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The Federal Energy Regulatory Commission (Commission) is issuing this notice to update filing fees that the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to 18 CFR 381.104, the Commission is establishing updated fees on the basis of the Commission's Fiscal Year 2007 costs. The adjusted fees announced in this notice are effective June 2, 2008. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this final rule is not a major rule within the meaning of section 251 of Subtitle E of Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. 804(2). The Commission is submitting this final rule to both houses of the United States Congress and to the Comptroller General of the United States.

The new fee schedule is as follows:

Fees Applicable to the Natural Gas Policy Act	
1. Petitions for rate approval pursuant to 18 CFR 284.123(b)(2). (18 CFR 381.403)	$10,440
Fees Applicable to General Activities	
1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act). (18 CFR 381.302(a))	20,970
2. Review of a Department of Energy remedial order:	
Amount in controversy	
$0–9,999. (18 CFR 381.303(b))	100
$10,000–29,999. (18 CFR 381.303(b))	600
$30,000 or more. (18 CFR 381.303(a))	30,620
3. Review of a Department of Energy denial of adjustment:	
Amount in controversy	
$0–9,999. (18 CFR 381.304(b))	100
$10,000–29,999. (18 CFR 381.304(b))	600
$30,000 or more. (18 CFR 381.304(a))	16,050
4. Written legal interpretations by the Office of General Counsel. (18 CFR 381.305(a))	6,010
Fees Applicable to Natural Gas Pipelines	
1. Pipeline certificate applications pursuant to 18 CFR 284.224. (18 CFR 381.207(b))	* 1,000
Fees Applicable to Cogenerators and Small Power Producers	
1. Certification of qualifying status as a small power production facility. (18 CFR 381.505(a))	18,030
2. Certification of qualifying status as a cogeneration facility. (18 CFR 381.505(a))	20,410

* This fee has not been changed.

List of Subjects in 18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

Thomas R. Herlihy,

Executive Director.

■ In consideration of the foregoing, the Commission amends Part 381, Chapter I, Title 18, Code of Federal Regulations, as set forth below.

PART 381—FEES

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

§ 381.302 [Amended]

■ 2. In 381.302, paragraph (a) is amended by removing ''$20,940'' and adding ''$20,970'' in its place.

§ 381.303 [Amended]

■ 3. In 381.303, paragraph (a) is amended by removing ''$30,560'' and adding ''$30,620'' in its place.

§ 381.304 [Amended]

■ 4. In 381.304, paragraph (a) is amended by removing ''$16,020'' and adding ''$16,050'' in its place.

§ 381.305 [Amended]

■ 5. In 381.305, paragraph (a) is amended by removing ''$6,000'' and adding ''$6,010'' in its place.

§ 381.403 [Amended]

■ 6. Section 381.403 is amended by removing ''$10,420'' and adding ''$10,440'' in its place.

§ 381.505 [Amended]

■ 7. In 381.505, paragraph (a) is amended by removing ''$18,000'' and adding ''$18,030'' in its place and by removing ''$20,380'' and adding ''$20,410'' in its place.

[FR Doc. E8–9548 Filed 4–30–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2006–P–0405] (formerly Docket No. 2006P–0069)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation authorizing a health claim on the relationship between soluble fiber from certain foods and risk of coronary heart disease (CHD). The amendment exempts certain foods from the nutrient content requirement of ''low fat.'' The exemption will apply if the food exceeds the ''low fat'' requirement due to fat content derived from whole oat sources. The amendment expands the use of this health claim to some whole oat products that are currently ineligible for the health claim. FDA is taking this

action in response to a petition submitted by the Quaker Oats Co.

DATES: This final rule is effective May 1, 2008.

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, 301–436–1774.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 6, 2007 (72 FR 5367), FDA published a proposed rule to amend the regulation authorizing a health claim on the relationship between soluble fiber from certain foods and risk of CHD. FDA proposed to amend the CHD health claim at § 101.81 (21 CFR 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. Specifically, FDA proposed 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). FDA issued this proposed rule in response to a health claim petition submitted by the Quaker Oats Co. (the petitioner) on November 7, 2005, under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)). Section 403(r)(3)(B)(i) of the act (21 U.S.C. 343(r)(3)(B)(i)) states that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) shall issue regulations for health claims if the Secretary determines, based on the totality of publicly available scientific evidence, that there is significant scientific agreement that the claim is supported by such evidence (see also 21 CFR 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on February 15, 2006.

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),[1] 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).

Prior to the publication of this final rule, foods such as Quaker Oats Co.'s flavored reduced sugar instant oatmeal products were ineligible for the soluble fiber from certain foods and CHD health claim because these products did not meet the ''low fat'' criterion, whereas its flavored, unmodified instant oatmeal product containing the same amount of rolled oats and fat, but 12 grams (g) more sugar, per packet does meet the criterion. The removal of sugar from the flavored unmodified instant oatmeal product resulted in more whole oats (and thus fat from whole oats) per RACC. Thus, these food products were not eligible to bear the soluble fiber from certain foods and CHD health claim because these foods exceed the ''low fat'' criterion due to the fat contained in the whole oat source.

In the proposed rule, FDA stated that a food product that contains any fat from ingredients other than whole oat sources would not be exempt from the ''low fat'' requirement. However, FDA asked for comment on whether 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 types(s) of fat contributed by these sources would be acceptable (72 FR 5367 at 5370).

FDA solicited comments on the proposed rule. The comment period closed on April 23, 2007. The agency received eight responses, each containing one or more comments, to the proposed rule. The comments were from trade associations, industry, a health professional organization, a foreign government, and consumers. Most of the comments supported the proposed amendment. One comment raised issues that were outside the scope of this rulemaking and will not be discussed in this document. The remaining comments and the agency's responses are discussed below.

(Comment 1) One comment opposed FDA exempting whole oat food products from the ''low fat'' requirement, but did not provide any specific information or data in support of its position.

(Response) The agency disagrees with this comment. FDA believes that the consumption of foods containing whole oat products is helpful in reducing the risk of CHD, and the amount by which the fat content derived solely from whole oat sources may exceed the low fat criterion would not be very significant and is not likely to be a health concern. Moreover, the exemption does not cover a food product that contains any fat from ingredients other than whole oat sources and granting this exemption will provide consumers more choices of whole oat products (72 FR 5367 at 5370). The comment did not provide any information or data in support of its position.

(Comment 2) One comment opposing the proposed rule argued that granting the exemption would be the same as saying that full fat whole oatmeal cookies could reduce the risk of heart disease.

(Response) The agency disagrees with the comment. As discussed in the proposed rule, only a limited number of products would be newly eligible to bear the claim (72 FR 5367 at 5372). Under the new exemption, a food must meet the ''low fat'' requirement ''unless the food exceeds this requirement due to fat content derived from whole oat sources'' (§ 101.81(c)(2)(iii)(D)). The products eligible to bear the claim would not contain any fat from sources other than the fat inherent in the whole oat sources. Food products that are typically made with other fat sources, such as cookies, would likely be ineligible for the claim.

(Comment 3) One comment opposing the proposed rule was concerned that the exemption allowing an exception to a marketing claim for a single food product that has been modified would confuse consumers.

(Response) FDA disagrees with the comment. Consumers will not be confused by this exemption because it does not apply only to a single food product. The final rule merely expands the use of this health claim to cover any whole oat product that was previously ineligible for the claim due to the fat derived from the whole oat source. The food product described in the petition only serves as an example of a consequence that was not intended

[1] ''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 reference amount customarily consumed (RACC) and per 50 g of food.

Further, under § 101.62(b)(3), meal products and main dish products (as defined in § 101.13(l) and § 101.13(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.

(reduction of sugar leading to ineligibility for the claim) in the authorization of the original health claim. The agency wishes to eliminate this unintended consequence and allow consumers access to information about the health benefits of whole oat sources.

(Comment 4) One comment stated that any health claim related to CHD should meet requirements of ''low soluble fibre, low saturated fat, and low cholesterol.'' The comment did not provide any specific information or data in support of its position.

(Response) Foods eligible for CHD-related health claims are currently required to meet the definition of ''low fat,'' ''low saturated fat,'' and ''low cholesterol,'' unless specifically exempted (see 21 CFR 101.75 (dietary saturated fat and cholesterol and CHD)), 21 CFR 101.77 (fruits, vegetables, and grain products containing fiber and CHD), § 101.81 (soluble fiber and CHD), 21 CFR 101.82 (soy protein and CHD), and 21 CFR 101.83 (plant sterol/stanol esters and CHD)). This final rule does not change the nutrient content requirements for ''low saturated fat,'' ''low fat,''or ''low cholesterol'' found in these CHD-related health claims. The agency notes that the soy protein and CHD health claim also contains an exemption for the ''low fat'' requirement. Specifically, the soy protein and CHD health claim requires the food to meet the nutrient content requirement for ''low fat'' found in § 101.62 ''unless it consists of or is derived from whole soybeans and contains no fat in addition to the fat inherently present in the whole soybeans it contains or from which it is derived'' (§ 101.82(c)(2)(iii)(C)).

Contrary to what the comment infers, foods are not required to meet any soluble fiber requirements to bear a CHD-related health claim except in the specific case where fiber has been declared as the substance that is the subject of the claim (i.e., the fruits, vegetables, and grain products containing fiber and CHD-related health claim found at § 101.77 and the health claim discussed in this rule). Even in these cases, the fiber requirement is to meet certain fiber levels, not to keep the fiber (soluble or otherwise) ''low.'' The agency has determined in these CHD-related health claims that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods may reduce the risk of CHD (see §§ 101.77(a) and 101.81(a) for explanations of the relationship between diets low in saturated fat and cholesterol that contain fiber). Therefore for these CHD-related health claims, the goal is to encourage the consumption of fiber-rich foods, and not to limit the amount of fiber in the food as the comment suggests.

(Comment 5) Two comments requested that FDA extend the exemption from the ''low fat'' requirement to other beta-glucan-containing food products, specifically whole grain barley, dry milled barley, and other barley products.

(Response) FDA is not now exempting other beta-glucan-containing food products from the ''low fat'' nutrient content requirement. As discussed in the proposed rule, 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. The total fat content of whole oat sources can be as high as 7.0 g per 100 g, whereas other cereal grain products are lower in fat. ''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)'' (72 FR 5367 at 5369). As a result of these nutrient compositions, it is likely that additional cereal grain food products on the market consisting of other cereal grains (and not including other sources of fat) would already meet the ''low fat'' requirement for the soluble fiber claim and would not require any exemption to this requirement. The agency is aware, however, that advances in food technology (such as the reduction of sugar in oatmeal products) can lead to consequences unintended by the original health claim, and in those cases, the agency can be petitioned under section 403(r)(4) of the act to address the issue in rulemaking.

(Comment 6) Two comments requested that FDA eliminate the ''low fat'' requirement for this health claim based on the latest 2005 *Dietary Guidelines for Americans* science and dietary recommendations. The comments recommended that a ''moderate'' level of fat should be the requirement that foods eligible for the claim should have to meet. This change, the comments noted, could allow food products eligible to bear the claim to contain as much as 13 g total fat (the total fat disqualifying level). In support of their position, the comments pointed out that the 2005 *Dietary Guidelines for Americans* do not require that diets be low in fat.

(Response) FDA is not revising the rule as requested by the comment. Section 101.81(c)(2)(iii)(C) states that a food eligible to bear a soluble fiber and CHD health claim must meet the nutrient content requirements in § 101.62 for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food. ''Low saturated fat,'' ''low cholesterol,'' and ''low fat'' are nutrient content claims defined by regulation (§ 101.62). ''Moderate fat'' is not defined by regulation nor was defining this term foreshadowed in the proposal. However, any interested person can petition the agency to define and authorize a new nutrient content claim for ''moderate fat'' under section 403(r)(4) of the act.

(Comment 7) One comment requested that FDA exempt fat from fortificants (e.g., vitamin A palmitate) from the ''low fat'' requirement because the amount of fat from fortificants would likely be ''inconsequential.''

(Response) FDA is not granting the requested exemption. The agency asked for comment in the proposed rule about whether to exempt whole oat products that contain sources of fat other than whole oat sources and, if so, how much and what type(s) of fat contributed by these sources would be acceptable. However, FDA did not receive, nor does it have, sufficient data regarding fortificants, such as vitamin A palmitate, to determine if whole oat foods that contain sources of fat from fortificants should be exempted from the ''low fat'' requirement.

Although FDA is not now revising the rule to include fat from fortificants as a source of fat eligible for the exemption from the ''low fat'' requirement, any interested person can petition the agency for such an exemption under section 403(r)(4) of the act.

(Comment 8) One comment requested that FDA confirm the nutrient composition values for total fat because the USDA National Nutrient Database has been updated since the proposal was published in February 2007.

(Response) The agency has confirmed that the values for fat composition of the grains cited in the proposed rule (i.e., about 6.9 g per 100 g for whole oats (same as whole oat flour), 6.3 g per 100 g for rolled oats, and 7.0 g per 100 g for oat bran) have remained unchanged in the newest release of the USDA National Nutrient Database for Standard Reference, Release 20 (Ref. 1).

(Comment 9) One comment suggested that FDA also provide exemptions to the per 50 g provision of the ''low fat'' requirement for foods with small serving sizes. The comment stated that products should not need to meet the ''low fat'' criteria on a per 50 g basis in addition to a per RACC and labeled serving size basis since products with small serving sizes (e.g., ready-to-eat cereals) would not be eligible for the health claim.

(Response) FDA advises that the exemption to the ''low fat'' requirement is not restricted by this final rule to food products with typical serving sizes. If a whole oat food product with a small serving size of 30 g or less or 2 tablespoons or less exceeds the ''low fat'' requirement on a 50 g basis due to fat derived solely from the whole oat source, it is exempted from the ''low fat'' requirement as well.

Given the information discussed in the preamble to the proposed rule and the absence of contrary information in the comments, FDA is adopting as a final rule, without change, the proposed amendment to § 101.81 to exempt certain foods from the nutrient content requirement of ''low fat'' if the food exceeds this requirement due to fat content derived from whole oat sources.

II. Analysis of Economic Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, 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 final rule is an economically significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule allows new voluntary behavior and imposes no additional restrictions on current practices, the agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

A. The Need for Regulation

Current 21 CFR 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 though 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 unintended consequence of the regulation. The current regulation, without amendment, causes a 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 final rule is needed to remove this unintended consequence.

B. Regulatory Options Considered

The final rule amends the regulation authorizing a health claim on the relationship between soluble fiber from certain foods and risk of CHD. The amendment exempts 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 certain oat sources.

In drafting this rule, FDA considered two regulatory alternatives in addition to the final rule. The agency considered the following alternatives: (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 final rule will not be an economically significant regulatory action. FDA is not quantitatively estimating the benefits and costs of the regulatory alternatives to the final rule. In what follows, FDA qualitatively compares the costs and benefits of the regulatory options to the costs and benefits of the final rule.

1. Option one. The first option considered is no action. As stated earlier, 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.

2. *Option two*. A second alternative to the final 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. 1), 6.3 g per 100 g for rolled oats (Ref. 1), 7.0 g per 100 g for oat bran (Ref. 1), and 2.1 g per 100 g for oatrim (Ref. 2). 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. 1). 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 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. 1), 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. 3) 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/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. 3). 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 final rule.

C. The Final Rule

This section details the costs and benefits of the final rule. The baseline in this case is the current rule, option one listed above, so the benefits of the final rule are derived from an increase in the number of products consumers have to choose from that carry the CHD claim. The costs of the final 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.[2]

1. Coverage of the 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 label, FDA does not know with certainty how many products currently marketed will be affected by the final rule.[3] Furthermore, FDA cannot predict how many new products will be introduced because of the final rule.

In estimating the baseline number of products, FDA identified five products in the 2001 Food Label and Package Survey (FLAPS) (Ref. 4) 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 final 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 final 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 6 cold cereals sampled 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.

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 final 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 final 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 one and ten current and future products will be affected by this final rule.

2. Benefits

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

a. Increased consumer information. Consumers place a premium on products bearing a reduced CHD 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,[4] This is where you want the beginning of your text to appear instantly gives the consumer a lot of information about the product and therefore reduces search costs. The final 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.

b. Potential health benefit. If consumers substitute the new CHD claim products for less healthy alternatives, the final rule will 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

[2] As discussed in detail in section C.3 of this regulatory impact analysis, a firm will not choose to label its product with the CHD claim if the firm can not make up the cost in higher margins for its product, increased volume of sales, or a combination of the two. Further, consumers will not pay the higher margin, or CHD claim premium, if they do 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.

[3] For example, the source of the fat content is not required on the Nutrition Facts label.

[4] In section B.2 of this regulatory impact analysis, 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.

oat bran consumed daily (Ref. 5). 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.

3. Costs

The principal costs of the final 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.

a. 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 Labeling Cost Model (Ref. 6) to calculate the potential new labeling costs produced by the final 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. Since 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 $4,900 and $10,600 (mean = $6,800) 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 final rule will not incur new labeling costs due to the CHD claim label. They will simply work the claim into their initial label development. Since 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 final rule, the one time new labeling costs are estimated to be between zero and $10,600.

b. 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 final rule. Under the final 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. 3). 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 final rule with respect to fat intake will probably be positive.

4. Summary of Benefits and Costs

Benefits and costs of the final rule are likely to be small because few products will be affected. Voluntary labeling costs for those manufacturers who choose to use the health claim are small (less than a one-time cost of $11,000) and necessarily less than the consumer premium placed on the products. Furthermore, 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.

III. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of the 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.

IV. Paperwork Reduction Act of 1995

FDA concludes that labeling provisions of this 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)).

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will 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 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) made in the label or labeling of food that is not identical to the requirement of section 403(r). * * *''

This final rule amends existing food labeling regulations to provide an exemption for certain foods from the nutrient content requirement of ''low fat.'' Although this rule has 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 final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both state legislative requirements and state common law duties. (*Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)).

FDA believes that the preemptive effect of this final rule 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.'' On February 5, 2007, FDA's Division of Federal and State Relations provided notice by 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).

In addition, the agency sought input from all stakeholders through publication of the proposed rule (72 FR 5367). FDA received no comments from any states on the proposed rulemaking.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive Order and has determined that the preemptive effects of this final rule are consistent with Executive Order 13132.

VI. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified all 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. U.S. Department of Agriculture, Agricultural Research Service. 2007. USDA National Nutrient Database for Standard Reference, Release 20. Nutrient Data Laboratory Home Page, *http://www.ars.usda.gov/ba/bhnrc/ndl*.

2. The Quaker Oats Co. and Rhodia, Inc., ''Oatrim [Beta Trim™] Health Petition,'' HCN1, vol. 1, Docket No. 01A–0313, April 12, 2001.

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

4. 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.

5. 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, DC, 2005, pp. 367–368.

6. RTI International, *FDA Labeling Cost Model, Final Report*, (*http://www.foodrisk.org/exclusives/FDA_LCM/*), 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, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

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

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

■ 2. Section 101.81 is amended by revising 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: April 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–9590 Filed 4–30–08; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 204

[DoD–2006–OS–0005]

RIN 0790–AH93

User Fees

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of Defense is revising 32 CFR Part 204 to better align it with Office of Management and Budget (OMB) Circular A–25, ''User Charges.'' This part provides guidelines to establish appropriate fees for authorized services supplied by Department of Defense organizations when such services provide special benefits to an identifiable recipient beyond those that accrue to the general public.

DATES: *Effective Date:* This rule is effective May 1, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Elaine Carpenter-Schmied, 703–697–0859.

SUPPLEMENTARY INFORMATION: On January 26, 2006 (71 FR 4332), the Department of Defense published a proposed rule on user charges with a comment period ending May 11, 2006. Comments included updating sited directives, spelling out acronyms, and inserting punctuation. All relevant comments were accepted. However, the revision did not include a schedule of fees and rates because DoD Components were responsible for computing user fees. With the exclusion of the fee and rate schedule proposed rule 32 CFR Part 204 no longer had an impact on the public. Upon further review and discussions between White House Services and the Government Accountability Office, it was determined fees should be based on full cost or market price and the rule should specify the principles used to compute these values. The revision was completed in October 2007.

Executive Order 12866, ''Regulatory Planning and Review''

It has been determined that 32 CFR Part 204 is a significant regulatory action. The rule has an annual effect to the economy of over $100 million.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4)

It has been certified that this rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any 1 year.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

It has been certified that 32 CFR part 204 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. The rule being promulgated provides guidelines to establish appropriate fees for authorized services supplied by Department of Defense organizations when such services provide special benefits to an identifiable recipient beyond those that accrue to the general public.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 204 does not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.