, FDA and the petitioner mutually agreed to extend the deadline again to March 30, 2007.

The petition described a problem certain products have in meeting the eligibility criteria of the soluble fiber and CHD health claim. Quaker Oats Company produces, among other things, flavored varieties of reduced sugar instant oatmeal products as well as unmodified (with respect to sugar content) instant oatmeal products. The petition stated that Quaker Oats Company's flavored, unmodified instant oatmeal products are eligible to bear the soluble fiber and CHD health claim, but flavored, reduced sugar instant oatmeal products are not because the latter products do not meet the nutrient content requirement in § 101.62 for ''low fat.''

The petition stated that the formulation of flavored instant oatmeal products with ''reduced sugar'' (the term consistent with 21 CFR

101.60(c)(5)) made these products technically ineligible to bear the oat beta-glucan health claim because by reducing sugar, the products contain more whole oats (and fat from whole oats) per RACC. The petition provided the information on the amount of rolled oats, sugar, and total fat per packet and total fat content per 55 g RACC for both flavored unmodified instant oatmeal and flavored reduced sugar instant oatmeal. Both products contain the same amount of rolled oats (28 g) and total fat (2 g) per packet but differ in sugar content: 15 g per packet of flavored unmodified instant oatmeal and 3 g per packet of flavored reduced sugar instant oatmeal. According to the petition, the 12 g difference in sugar content corresponds with a 12 g difference in packet weight (31 g packet weight for the flavored reduced sugar instant oatmeal and 43 g packet weight for the flavored unmodified product). Therefore, at the RACC for flavored instant oatmeal (55 g), the reduced sugar product has more rolled oats than the unmodified instant oatmeal. The petition computed total fat per 55 g RACC to be 2.558 g for flavored unmodified instant oatmeal and 3.548 g for flavored reduced sugar instant oatmeal. Because the total fat content of the flavored reduced sugar instant oatmeal exceeds 3 g per 55 g RACC (even considering permissible rounding), this product is not eligible for the health claim.

The petition requested that FDA amend § 101.81(c)(2)(iii)(C) such that the ''low fat'' eligibility standard would not be applicable to foods exceeding this standard due to the total fat inherent in whole oat sources. The petition stated that such an amendment would have no impact on the benefit described in the soluble fiber and CHD health claim and discussed that the *2000 Dietary Guidelines for Americans* modified recommendations regarding total fat intake from a diet low in total fat to a diet moderate in total fat. The petition further stated that the total fat content and fatty acid composition of whole oats are consistent with the current authoritative understanding of dietary patterns likely to promote health and reduce risk of CHD, and referenced the executive summary of the *2005 Dietary Guidelines for Americans* for recommending less than 10 percent of total calories from saturated fatty acids and 20 to 35 percent of total calories from total fat, mostly from sources of polyunsaturated and monounsaturated fatty acids. The petition noted that the percent of calories from saturated fat and total fat in whole oats is 3 percent and 16 percent, respectively, and the ratio of saturated fatty acids to polyunsaturated plus monounsaturated fatty acids in whole oats is approximately 1:5.

The petition stated that amending the soluble fiber from certain foods and CHD health claim regulation to allow use of the claim on products with greater fat content due to a greater proportion of whole oat sources would: (1) Encourage food manufacturers to create products that are lower in added sugar while still retaining the heart-protective qualities of these whole oat-based foods and (2) enhance consumer's ability to incorporate beta-glucan soluble fiber into their diets while reducing their sugar consumption. The petition also stated that the additional level of inherent fat in whole oats would not have a negative impact on the benefit of the oat beta-glucan health claim.

The petition requested the following specific changes in the regulation governing the oat beta-glucan health claim:

- Modify § 101.81(c)(2)(iii)(C) to state ''The food shall meet the nutrient content requirement in § 101.62 for a 'low saturated fat' and 'low cholesterol' food'' and
- Create a new paragraph (c)(2)(iii)(D) stating ''The food shall meet the nutrient content requirement in § 101.62 for a 'low fat' food, unless it exceeds this requirement due to fat content solely derived from whole oat sources listed in paragraph (c)(2)(ii)(A).''

III. Decision To Amend the Health Claim

In regulations authorizing CHD-related health claims, FDA has required, with a few exceptions, that foods bearing such claims meet the ''low fat'' criterion defined by § 101.62(b)(2),[2] the ''low saturated fat'' criterion defined by § 101.62(c)(2), and the ''low cholesterol'' criterion defined by § 101.62(d)(2) (see authorized claims in 21 CFR 101.75, 101.77, 101.81, 101.82, and 101.83) rather than applying the total fat, saturated fat, and cholesterol content disqualifying levels specified in the general requirement for health claims (§ 101.14(a)(4)). The ''low fat'' criterion is currently applied to the soluble fiber from certain foods and CHD health claim in § 101.81(c)(2)(iii)(C).

As set out in § 101.62(b)(2), for purposes of the requirements for ''low fat,'' the measure of a food's total fat is the total fat per RACC (if the food has a RACC of 30 g or less or 2 tablespoons or less, the total fat measure is also based per 50 g of food). Hot dry breakfast cereals have two separate RACCs: 55 g for flavored, sweetened dry cereal and 40 g for plain dry cereal (21 CFR 101.12(b)). Thus, flavored, sweetened dry cereal has to contain 3 g or less of fat per 55 g, whereas plain dry cereal has to contain 3 g or less of fat per 40 g to meet the ''low fat'' criterion.

The petition discussed that the Quaker Oats Company's flavored reduced sugar instant oatmeal products are ineligible for the oat beta-glucan health claim because these products do not meet the ''low fat'' criterion, whereas its flavored, unmodified instant oatmeal product containing the same amount of rolled oats and fat, but 12 g more sugar per packet does meet the criterion. The petition stated that removing sugar from the flavored unmodified instant oatmeal product results in more whole oats (and thus fat from whole oats) per RACC. The petition requested an exemption to the requirement of ''low fat'' for foods that exceed this requirement due to fat contained in whole oat soluble fiber sources listed in § 101.81(c)(2)(ii)(A) (i.e., oat bran, rolled oats, whole oat flour, and oatrim).

To determine if the requested amendment is appropriate, the agency examined the amount of fat in the whole oat soluble fiber sources (i.e., whole oat flour, rolled oats, oat bran, and oatrim) eligible to bear the claim. The total fat content is about 6.9 g per 100 g for whole oats (same as whole oat flour) (Ref. 2), 6.3 g per 100 g for rolled oats (Ref. 2), 7.0 g per 100 g for oat bran (Ref. 2), and 2.1 g per 100 g for oatrim (Ref. 3). Whole oats contain a higher amount of total fat than barley (2.3 g per 100 g) or other cereal grains such as whole wheat (1.9 g per 100 g whole wheat flour), rice (2.9 g per 100 g brown rice), or corn (1.2 g per 100 g dry corn grits) (Ref. 2). As a result, it is possible that a product could exceed the maximum total fat permitted under the ''low fat'' requirement solely due to fat from whole oat sources. However, most whole oat products that are essentially all whole oats meet the ''low fat'' requirement unless fat from other sources are added. For some products that do not meet the ''low fat'' requirement due to fat from whole oat sources, the amount of fat exceeding the ''low fat'' requirement may be small. For

[2] ''Low fat'' food is defined in § 101.62(b)(2) as follows: (1) A food that has a RACC greater than 30 g or greater than 2 tablespoons and contains 3 g or less of fat per RACC or (2) a food that has a RACC of 30 g or less or 2 tablespoons or less and contains 3 g or less of fat per RACC and per 50 g of food. Further, meal products and main dish products, as defined in 21 CFR 101.13(l) and (m), respectively, are ''low fat'' if they contain 3 g or less of total fat per 100 g and not more than 30 percent of calories from fat (§ 101.62(b)(3)).

example, if a flavored, sweetened instant oatmeal product were made almost entirely of whole oats, the total fat content of this product would exceed the 3 g per RACC maximum to meet the ''low fat'' requirement, but would not exceed 4 g per RACC.

FDA also evaluated the type of fat in whole oats. Whole oats contain 1.2 g saturated fatty acids, 2.2 g monounsaturated fatty acids, and 2.5 g polyunsaturated fatty acids per 100 g (Ref. 2). Thus, polyunsaturated and monounsaturated fatty acids are the predominant types of fat in whole oats. Whole oats do not contain cholesterol. The *2005 Dietary Guidelines for Americans* (Ref. 4) recommended that total fat intake be kept between 20 and 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, that less than 10 percent of calories come from saturated fatty acids, and that cholesterol intake be less than 300 milligrams (mg) per day. Thus, the fat profile of whole oats is consistent with the *2005 Dietary Guidelines for Americans* recommendation of consuming a moderate amount of total fat with most sources coming from polyunsaturated and monounsaturated fatty acids, and limiting intake of saturated fatty acids and cholesterol.

FDA tentatively concludes that, for purposes of the oat beta-glucan health claim, it is appropriate to exempt foods that exceed the ''low fat'' criterion due to fat contained in whole oat sources listed in § 101.81(c)(2)(ii)(A) (i.e., oat bran, rolled oats, whole oat flour, and oatrim) from the requirement of ''low fat'' because: (1) The fat profile in whole oats is consistent with the *2005 Dietary Guidelines for Americans*; (2) the consumption of foods containing beta-glucan soluble fiber, such as whole oat products, is helpful in reducing the risk of CHD; and (3) the amount by which the fat content from whole oat sources may exceed the criterion of 3 g of fat per RACC (e.g., by no more than 1 g) is not likely to be a health concern.

FDA agrees with the petitioner that foods eligible for the oat beta-glucan health claim should meet the nutrient content requirement for a ''low fat'' food, unless it exceeds this requirement due to fat content solely derived from whole oat sources. The agency is aware that some whole oat products contain a small amount of fat from ingredients other than whole oat sources. Examples of the sources of fat included in these products are vitamin A palmitate, hydrogenated soybean oil, and soy lecithin. The petition has only requested that an exemption to the ''low fat'' requirement be given to foods that exceed this requirement ''due to fat content solely derived from whole oat sources listed in paragraph (c)(2)(ii)(A).'' Therefore, a food product that contains any fat from ingredients other than whole oat sources would not be exempt from the ''low fat'' requirement. The agency has not been given any justification why whole oat foods that contain sources of fat other than whole oat sources should be exempt from the ''low fat'' requirement. However, the agency would like to ensure that this proposed rule achieves its intent of providing consumers with more choices of whole oat products. Therefore, FDA asks for comment on whether or not whole oat food products that contain sources of fat other than whole oat sources should be exempt from the ''low fat'' requirement and, if so, how much and what type(s) of fat contributed by these sources would be acceptable.

IV. Description of Amendments to § 101.81

In light of the FDA's tentative decision to accept the petitioner's request, the agency is proposing to amend § 101.81(c)(2)(iii)(C) by removing the phrase, ''low fat'' food and creating a new § 101.81(c)(2)(iii)(D) to specify that the food shall meet the ''low fat'' food requirement, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in § 101.81(c)(2)(ii)(A).

V. Environmental Impact

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

VI. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed 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 does not believe that this proposed rule is an economically significant regulatory action as defined by the Executive order.

1. The Need for Regulation

Current § 101.81 authorizes a health claim on foods for the relationship between soluble fiber from certain foods and reduced risk of CHD. One of the requirements for the claim is the nutrient content requirement for ''low fat.'' In order to bear the claim, foods must contain no more than 3 g of fat per RACC. The RACC for plain oatmeal is 40 g dry weight and the RACC for flavored, sweetened oatmeal is 55 g dry weight, assuming that 15 g of sugar is added. The amount of fat in 40 g of rolled oats is just below 3 g, mostly polyunsaturated fatty acids and monounsaturated fatty acids. A recently introduced flavored reduced-sugar oatmeal does not meet the criterion of 3 g or less of fat per 55 g dry weight. Because the amount of added sugar in this reduced-sugar oatmeal is less than 15 g, the proportional amount of fat, essentially all from whole oats, is slightly more than 3 g of fat per 55 g of the product compared to the sweetened oatmeal, even thougth the total amount of fat in both the sweetened and reduced-sugar oatmeal products is the same.

The ineligibility of reduced-sugar oatmeal for this health claim, due to less added sugar, is an uninitended consequence of the regulation. The current regulation, without amendment, causes distortion in the market, where products are essentially penalized for adding less sugar or filler. In certain instances where two products are identical at the package level, except for the amount of sugar added, only the product with more sugar is able to carry the CHD health claim because the product with less sugar has more oats per RACC and exceeds the ''low fat'' requirement. The proposed rule is needed to remove this unintended consequence.

2. Regulatory Options Considered

The proposed rule would amend the regulation authorizing a health claim on the relationship between soluble fiber from certain foods and risk of CHD. The amendment would exempt certain foods from the nutrient content requirement of ''low fat.'' The exemption applies if the food exceeds this requirement due to fat content derived from oat sources.

In drafting this document, FDA considered two regulatory alternatives in addition to these proposed amendments. The agency considered: (1) No additional regulatory action and (2) general relaxation of the total fat requirement, while keeping in place

restrictions on saturated fat and cholesterol. This proposed rule would not be an economically significant regulatory action. FDA is not quantitatively estimating the benefits and costs of the regulatory alternatives to the proposed rule. In the following paragraphs, FDA qualitatively compares the costs and benefits of the regulatory options to the costs and benefits of the proposed rule.

a. *Option one*. The first option would be no action. As stated earlier in this document, the current rule as it stands causes an unintended distortion in the market. Consumers have a higher than necessary search cost to find products that are both reduced in sugar and that have similar attributes of those currently carrying the CHD claim. Furthermore, taking no action stifles the innovation of new products that have all of the attributes of those with the CHD claim and that are reduced in sugar.

b. *Option two*. A second alternative to the proposed rule is a general relaxation of the total fat requirement from all fat sources for all products covered by the rule, while keeping in place restrictions on saturated fat and cholesterol. Relaxing the restriction for total fat from whole oat sources will not dampen the signal of the CHD claim (i.e., it will not reduce the clarity of the message that products bearing that claim in their labeling may reduce the risk of CHD), whereas a general relaxation of total fat from all fat sources in such products may have a deleterious effect in that the fat content may be excessive and increase the risk of CHD and negate the health benefits from the beta-glucan soluble fiber sources. The total fat content is about 6.9 g per 100 g for whole oats (same as whole oat flour) (Ref. 2), 6.3 g per 100 g for rolled oats (Ref. 2), 7.0 g per 100 g for oat bran (Ref. 2), and 2.1 g per 100 g for oatrim (Ref. 3). Whole oats contain a higher amount of total fat than barley (2.3 g per 100 g) or other cereal grains such as whole wheat (1.9 g per 100 g whole wheat flour), rice (2.9 g per 100 g brown rice), or corn (1.2 g per 100 g dry corn grits) (Ref. 2). However, most whole oat products that are essentially all whole oats meet the ''low fat'' requirement unless fat from other sources is added. For some products that do not meet the ''low fat'' requirement due to fat from whole oat sources, the amount of fat exceeding the ''low fat'' requirement may be small. For example, if a flavored sweetened oatmeal product were made almost entirely of whole oats, the total fat content of this product would not exceed 4 g per 55 g of RACC.

Further, whole oats contain 1.2 g saturated fatty acids, 2.2 g monounsaturated fatty acids, and 2.5 g polyunsaturated fatty acids per 100 g (Ref. 2), and thus, polyunsaturated and monounsaturated fatty acids are the predominant types of fat in whole oats. Whole oats do not contain cholesterol. The *2005 Dietary Guidelines for Americans* (Ref. 4) recommends total fat intake be kept between 20 to 35 percent of calories, with most fats coming from sources of polyunsaturated and monounsaturated fatty acids, and less than 10 percent of calories from saturated fatty acids, and cholesterol intake be kept at less than 300 mg per day. Thus, the fat profile of whole oats is consistent with the *2005 Dietary Guidelines for Americans* recommendation of a moderate amount of total fat with most sources coming from polyunsaturated and monounsaturated fatty acids, and limiting intake of saturated fatty acids and cholesterol. Relaxing the total fat requirement for fat from whole oats will not have a negative health effect and will allow the CHD claim to retain clarity when directing consumers to products consistent with a diet that is low in saturated fat and cholesterol, and high in soluble fiber.

Relaxing the total fat requirement for fat from all fat sources in whole oat products may weaken the CHD claim signal that products bearing that claim in their labeling may reduce the risk of CHD. Under this scenario, products carrying the CHD claim could contain up to 13 g of fat per 55 g serving (i.e., the total fat disqualifying level for an individual food). The total fat disqualifying level is the level of total fat in a food above which the food will be disqualified from making a health claim (§ 101.14(a)(4)). Unlike whole oat sources, other products may have significantly more than the 3 g of fat per RACC that is the current total fat allowance for products carrying the CHD claim, and some may even approach the 13 g per RACC. Consumers using these products could easily increase their fat intake to levels above those recommended by the *2005 Dietary Guidelines for Americans* (Ref. 4). Furthermore, under current regulation that only stipulates disqualifying levels for saturated fat, cholesterol, and total fat, some of the increased fat intake could include *trans* fat.

The potential health benefits would therefore be lower and the costs higher under this option than under the proposed rule.

3. The Proposed Rule

This section details the potential costs and benefits of the proposed rule. The baseline in this case is the current rule, option 1 listed earlier in this section. Thus, the benefits of the proposed rule are derived from an increase in the number of products that carry the CHD claim from which consumers may choose. The costs of the proposed rule are the health effects associated with the potential net increase in fat intake and the new labeling costs if a manufacturer decides to voluntarily use the health claim.[3]

a. *Coverage of the rule*. FDA asks for comment on the number of products currently on the market that will qualify for the CHD claim if FDA finalizes the rule to permit the relaxation of the total fat requirement for fat from whole oat sources. FDA also requests comment on the number of new products that may be introduced due to the proposed rule. Because much of the information required to assess whether a product will qualify for the CHD claim is not required on the Nutrition Facts panel (NFP), FDA does not know with certainty how many products currently marketed will be affected by the proposed rule.[4] Furthermore, FDA cannot predict how many new products will be introduced because of the proposed rule.

In estimating the baseline number of products, FDA identified 5 products in the 2001 Food Label and Package Survey (FLAPS) (Ref. 5) that use the fiber related CHD claim. Of these products, three are hot cereals, one is a cold cereal, and one is wheat germ. Wheat germ products will not be affected by the proposed rule. Other types of products containing whole oats, such as cereal and snack bars, muffins, and cookies, will also not likely be affected by the proposed rule, as these products typically contain fat from sources other than whole oat sources, and would not be eligible to carry the CHD claim.

FLAPS is only a sample of all of the products available on the market. The five hot cereal products sampled made up 90 percent of all hot cereal sales in 2001. Therefore, it is possible that one or two products on the market that carry the CHD claim in 2001 were missed by the survey. The six cold cereals sampled

[3] As discussed in detail in section VI.A.3.c of this document, firms will not choose to label their product with the CHD claim if they could not make up the cost in higher margins for their products, increased volume of sales, or a combination of the two. Further, consumers would not pay the higher margin, or CHD claim premium, if they did not value the product relatively more than other products not carrying the claim. This increase in consumer willingness to pay for the CHD claim, though not to be confused with health benefits, will offset the private cost of the new labels.

[4] For example, the source of the fat content is not required on the NFP.

made up only 18 percent of all cold cereal sales in 2001. Assuming the sample is representative implies that six or more products carrying the CHD claim were not included in the survey. Since 2001, new products carrying the claim may have entered the market and some products may have dropped out. FDA requests comment on the baseline number of products carrying the CHD claim.

Through a search of the web and local grocery stores, FDA identified a single ''lower sugar'' hot cereal product that does not currently qualify for the CHD claim, but might under the proposed rule. The company that produces this product also produces two other ''lower sugar'' hot cereal products that qualify for the claim under the current rule. Beyond this single product, it is difficult to accurately predict how many products will be developed that would qualify for the claim under the proposed rule. Other ''lower sugar'' flavors might be developed. Furthermore, ''no sugar added'' products could be developed that could qualify for the CHD claim. Based on the current, limited information FDA estimates that between 1 and 10 current and future products will be affected by this proposed rule. FDA requests comment on this estimate.

b. *Benefits.* The principal benefits of the proposed rule are derived from an increase in the number of products that carry the CHD claim from which consumers may choose. Society benefits from the increased number of CHD claim products in two ways: (1) Increased consumer information and (2) a potential health benefit.

i. *Increased consumer information.* Consumers place a premium on products bearing a reduced CDH risk claim. That is, they value these products more than similar products not carrying the CHD claim. Part of this premium is due to a perceived health benefit. Part of it is also due to the fact that the CHD claim on the label, if consistent,[5] instantly gives the consumer a lot of information about the product and therefore reduces search costs. The proposed rule, for example, will greatly increase the efficiency of a consumer's search for a product that is lower in sugar and also has all the qualities of a product carrying the CHD claim. FDA requests comment on the magnitude of this benefit.

ii. *Potential health benefit.* If consumers substitute the new CHD claim products for less healthy alternatives, the proposed rule would have a positive health effect. If a consumer is currently eating a product daily that is ''lower in sugar'' but happens to be relatively high in saturated fat and cholesterol, that consumer could potentially enjoy better health by switching to the new ''lower in sugar'' product that also carries the CHD claim. For example, some evidence suggests that the risk of CHD may be decreased by more than 2 percent for every 1 g of oat bran consumed daily (Ref. 6). Without data allowing a prediction of consumer response, FDA cannot quantify this effect. Because the number of new products is likely to be small and the total dietary intake of consumers across the population is not likely to change drastically due to substitution between breakfast cereals, the health benefit is expected to be small.

c. *Costs.* The principal costs of the proposed rule are the new labeling costs, if a manufacturer decides to voluntarily use the health claim, and the possible negative health effect due to a potential increase in fat intake.

i. *Labeling costs.* Although voluntary labeling costs are necessarily less than the consumer premium placed on the products, it is useful to estimate the costs. Doing so gives a better idea of the costs generated and provides a lower bound to the total consumer utility gained from such products.

FDA used the *2004 FDA Labeling Cost Model* (Ref. 7) to calculate the potential new labeling costs produced by the proposed rule. The model calculates the cost of a new label based on the product type, label type, type of analytical and market tests necessary to develop the new label, compliance time, and inflation. Because the label is voluntary, firms can choose when to add the CHD label to their packaging and therefore can control the cost of the new label. If the firm chooses to immediately add the new label to the packaging, the full cost of redoing the label can be attributed to the CHD claim. Costs in this case will fall between $4.9 thousand and $10.6 thousand (mean = $6.8 thousand) per unique product. Firms typically update their label about every 3 years. If firms add the CHD claim when they would normally update their label, the cost of adding the new information on the package approaches zero.

New products that are developed because of the proposed rule will not incur new labeling costs due to the CHD claim label. They will simply work the claim into their initial label development. Because FDA only identified one current existing product that may qualify for the CHD claim because of the relaxation of the total fat requirement in the proposed rule, the one-time new labeling costs may fall between zero and $10.6 thousand.

ii. *Potential increase in fat intake.* One other potential cost arises if total fat intake increases as a result of this claim. Total fat intake could either increase or decrease due to the proposed rule. Under the proposed rule, products carrying the CHD claim will, on average, contain more total fat than under the current rule. If there is no substitution between CHD claim products and other products, then the total intake of mostly polyunsaturated and monounsaturated fats would increase slightly in the population currently consuming CHD claim products. There is no evidence that a small increase in unsaturated fatty acids due to increased consumption of whole oat sources, even for a person eating multiple servings daily, would cause a negative health effect. In fact, a person with such a diet would still easily fall within the recommended fat intake (Ref. 4). If there is substitution between other products and CHD claims products (for example, between CHD claims cereal and other cereals that are higher in fat), it is possible that new CHD claims products might actually cause a decrease in total fat consumption.

Due to the small number of products likely to make the CHD claim in the future, the health effect is likely to be small, but because some substitution from higher fat products is likely to occur, the health effect of the proposed rule with respect to fat intake will probably be positive.

d. *Summary of benefits and costs.* Benefits and costs of the proposed rule are likely to be small because few products will be affected. Voluntary labeling costs for those manufacturers who choose voluntarily to use the health claim are small (less than a one-time cost of $11 thousand) and necessarily less than the consumer premium placed on the products. Futhermore it is likely that, with more product choices available bearing the CHD claim, there will be a net shift towards these products carrying the claim and away from other products. Although the size of this shift cannot be estimated with available data, it would result in a public health benefit.

B. Small Entity Analysis

FDA has examined the economic implications of this proposed 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

[5] In section VI.A.2.b of this document, we assert that the relaxation of the total fat requirement for products made primarily of whole oats does not decrease the consistency or strength of the signal given by the CHD claim.

agencies to analyze the regulatory options that would lessen the economic effect of the rule on small entities. This proposed rule relaxes the total fat content requirement in the soluble fiber and CHD health claim for products whose fat content is derived solely from whole oat sources. Without this proposed rule, the more restrictive total fat content requirement would disqualify some products from being marketed with a CHD health claim. The proposed rule will not generate any compliance costs for any small entities because it does not require small entities to undertake any new activity. FDA therefore certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandate Analysis

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 one year.'' The current threshold after adjustment for inflation is $118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule, if finalized, to result in 1-year expenditures that would meet or exceed this amount and has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995.

VII. The Paperwork Reduction Act of 1995

FDA tentatively concludes that labeling provisions of this proposed 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 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)).

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have 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 (21 U.S.C. 343–1(a)(5)) 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—* * *(5) 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 soluble fiber from certain foods and reduced risk of CHD because no such requirements had been imposed by FDA under section 403(r) of the act. This proposed rule, if finalized as proposed, would amend existing food labeling regulations to provide an exemption for certain foods from the nutrient content requirement of ''low fat.'' Although the final rule would have a preemptive effect in that it would preclude States from issuing any health claim labeling requirements for soluble fiber from certain foods and a reduced risk of CHD that are not identical to those required by this proposed 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 the proposed rule, if finalized as proposed, 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's Division of Federal and State Relations is inviting the States' participation in this rulemaking by providing notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel of FDA's publication of the proposed amendment to the health claim regulation authorizing the health claim for soluble fiber from certain foods and CHD (§ 101.81). The notice provides the States with further opportunity for input on the rule. It advises the States of FDA's publication of this proposed rule and encourages the States and local governments to review the notice of proposed rulemaking and to provide any comments to the docket (Docket No. 2006P–0069).

In conclusion, the agency has determined that the preemptive effects of this proposed rule, if finalized as proposed, are consistent with Executive Order 13132.

IX. 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.

X. 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 addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. The Quaker Oats Company, ''Petition for Amendment of Health Claim Regulation (21 CFR § 101.81)—Beta-Glucan Soluble Fiber from Whole Oat Sources and Risk of Coronary Heart Disease,'' Item CP1, Docket 2005P–0449, November 7, 2005.

2. U.S. Department of Agriculture, Agricultural Research Service, *USDA National Nutrient Database for Standard Reference, Release 18*, Nutrient Data Laboratory Home Page (*http://www.ars.usda.gov/Services/docs.htm?docid=13747*), 2005.

3. The Quaker Oats Company and Rhodia, Inc., ''Oatrim [Beta Trim™] Health Petition,''

HCN1, vol. 1, Docket No. 01A–0313, April 12, 2001.

4. U.S. Department of Health and Human Services and U.S. Department of Agriculture, *Dietary Guidelines for Americans, 2005*, 6th Edition, Washington, D.C.: U.S. Government Printing Office, (*http://www.health.gov/dietaryguidelines/dga2005/document/*), January 2005.

5. U.S. Food and Drug Administration, CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements, *Food Label and Package Survey 2000–2001*, (*http://www.cfsan.fda.gov/~dms/lab-flap.html*), May 2006.

6. Institute of Medicine of the National Academies, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, the National Academies Press, Washington, D.C., pp. 367–368, 2005.

7. RTI International, *FDA Labeling Cost Model, Final Report*, (*http://www.foodrisk.org/lcm.htm*), October 2004.

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, and redelegated to the Deputy Director for Regulatory Affairs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

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

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

2. Section 101.81 is amended by revising paragraph (c)(2)(iii)(C) and by adding new paragraph (c)(2)(iii)(D) to read as follows:

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

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(C) The food shall meet the nutrient content requirement in § 101.62 for a ''low saturated fat'' and ''low cholesterol'' food; and

(D) The food shall meet the nutrient content requirement in § 101.62(b)(2) for a ''low fat'' food, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in paragraph (c)(2)(ii)(A) of this section.

* * * * *

Dated: January 30, 2007.

Michael M. Landa,

Deputy Director, Regulatory Affairs, Center for Food Safety and Applied Nutrition.

[FR Doc. E7–1849 Filed 2–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[Docket No. IN–156–FOR]

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The Indiana Department of Natural Resources, Division of Reclamation (IDNR, department, or Indiana) proposes revisions to its rules concerning the definition of ''government-financed construction''; underground mining reclamation plans for siltation structures, impoundments, dams, embankments, and refuse piles; performance bond release; surface mining permanent and temporary impoundments; surface mining primary roads; and inspections of sites. Indiana intends to revise its program to be consistent with the corresponding Federal regulations, to clarify ambiguities, and to improve operational efficiency.

This document gives the times and locations that the Indiana program and proposed amendments to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., e.t., March 8, 2007. If requested, we will hold a public hearing on the amendment on March 5, 2007. We will accept requests to speak at a hearing until 4 p.m., e.t. on February 21, 2007.

ADDRESSES: You may submit comments, identified by Docket No. IN–156–FOR, by any of the following methods:

- *E-mail: IFOMAIL@osmre.gov.* Include Docket No. IN–156–FOR in the subject line of the message.
- *Mail/Hand Delivery:* Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204.
- *Fax:* (317) 226–6182.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Comment Procedures'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Indiana program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Indianapolis Area Office: Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204, *Telephone:* (317) 226–6700, *E-mail: IFOMAIL@osmre.gov.*

In addition, you may review a copy of the amendment during regular business hours at the following location: Indiana Department of Natural Resources, Division of Reclamation, R.R. 2, Box 129, Jasonville, Indiana 47438–9517, *Telephone:* (812) 665–2207.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office. *Telephone:* (317) 226–6700. *E-mail: IFOMAIL@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders