

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. 95P-0197]

RIN 0910-AA19

Food Labeling: Health Claims; Oats and Coronary Heart Disease**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use, on food labels and in food labeling, of health claims on the association between soluble fiber from whole oats and a reduced risk of coronary heart disease (CHD). Based on its review of evidence submitted with comments to the proposal, as well as of the evidence described in the proposal, the agency has concluded that the type of soluble fiber found in whole oats, i.e., beta (β)-glucan soluble fiber, is primarily responsible for the association between consumption of whole oats, including oat bran, rolled oats, and whole oat flour, and an observed lowering of blood cholesterol levels. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts to support the relationship between soluble fiber in whole oats and CHD. Therefore, FDA has decided to make the subject of the health claim "soluble fiber from whole oats" and has concluded that claims on foods relating the consumption of soluble fiber from whole oats to reduced risk of heart disease are justified. FDA is announcing this action in response to a petition filed by the Quaker Oats Company (the petitioner).

DATES: The regulation is effective January 23, 1997. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 101.81(c)(2)(ii)(A), effective January 23, 1997.

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SUPPLEMENTARY INFORMATION**I. Background**

In the Federal Register of January 4, 1996 (61 FR 296), the agency proposed

to authorize the use, on food labels and in food labeling, of health claims on the association between oat bran and oatmeal and reduced risk of CHD. The proposed rule was issued in response to a petition filed under section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall promulgate regulations authorizing health claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (see also § 101.14(c)).

FDA considered the relevant scientific studies and data presented in the petition as part of its review of the scientific literature on oat bran and oatmeal, i.e., rolled oats, and heart disease. The agency summarized this evidence in the proposed rule (61 FR 296).

The proposed rule included qualifying and disqualifying criteria for the purpose of identifying foods eligible to bear the proposed health claim. The proposed qualifying criteria were that a food provide 13 grams (g) of oat bran or 20 g of oatmeal, and that the oat bran and oatmeal contain, without fortification, at least 1 g of β -glucan soluble fiber. The proposal also specified mandatory content and label information for health claim statements and provided model health claims.

As part of the requirements for the claim, the agency proposed to allow a shortened version of the claim describing the relationship between diets high in oat bran and oatmeal and risk of heart disease that included a referral statement to the location of the full claim. The proposed version of the full claim described the relationship between diets low in saturated fat and cholesterol and high in oat bran and oatmeal and heart disease. FDA requested data on whether permitting a shortened claim will affect whether consumers will also read the full claim.

The agency also proposed to make the phrase "depends on many factors" optional information. The agency agreed with the petitioner's arguments that, based on an ever increasing background of health information made available through various media, consumers already understand that foods are not

drugs, and that health enhancement depends not only on consumption of a particular food but also on other dietary practices, exercise, heredity, lifestyle, and a host of other factors. The agency also agreed with the petitioner that the requirement that the claim use the term "may" or "might" to relate the ability of oat bran or oatmeal to reduce the risk of heart disease is intended to reflect the multifactorial nature of the disease. The agency requested written comments on the proposed rule, including comments on the agency's tentative decision to make the phrase "depends on many factors" optional information.

II. Summary of Comments and the Agency's Responses

In response to the proposal, the agency received approximately 1,450 letters, each containing one or more comments, from consumers, professional organizations, government agencies, industry, trade associations, and health care professionals.

The majority of the comments that the agency received agreed with one or more provisions of the proposed rule without providing grounds for this support other than those provided by FDA in the preamble to the proposal. Many of these comments also requested modification of one or more provisions of the proposed rule. A few comments disagreed with the proposed rule and provided specific support for their positions. The agency has summarized and addressed the relevant issues raised in all comments in the sections of this document that follow.

A. Food Substance Associated with Reduced Risk of CHD

Health claims have two essential elements: a food substance and a disease or health-related condition (§ 101.14). The agency proposed to authorize a health claim that diets high in oat bran and oatmeal and low in saturated fat and cholesterol may reduce the risk of CHD. Further, in the proposal, the agency tentatively agreed with the petitioner's position that, while current research may not demonstrate that β -glucan soluble fiber is the only component of oats that affects blood total- and low density lipoprotein (LDL)-cholesterol levels, potentially reducing the risk of CHD, β -glucan soluble fiber can serve as a marker for the food substance that is the subject of the claim. Therefore, FDA tentatively concluded that the relationship is based on a daily intake of not less than 40 g oat bran or 60 g oatmeal, without fortification, that provide 3 g or more per day β -glucan soluble fiber. The disease element of the claim is CHD, as

assessed by changes in serum total- and LDL-cholesterol levels in response to the consumption of specified levels of oatmeal or oat bran. A number of comments dealt with what should be the appropriate description of the food substance that is part of the health claim relationship.

1. Terminology

(Comment 1)

Some comments stated that the proposed claim seemed to be limited to hot cereals because the agency used the term "oatmeal" to describe one of the qualifying foods. A few comments suggested that the agency inappropriately used the term "oatmeal" for the more technically correct term "rolled oats," the dry form of the food before cooking or processing.

The agency did not intend to limit the proposed claim to hot cereals. As suggested by the comments, the agency was using the term "oatmeal" to be synonymous with the term "rolled oats," i.e., the dry oat product.

Likewise, the agency did not intend that use of the terms "oatmeal" and "oat bran" would mean that only hot, cooked cereals could bear the claim. The proposed claim was intended to describe the relationship between oat bran and rolled oats which can be used as single ingredients, such as in hot or ready-to-eat cereals, or as components of other foods that are served either hot or cold. Under the proposal, any oat product meeting the eligibility requirements for the claim could bear the claim. Because the term "rolled oats" is the technical term more commonly used to describe the dry form of the food, the agency has replaced the term "oatmeal" with "rolled oats" throughout this final rule.

2. Component of Oat Bran and Rolled Oats Responsible for the Effect

(Comment 2)

Some comments stated that the proposed claim inappropriately focused on oat bran and rolled oats as providing an effect on CHD risk. These comments suggested that it was the type of soluble fiber in oat products, specifically β -glucan, that was the primary component responsible for the relationship between the oat products and CHD. FDA had noted in its proposal that β -glucan soluble fiber was closely associated with the observed effect, but at the time, the agency tentatively concluded that β -glucan soluble fiber served as a marker for the food with potential to reduce the risk of CHD. Comments offered support for the view that β -glucan soluble fiber is more than just a marker in whole oats by referencing studies that

demonstrated effects of β -glucan independent of the food. These comments cited references in FDA's proposed rule (Refs. 12, 15, 33, 35, 38) and also provided additional references (Refs. 60 through 74) in support of their argument. According to these comments, this evidence suggests that β -glucan soluble fiber can provide an independent and meaningful effect and, in turn, supports that β -glucan is the primary component in whole oat products responsible for that effect on CHD risk factors. A few comments also noted that studies suggest a dose-response relationship between β -glucan soluble fiber and the effect on blood total- and LDL-cholesterol levels because the degree of effect is linearly related to the amount of β -glucan consumed (Ref. 66). Conversely, some comments supported the agency's proposed treatment of β -glucan soluble fiber as a marker for identifying a useful food product rather than as the active component.

In addition, several comments cited references to demonstrate that processing of oat products in ways that alter the physical structure of the β -glucan soluble fiber component (e.g., alter molecular structure and hence viscosity) results in a loss of effect on blood total- and LDL-cholesterol levels (Refs. 63 through 64). Several comments also noted that FDA's proposal cited the Torrenen et al. study (Ref. 38), showing that a special processing technique, when used with oat bran concentrate, appeared to reduce its effect on serum lipid levels. These comments cited the loss of effect with changes in the physical structure of β -glucan soluble fiber as evidence that there is a direct effect attributable to the presence of β -glucan soluble fiber, and that this effect is dependent not only on the chemical characteristics of the β -glucan soluble fiber but also on the retention of important physical characteristics such as viscosity.

Moreover, several comments cited references to show that it is the presence of a highly viscous soluble fiber in the intestinal tract that is determinative of the desired effect on CHD risk factors, and that, holding all other factors constant, changes in viscosity of intestinal contents alone result in significant effects on blood total- and LDL-cholesterol levels (Refs. 72 through 74). These comments, which were submitted by fiber experts, suggested that the ability of β -glucan soluble fiber to produce viscosity in the intestinal contents, while not the only mechanism by which soluble fibers have an effect on CHD risk, can be a clinically meaningful and independent factor

affecting CHD risk. Other comments cited studies that showed that oat β -glucan soluble fiber has viscous properties that are responsible for physiological effects on the glycemic response (i.e., changes in blood sugar levels following ingestion of foods) and suggested that the same viscous properties may also play a role in affecting blood total cholesterol levels (Refs. 60 and 69).

On the other hand, some comments stated that, while β -glucan soluble fiber is an important factor, other components in the oat products, including certain chemical characteristics and the tocotrienols that are part of the lipid fraction of whole oats, also contribute to the association with CHD risk reduction. Thus, according to these comments, specifying requirements for only β -glucan soluble fiber in the proposed regulation is not appropriate.

The agency has carefully reviewed the comments and evidence submitted on the issue of the significance of the β -glucan in the oat products and is persuaded that β -glucan soluble fiber is the primary, but not the only, component in whole oats that affects serum lipids. β -glucan thus plays a significant role in the relationship between whole grain oats and the risk of CHD. The agency reached this conclusion based on evidence that there is a dose response between the level of β -glucan soluble fiber from whole oats and the level of reduction in blood total- and LDL-cholesterol (Refs. 15 and 33), and that intakes of β -glucan soluble fiber at or above 3 g per day were more effective in lowering serum lipids than lower intake levels. These results are consistent with the results of the individual human studies reviewed in the proposal.

FDA, therefore, concludes that it is appropriate to change the food substance that is the subject of this authorization for claims from oat bran and rolled oats to β -glucan soluble fiber from whole oats.

3. Eligibility of Whole Oat Flour

(Comment 3)

A number of comments suggested that products containing whole oat flour made from 100 percent oat groats should be eligible to bear the health claim. The reasons given, some supported by data, included: (a) Evidence suggests that β -glucan soluble fiber is the primary contributor to the observed effect of oat bran and rolled oats, and whole oat flour contains β -glucan; (b) whole oat flour is derived from the same starting material as rolled oats (i.e., whole oat groats) and, other

than the smaller particle size of whole oat flour, possesses a chemical and physical composition virtually identical to rolled oats (Ref. 57); (c) animal studies demonstrate that, like the β -glucan soluble fiber from oat bran and rolled oats, whole oat flour β -glucan soluble fiber retains important physical characteristics during digestion (Ref. 68); and (d) data from a human study (Ref. 70) and several animal studies (Refs. 57, 66, and 71) show a positive effect of ready-to-eat cereals made with whole oat flour on risk factors for CHD. One comment submitted a recent, unpublished human clinical trial in which a ready-to-eat cereal made from whole oat flour was used as the test product (Ref. 70). Results showed that consumption of the cereal had a significant effect on blood total- and LDL-cholesterol levels as compared to the placebo cereal.

In considering the comments concerning the inclusion of whole oat flour in this rulemaking, the agency has reviewed the evidence referenced in these comments, including the additional data submitted. The agency noted the similarity of whole oat flour to rolled oats in terms of chemical and physical properties and type of processing. After careful consideration of the scientific evidence and the nature of the proposed health claim, FDA has concluded that products made with whole oat flour from 100 percent oat groats should be eligible to bear a claim.

FDA originally proposed the health claim that is the subject of this rulemaking for oat bran and oatmeal (i.e., rolled oats) because this was the claim requested in the petition that began this proceeding, and because the submitted evidence supported the relationship between the consumption of these foods and a reduced risk of CHD. However, the agency did not conclude in its proposal that the effect was uniquely that of oat bran and rolled oats, but rather that the evidence submitted by the petitioner supported the relationship for these foods. The comments argued, and pointed to evidence in the record as well as to evidence that they submitted that supported their claim, that whole oat flour has a similar composition, and had similar effects on blood cholesterol levels, as oat bran and rolled oats. They argued that, given these facts, it was the logical outgrowth of the proposal to enlarge the substances that could be the subject of a claim as part of this final rule to include whole oat flour.

FDA notes that one study submitted with a comment examined the effect of whole oat flour-based cereal on serum lipids in mildly hypercholesterolemic

subjects. Forty-three patients, aged 27 to 68 years, with mild to moderate hypercholesterolemia participated in this placebo-controlled study. The study consisted of three parts: a 4-week run-in on a Step 1 diet (i.e., a diet with less than 30 percent calories from fat, less than 10 percent calories from saturated fat, and less than 300 mg cholesterol), a 2-week baseline, and a 4-week treatment period. During the treatment period, subjects in the oat group continued to adhere to the Step I diet and consumed one prepackaged portion (1.5 oz.) of cereal twice a day, resulting in an estimated total daily intake of 3 g β -glucan from whole oat flour. Body weights were maintained at a constant level throughout the treatment period. Although there were differences in total-, high density lipoprotein (HDL)-, and LDL-cholesterol levels between the groups at baseline, the authors used an analysis of covariance to adjust data to a common baseline.

The results of the study showed that subjects consuming the whole grain oat cereal experienced a significant decrease in total cholesterol (4.4 percent or 10.0 milligrams (mg)/deciliter (dL)) and LDL-cholesterol (4.9 percent or 7.8 mg/dL), and no significant difference in HDL-cholesterol, compared to the placebo group. These results are consistent with the findings for oat bran and rolled oats, i.e., positive effects on blood total- and LDL-cholesterol levels in mildly hypercholesterolemic subjects adhering to a diet low in saturated fat and cholesterol. Therefore, this study, along with evidence submitted by comments showing compositional similarities between whole oat flour and rolled oats, provides sufficient evidence for the agency to conclude that whole oat flour has the same effects relative to reduced risk of CHD as do oat bran and rolled oats. Further, there is evidence that corroborates this conclusion that is provided by animal studies (Ref. 68). These animal studies addressed the issue of retention of viscosity characteristics during processing and digestion. Because viscosity of intestinal contents is known to be a critical factor in determining the ability of soluble fibers to reduce the risk of CHD (Refs. 56, 72, and 73), and because viscosity is known to be affected by food processing procedures or, following ingestion, by the digestive system in ways that are unpredictable (Refs. 56 and 65), evidence to demonstrate that the β -glucan soluble fiber from whole oat flour retains the same level of viscosity in the digestive tract as does that from rolled oats is crucial to the question of

whether whole oat flour can provide the same benefits as rolled oats.

The animal studies cited by one comment (Ref. 68) demonstrate that there is bioequivalence relative to these important physical characteristics between whole oat flour and rolled oats. When taken together, the available evidence provides a basis for concluding that it is appropriate to make whole oat flour, as well as oat bran and rolled oats, the subject of the authorized substance-disease relationship.

Therefore, for the purposes of § 101.81, the term "whole oats" includes oat bran, rolled oats, and whole oat flour. Changes to the codified sections of this rule to reflect the inclusion of whole oat flour are discussed in section II.B. of this document.

While FDA has added whole oat flour as a subject of the health claim in this proceeding, it must caution that it has done so here only because of the close relationship of whole oat flour to the substances that were the subject of the proposal and the very narrow increment of evidence necessary to broaden the claim to include this substance. Given the very tight timeframes that are established by the statute, and the agency's interest in ensuring that scientifically valid claims are authorized as quickly as possible, the agency cautions that it will not frequently be in a position to authorize claims about additional substances during the comment period. Thus, interested people would be well advised, if they are aware of a substance that should be the subject of a health claim, to petition for authorization for a claim about the substance rather than relying on the comment process to achieve that end.

4. β -glucan Soluble Fiber From Other Sources

(Comment 4)

Some comments, in noting the evidence to suggest that β -glucan soluble fiber is the component in oat bran and rolled oats responsible for their effect, further noted that the evidence suggests that β -glucan soluble fiber from other sources, such as barley and oat gums, affects the risk of CHD in the same way as β -glucan from the oat bran and rolled oats (Refs. 61 through 65, and 67). These comments requested that the proposed health claim be extended to any food product containing a specified level of β -glucan soluble fiber from any source including processed or novel sources of β -glucan soluble fiber.

Several comments suggested that one type of evidence to demonstrate that β -glucan soluble fiber from other food sources can affect the risk of CHD is the studies showing similar effects on blood total- and LDL-cholesterol levels among different β -glucan containing foods, including barley and oats (Refs. 61 through 65, and 67). Another comment cited a study showing that variability in effects on serum cholesterol levels among different barley cultivars is associated with differences in amounts of β -glucan soluble fiber (Ref. 64).

While acknowledging that there is evidence suggesting that consumption of β -glucan soluble fiber from a variety of food sources may help to lower blood total- and LDL-cholesterol levels, and thus reduce the risk of CHD, the agency disagrees that the claim should be extended at this time to all foods that contain a specified amount of β -glucan soluble from any source. The agency's decision to limit eligibility to bear a claim to oat bran, rolled oats, and whole oat flour is based on several considerations.

First, the proposed subject of this rulemaking was oatmeal and oat bran and their effect on the risk of CHD. FDA has examined in detail only the evidence for these oat products and whole oat flour. Other food sources of β -glucan soluble fiber (oat and non-oat sources) have not been carefully reviewed by FDA, nor has the totality of the evidence on these other sources of the fiber been submitted to the agency for review. Thus, the basis for including a wider range of food sources of β -glucan beyond whole oats in the regulation authorizing health claims is not presented by the administrative record, and consideration of these other sources is beyond the scope of this rulemaking.

Nonetheless, the agency recognizes that it is likely that consumption of other sources of β -glucan soluble fiber in addition to those that are the subject of this rulemaking will affect blood cholesterol levels. For this reason, and for reasons described elsewhere in this document in response to related comments about other soluble fibers, FDA is adopting a final rule that is structured so that it can be amended to establish a framework that will accommodate claims for other sources and types of soluble fibers and the risk of CHD.

Second, there currently are no generally accepted or validated criteria for predicting which sources or processed forms of β -glucan soluble fiber, beyond oat bran, rolled oats, and whole oat flour, are capable of reducing blood total- and LDL-cholesterol levels.

FDA, therefore, lacks criteria for differentiating among those sources that provide such effects and those that do not. This lack of evidence is of concern to the agency because, as discussed previously, certain types of processing may decrease the ability of the fiber to have the desired effect for reasons that are unpredictable and that vary from source to source. At the same time, it is known that certain physical characteristics related to the fiber's ability to maintain the viscosity of the intestinal contents must be present. However, the extent to which this capacity can be influenced by different food sources or by processing is unclear. Validated and accepted in vitro or animal methods for identifying this characteristic are not part of the administrative record for this rulemaking.

Human clinical trials can be used to resolve these issues. However, in the absence of clinical or other appropriate types of data in the administrative record, assumptions about the bioequivalence of all sources of β -glucan soluble fiber cannot be made at this time.

In authorizing the claim for whole oat flour as a result of comments to the proposal, FDA is relying on in vivo (animal) studies as evidence of the bioequivalence of whole oat flour relative to rolled oats. The agency feels comfortable in doing so because there is a human study to demonstrate the effectiveness of whole oat flour in reducing the risk of CHD, as well as information on the similarity in composition of whole oat flour to rolled oats. It is unclear to what extent such in vivo data from animal studies can be relied upon in the absence of corroborating human data. FDA will make decisions on this issue based on the totality of the available evidence. Thus, future petitions for other sources of β -glucan soluble fiber to be added as subjects of a health claim, which the agency anticipates receiving, should specifically address the appropriateness, the protocol used to develop, and the interpretation of, in vivo data from animal studies in demonstrating bioequivalence among soluble fibers.

5. Claims for Other Soluble Fibers (Comment 5)

Some comments stated that by proposing the oat bran and rolled oats health claim, the agency has acknowledged that soluble fibers themselves are an important functional component that affect serum lipid levels and thereby reduce the risk of CHD. These comments suggested that other soluble fibers have been shown to have

the same effects as that of β -glucan soluble fiber from whole oats on the risk of CHD. One comment discussed the evidence for psyllium and its capacity to affect serum lipid levels and thereby reduce the risk of CHD. These comments stated that, because other soluble fibers and purified gums can demonstrate cholesterol-lowering effects, the agency should authorize a broad claim for soluble fibers and reduced risk of CHD.

Several comments suggested that consumers would benefit from a soluble fiber and CHD claim in that it would be consistent with dietary recommendations to consume diets high in fiber and low in fat. However, some of the comments noted that differences in the source and method of processing whole oat β -glucan result in varied and unpredictable effects on the physical characteristics of the fiber, and that these differences may apply to other types of soluble fibers as well. The comments stated that, therefore, a claim for soluble fiber and heart disease should only be extended to those soluble fibers that have been demonstrated to reduce the risk factors related to CHD.

Another comment noted that, from a regulatory standpoint, a single claim on the relationship between certain soluble fibers and heart disease would be more manageable for the agency than would be attempting to authorize individual health claims for all the different soluble fiber sources that might be eligible to bear a CHD claim. The comment explained that, as other soluble fibers are shown to qualify to bear a soluble fiber/CHD claim, the regulation could be amended to include the additional substance.

FDA agrees with the comments that stated that there is evidence to suggest that consumption of a number of soluble fibers, in addition to β -glucan, affect blood total- and LDL-cholesterol levels and thus affect the risk of CHD. The agency reviewed evidence to this effect in evaluating the relationship between total dietary fiber and CHD in the final regulation published in the January 6, 1993 Federal Register (58 FR 2552). The agency noted, however, that there was some evidence that soluble fiber from different foods has different effects, and that the analytical measure of soluble fiber may not be adequately predictive of its physiological effects (58 FR 2552 at 2562). Therefore, FDA encouraged manufacturers to petition for a claim for their soluble fiber product if there was evidence to demonstrate that the particular soluble fiber-containing product is effective in lowering serum lipid levels (58 FR 2552 at 2562).

Further, FDA agrees that its decision to authorize claims on the association between oat bran, rolled oats, and whole oat flour and CHD represents acceptance that one type of soluble fiber, i.e., β -glucan soluble fiber from whole oats, has been adequately shown scientifically to have this effect. However, while the agency agrees with the comments that there is considerable likelihood that a similar showing will be made for certain other soluble fibers, based on the record now before the agency, it cannot take the steps suggested by the comments and broaden this claim. As the agency explained in the 1993 dietary fiber final rule, the effect of individual soluble fibers needs to be documented on a case-by-case basis. A concern about the ability of particular soluble fibers to affect CHD risk was expressed in several comments to the oat bran and oatmeal proposal. As mentioned previously, those comments stated that only soluble fibers that have been demonstrated to reduce serum lipids should qualify to bear a claim. The agency notes that a petition for soluble fiber from psyllium and risk of CHD is currently under consideration by the agency.

As mentioned previously, in the 1993 dietary fiber final rule, the agency encouraged manufacturers to petition for a health claim if the manufacturer could present scientific evidence to support the relationship between its soluble fiber product and risk of CHD (58 FR 2552 at 2567). By encouraging manufacturers to petition for a more specific health claim, the agency implied that it would consider a new claim for those soluble fiber products that had been shown to affect the risk of CHD. However, the agency did not commit to any particular course for how it would authorize health claims about a specific fiber source should it find them to be justified.

One way of doing so would be a regulation about each particular ingredient source of soluble fiber. This model is essentially the one that the agency utilized in the proposal. An alternative approach would be to adopt an umbrella regulation authorizing a claim for diets containing soluble fiber from certain foods and CHD but authorize the use of the claim for specific food sources of soluble fiber only when consumption of those foods has been demonstrated to help reduce the risk of heart disease. FDA agrees with comments that this alternative mechanism would provide flexibility, and that this flexibility may ultimately provide efficiency. However, based on the fact that it was not the agency's charge, in responding to this petition to

review the totality of evidence from other, non-oat sources of β -glucan soluble fiber or other types of soluble fiber, the agency finds that it is premature to authorize a broader claim for "soluble fiber from certain foods."

The agency may, at some point, decide to amend § 101.81 to cover types of soluble fiber other than β -glucan from whole oats. If a manufacturer can document, through appropriate studies, that a soluble fiber product has an effect on blood total- and LDL-cholesterol levels, and thereby the product can be useful in reducing the risk of CHD, the manufacturer may petition to amend § 101.81 to include that type of soluble fiber-containing product among the substances about which claims are authorized. This case-by-case approach is necessary because, as discussed in the oat bran and oatmeal proposal, soluble fiber is a family of very heterogeneous substances that vary greatly in their effect on the risk of CHD (61 FR 296).

In summary, in its proposal, the agency was responding to a specific petition to authorize claims about the relationship between oat bran and rolled oats and the reduced risk of CHD. In response to comments, however, FDA is now authorizing claims that describe the relationship between consumption of only a specific type of soluble fiber, β -glucan from whole oats, and reduced risk of CHD.

As suggested by comments, on-going research efforts are likely to build support for the relationship between CHD and consumption of other soluble fibers not addressed in this rulemaking. While the narrow focus of this rulemaking, and limitations on agency time and resources, preclude review of all such soluble fibers as part of this rulemaking, FDA will consider amending § 101.81 to establish a framework that will allow the agency to readily add the list of soluble fibers that can be the subject of a claim, as the evidence warrants.

Therefore, in this final rule, FDA has revised the title of § 101.81 to read: "Health claims; soluble fiber from whole oats and coronary heart disease." For this health claim, the statement "soluble fiber from whole oats" is intended to mean β -glucan soluble fiber from whole oats. Based on information provided in the petition and in some comments, the soluble fiber content of whole oats is predominantly (approximately 87 percent or more) β -glucan (Ref. 1, p. 22). Thus, the total soluble fiber content of whole oats significantly reflects the β -glucan present. Moreover, the term "soluble fiber" is more familiar to consumers than " β -glucan" because soluble fiber

can be used on the nutrition label under § 101.9(c)(6)(i)(A). β -glucan is a technical term that presumably is not widely understood.

Further, the agency has modified the regulation to reflect its decision to describe specifically the food substance that is the focus of the claim and to list the sources of β -glucan soluble fiber that have been shown to affect the risk of CHD. Thus, the agency has replaced the discussion in proposed section (c)(2)(ii) on the presentation of the claim with a new discussion, "Nature of the substance: Eligible sources of soluble fiber." This provision describes those sources of β -glucan soluble fiber that qualify for this claim. This section will be discussed in detail in section II.B., of this document.

Given the change in focus from oat bran and rolled oats to soluble fiber from whole oats, the agency is revising several sections of the proposed regulation. First, the words "diets high in oatmeal and oat bran" has been deleted from § 101.81(c)(2)(i) and reference to soluble fiber from whole oats is being added, so that § 101.81(c)(2)(i) will read, relevant part, "diets low in saturated fat and cholesterol that include soluble fiber from whole oats." The agency notes that the statement "diets low in saturated fat and cholesterol and high in soluble fiber from * * *" cannot be used at this time because the term "high" and its synonyms have been defined under § 101.54(b) as meaning that the food contains 20 percent or more of the Daily Reference Value (DRV) per reference amount customarily consumed (RACC) for a particular substance. There is no DRV for soluble fiber. While the agency recognizes that it would be helpful to encourage consumption of a specific amount of soluble fiber from whole oats, it cannot do so in the absence of a DRV for this nutrient. Therefore, the agency is wording § 101.81(c)(2)(i) to state that the diet "include" soluble fiber from whole oats, until such time that a DRV for soluble fiber is established. The agency intends to propose to establish a DRV for soluble fiber, and, once that rulemaking is completed, assuming it results in a DRV, it plans to revisit the requirements in § 101.81 and propose appropriate changes in the requirements for the wording of the claim. Other sections of the regulation that are affected by these changes include § 101.81(a), (b), and (c)(2)(i)(D). Additionally, FDA has deleted the phrase "oat bran and oatmeal" in paragraphs (c)(2)(i)(A), (c)(2)(i)(E), (d)(2), (d)(3), and (e) and replaced it with the statement "diets low in

saturated fat and cholesterol that include soluble fiber from whole oats.”

Other changes to the proposed regulation, in order of appearance, include the following: the second sentence of proposed § 101.81(a)(2) states “* * * These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as oatmeal and oat bran.” The agency is revising the last part of that sentence to read “* * * but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.”

Proposed § 101.81(a)(3) described oat bran and rolled oats as good sources of soluble fiber and stated that scientific evidence demonstrates that these products are associated with reduced blood total- and LDL-cholesterol levels. In light of the changes in this final rule intended to focus on the relationship between soluble fiber from whole oats and CHD, FDA has deleted the first sentence in proposed § 101.81(a)(3) and revised the second sentence to state, “Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from whole oats to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.” Again, the agency notes that it realizes that information about the amount of soluble fiber from whole oats to consume would be helpful information for consumers, but until a DRV is established, such information cannot be provided. The agency has concluded that the statements in paragraph (a)(3) accurately represent the relationship between diets low in saturated fat and cholesterol and CHD and between soluble fiber from whole oats and CHD.

Proposed § 101.81(c)(2)(i)(C) described what the claim could state in terms of a diet high in oat bran and oatmeal (paragraph (c)(2)(i)(C)(1)), and that the effect of a dietary intake of oat bran and oatmeal on risk of CHD was particularly evident when consumed as part of a diet low in saturated fat and cholesterol (paragraph (c)(2)(i)(C)(2)). In light of the change to a claim for soluble fiber from whole oats and the risk of CHD, FDA is deleting paragraph (c)(2)(i)(C) and adding two new paragraphs, (c)(2)(i)(C) and (D). These new paragraphs list the terms for use in specifying the soluble fiber and fat components of the claim (paragraphs (c)(2)(i)(C) and (D), respectively) and are discussed further in this section of this

document. With the addition of paragraphs (c)(2)(i)(C) and (D), FDA has redesignated proposed paragraphs (c)(2)(i)(D) and (E) as paragraphs (c)(2)(i)(E) and (F), respectively.

Section 101.81(d) contains optional information that may be included in the claim. In paragraph (d)(4) of the proposal, the agency proposed to permit manufacturers the option of describing oat bran and oatmeal as good sources of soluble fiber. For the reason given previously for the revision in paragraph (a)(3), the agency is deleting proposed paragraph (d)(4). FDA is replacing it with new paragraph (d)(4), which states “The claim may specify the name of the eligible soluble fiber.” Thus, the manufacturer may refer to “beta-glucan soluble fiber” in the health claim. The use of a specific soluble fiber name is appropriate as optional information but is likely too technical to be of interest to many consumers, and thus to require its inclusion in the claim would be contrary to the agency’s desire to provide for claims that are simple, concise, and easy for consumers to understand. The rationale for this change is discussed in more detail under section II.D.4. of this document.

6. Amounts of β -glucan Soluble Fiber Useful in Reducing the Risks of CHD (Comment 6)

One comment reexamined the data from the Davidson et al., study (Ref. 15) concerning the level of β -glucan consumption per day that is needed to affect blood total cholesterol levels and thereby reduce the risk of CHD. The results of the Davidson et al. study suggested a dose-response relationship between the level of β -glucan intake and the amount of change in blood total cholesterol. The petitioner presented the data from this study in a linear regression model to show the change in blood total cholesterol as a function of soluble fiber intake (Ref. 1, p. 26). The linear regression model showed that an estimated intake of 3 g per day soluble fiber (i.e., β -glucan soluble fiber) is associated with a reduction in blood total cholesterol of about 5 percent. The petitioner submitted the results of its analysis as support for the conclusion that 3 g per day of β -glucan soluble fiber is useful in affecting risks for CHD.

The comment stated that a nonlinear model fits the data better than the simple linear regression model. The comment stated that, based on the nonlinear model, 2.5 g/d β -glucan soluble fiber is necessary to lower blood total cholesterol 5 percent.

The agency does not agree that there is sufficient evidence to conclude that 2.5 g per day is more appropriate than

3 g per day, or that the nonlinear model is a better statistical approach than is the linear model. The data available from the Davidson et al. study are insufficient to determine superiority of the linear model compared to the curvilinear model. The results of the studies that showed an effect of soluble fiber from oat bran, rolled oats, and whole oat flour, and the results of the meta-analysis demonstrate that intakes of 3 g or more β -glucan are more likely to be effective. Thus, to use 2.5 g would be speculative, at best, and not supported by actual data. In contrast, the use of 3 g per day is. Therefore, the agency has concluded that, without further data, there is no justification for concluding that 2.5 g per day is a more appropriate estimate of the amount of β -glucan useful in reducing the risk of CHD than is 3 g per day.

7. Issues Related to a Food-specific Health Claim

(Comment 7)

Some comments stated that the proposed claim for oat bran and oatmeal should not be authorized because it will portray specific foods, i.e., oat products, as “magic bullets.” The comments suggested that the claim would mislead consumers in that it creates the impression that consumption of certain foods (oat bran and oatmeal) alone will protect against CHD, and in that it would not convey the concept that it is diets, not foods, that are important in risk reduction. The comments suggested that, as a result, consumers will be discouraged from making other important, and perhaps more effective, life-style changes to help reduce their risk of CHD. Some comments suggested that including reference to the diet in the claim will help prevent oat bran and rolled oats from appearing as “magic bullets.” However, there were many comments that stated that consumers are aware that no one food is a “magic bullet” in reducing the risk of disease.

Other comments stated that a claim for an individual food, such as that proposed for oat bran and oatmeal, is appropriate and would also be helpful to consumers because it would identify products that contribute to healthy dietary practices. A few comments expressed concern that consumers would inappropriately extrapolate from the effects of consuming oat bran and rolled oats set out in the health claim and assume a similar effect for all foods containing oat products, whether the foods are consistent with a total dietary pattern for risk reduction of heart disease or not. The comments likened this situation to the one that developed before the passage of the 1990

amendments, when some high-fiber food products bore a message from the National Cancer Institute suggesting that there was a relationship between fiber and risk of cancer. There was a proliferation of ingredient claims on products with trivial amounts of fiber.

A few comments stated that the proposed claim for oat bran and oatmeal should be folded into the authorized claim for fruits, vegetables, and grain products and heart disease (i.e., § 101.77). The comments stated that § 101.77 could be modified to permit the terms "oat bran" and "oatmeal" in the health claim. The comments explained that § 101.77 already establishes the specific requirements for foods that contain soluble fiber. The comments added that this would help prevent individual foods, such as rolled oats, from appearing to be "magic bullets."

The agency disagrees with the comments that stated that it should incorporate this health claim into the authorization for claims on the relationship between fruits, vegetables, and grain products and CHD (§ 101.77). Under § 101.77, soluble fiber is a marker for identifying useful foods, but no specific effect is attributed to the fiber. The claim that FDA is authorizing in this proceeding is based on the demonstrated effect of a certain type of soluble fiber (β -glucan soluble fiber) from a specific food source (whole oats). Therefore, the eligibility criteria and the scientific criteria set forth in § 101.81 are different from those set out in § 101.77. The agency concludes, consequently, that the two claims should not be combined.

The agency notes that, in this final rule, the relationship of whole oats to reduced risk of heart disease is being described in terms of the total diet. As discussed in more detail in response to comment 13 in section II.D.1. of this document, diets low in saturated fat and cholesterol are considered by expert groups to be the most effective dietary means of reducing heart disease risk (Ref. 5). While soluble fiber from whole oats can contribute to this effect, its role is generally recognized as being of smaller magnitude (Refs. 4 and 5). Describing the relationship of a total diet low in saturated fat and cholesterol that includes whole oats to the risk of CHD will prevent the oat-containing foods eligible to bear the claim from appearing to be "magic bullets."

B. Specifications for the Nature of the Food Substance Eligible to Bear the Claim

In the proposal, the food substances that were the subject of the claim were oat bran and rolled oats and the

products that contain them. The agency stated that the β -glucan soluble fiber content of these products is an appropriate marker for identifying the cholesterol-reducing potential of these products (61 FR 296 at 308) and established levels for β -glucan in foods that would qualify for the claim.

Based on its review of the comments, however, the agency has concluded that β -glucan is the primary component of whole oats that is responsible for the effect that consuming these foods has on the risk of CHD. Therefore, the agency has concluded that the substance-disease relationship that is appropriately the subject of a claim is that between β -glucan soluble fiber from whole oats and CHD. To reflect this judgment, the agency has modified the authorizing regulation to specify the sources of β -glucan that are appropriately the subject of a claim.

Section § 101.81(c)(2)(ii)(A) lists β -glucan soluble fiber and the whole oat sources of this substance. It also sets out the official Association of Official Analytical Chemists International (AOAC) method to be used to determine the β -glucan content of the food. Paragraph (c)(2)(ii)(A) states that the eligible source of β -glucan soluble fiber is from the whole oat sources specified in paragraphs (c)(2)(ii)(A)(1) through (3). Paragraph (c)(2)(ii)(A)(1) lists oat bran, paragraph (c)(2)(ii)(A)(2) lists rolled oats, and paragraph (c)(2)(ii)(A)(3) lists whole oat flour. The totality of the evidence establishes that consumption of these three sources of β -glucan soluble fiber as part of a diet that is low in saturated fat and cholesterol can reduce blood lipids and thus help reduce the risk of CHD.

1. Definition of Whole Oat Products

In the proposal, the agency set out a specific qualifying level of oat bran or rolled oats and β -glucan soluble fiber, i.e., 13 g of oat bran or 20 g of rolled oats that provide 1 g of β -glucan soluble fiber per RACC. (Comment 8)

Some comments noted that the variability in β -glucan soluble fiber content of oat products may affect whether these products qualify to bear this claim. Several comments stated that to ensure that products contain the appropriate amount of β -glucan soluble fiber, FDA needs to define oat bran because β -glucan soluble fiber levels vary among cultivars. Most of these comments encouraged adoption of the existing American Association of Cereal Chemists' (AACC) definition for oat bran.

The comments pointed out that the AACC definition requires that for a

product to be oat bran, it must have a total β -glucan content of at least 5.5 percent (dry weight basis (dwb)). As a result of processing oat groats to oat bran, β -glucan soluble fiber is more concentrated. Therefore, oat bran contains higher levels of this soluble fiber than rolled oats or oat flour.

Some comments explained that the level of β -glucan soluble fiber in rolled oats and oat flour more closely approximates the level of β -glucan in oat groats. This level may range from 3 to 5 percent, depending on the specific oat cultivar and on seasonal variation between crop years. One comment stated that the AACC had not adopted a definition of rolled oats because the product, oatmeal, has been on the market for over 100 years and is known to be a product made by rolling whole grain oats that have had 100 percent of the hull removed.

The agency is persuaded by the comments that, based on the variability in β -glucan soluble fiber content of oat cultivars, a definition of the eligible whole oat products that includes the β -glucan soluble fiber content will help ensure that a source of whole oats that bears a claim is consistent with those shown in clinical studies to lower blood lipids. In its review of studies in the proposal (61 FR 296 at 314), FDA observed that the results of most of the studies that failed to show a significant effect of oat bran on serum lipids used oat bran that provided less than 5.5 percent (dwb) of β -glucan soluble fiber (Refs. 13, 26, 27, 28, 36, and 41). For example, New Zealand oat bran was described to contain β -glucan soluble fiber within a range of 3.7 to 4.4 percent (Ref. 26). In the studies that showed an effect of oat bran on serum lipid levels, the oat bran provided more than 5.5 percent (the exact amount cannot be determined in all studies) β -glucan (Refs. 8, 11, 12, 15, 17, 20, 23 through 25, 29, 35, 39, and 42).

Thus, the agency agrees that adoption of the AACC definition of oat bran (Ref. 52), which requires that a product have a total β -glucan content of at least 5.5 percent (dwb) to qualify as oat bran, is appropriate. This definition was developed to respond to the confusion among oat processors, as well as others in industry and among home consumers, about a uniform identity of the product that was receiving widespread publicity with regards to its health benefits. Oat bran cannot be cleanly separated from the endosperm of oat groats (Ref. 52). Consequently, oat bran contains some flour and is rich in β -glucan soluble fiber, and debranned oat flour contains some bran but contains significantly less β -glucan.

Consequently, it became essential that the industry define what could be called "oat bran." It was the "rich" oat bran that has been used in clinical trials and that has been shown to lower serum lipids.

Therefore, FDA is adding the AACC definition of oat bran (Ref. 52) to § 101.81(c)(2)(ii)(A)(1). It states that oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions, such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dwb) β -glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber.

As discussed previously, there have been no formally accepted definitions of the terms rolled oats and whole oat flour. However, based on data provided in comments from fiber experts (Refs. 55 through 58), data from the U.S. Department of Agriculture National Nutrient Data Base (Ref. 75), and data provided in the petition (Ref. 1, p. 22 and Appendix II), the agency is providing general definitions for these terms that reflect the type of whole oat products used in clinical trials. As part of each definition, the agency is specifying the β -glucan soluble fiber and total dietary fiber contents of rolled oats and whole oat flour that are required for a product to qualify for this claim.

In light of the evidence presented in the proposal that some oat groats naturally contain low levels of β -glucan soluble fiber and, as a result, may not have hypocholesterolemic properties, the agency finds it important to set a minimum β -glucan content to ensure the effectiveness of these oat products. In new § 101.81(c)(2)(ii)(A)(2), the agency defines rolled oats, also known as oatmeal, as a product produced from 100 percent dehulled clean oat groats by steaming, cutting, rolling, and flaking, and that provides at least 4 percent (dwb) of β -glucan soluble fiber with a total dietary fiber content of at least 10 percent (Refs. 1, 55 through 58, and 75).

In new § 101.81(c)(2)(ii)(3), the agency is defining whole oat flour as a product that is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and that provides at least 4 percent (dwb) of β -glucan soluble fiber and 10 percent (dwb) total dietary fiber.

FDA agrees with the comments that definitions to identify of the whole oat substances that have been shown in clinical studies to help reduce serum lipids are important in light of the fact

that there are other whole oat substances, e.g., oat husks and fine oat flour, that have not been shown to provide this effect.

2. Testing of Oat Products to Ensure Retention of Characteristics (Comment 9)

Some comments suggested that the effect on blood lipids from consumption of β -glucan soluble fiber from whole oat products is related to the molecular weight and the solution viscosity of the β -glucan. The comments stated that processing methods can alter the size and molecular weight of the β -glucan molecule and may cause it to lose its effect on blood cholesterol levels. The comments suggested that to ensure that the processed oat-containing food product will provide the effects associated with the β -glucan soluble fiber in the starting material, i.e., oat bran, rolled oats, and whole oat flour, the finished oat product should be tested to determine whether its β -glucan soluble fiber has retained the physical properties, such as molecular weight, that it had in the starting material.

The agency is not persuaded that there is a need for testing for the molecular weight and solution viscosity of the β -glucan in products that contain oat bran, rolled oat, or whole oat flour. Although processing can produce extensive depolymerization of the β -glucan, oat bran and rolled oats were fed to subjects in a variety of processed foods as part of the scientific studies that evaluated the effects of these ingredients on blood cholesterol levels (see Table 1, 61 FR 296). Regardless of whether the whole oats were processed into cereals, muffins, breads, or other foods, or whether they were consumed hot or cold, the majority of oat products significantly lowered blood lipids when consumed as part of an appropriate diet.

The agency noted that, in the few studies that did not demonstrate cholesterol-lowering effects from the consumption of oat bran or rolled oats, the authors attributed the lack of an effect to either the source of the oat cultivar, specifically a New Zealand cultivar that had a low content of soluble fiber (one case), or to an effect of processing to purify an extract of the β -glucan soluble fiber (one case) (61 FR 296 at 305). Thus, the lack of an effect in one of these cases was associated with an unusually low level of β -glucan in the oats. This problem is protected against by the β -glucan content requirement in § 101.81(c)(2)(ii)(A)(1), (2), and (3). In the other case, the lack of effect was associated with the use of a highly processed oat gum extract. This result does not represent a problem

under § 101.81 because FDA is only authorizing claims on whole oat products.

Therefore, the agency finds that there is no need for testing the physical properties of the β -glucan soluble fiber in processed products containing whole grain oats.

C. Nature of the Food Eligible to Bear the Claim

Proposed section § 101.81(c)(2)(iii)(A) stated that for a food to be eligible to bear the claim, it must contain 13 g of oat bran or 20 g oatmeal, and that the oat bran or oatmeal must contain, without fortification, at least 1.0 g of β -glucan soluble fiber per RACC. The agency noted that consumption of 3 or more g of oat β -glucan soluble fiber per day was associated with significant reductions in blood total- and LDL-cholesterol levels. It tentatively concluded that it is reasonable to assume that a person could consume a total of at least 40 g oat bran, 60 g oatmeal, or a combination of the two, to provide 3 g β -glucan soluble fiber in the course of three eating occasions a day.

1. Qualifying Criteria for Foods (Comment 10)

Some comments agreed with the proposal and emphasized that foods should contain a significant amount of oat bran or oatmeal in order to qualify for this claim. A few comments stated that the claim should be allowed only on foods for which a customary serving enables consumers to achieve the desired effect on the risk of disease (i.e., 3 g β -glucan per serving of food). However, a number of comments suggested that it is unrealistic to assume consumers will eat enough oat bran or oatmeal daily for the rest of their lives to lower their risk of cardiovascular disease.

Some comments suggested that the proposed qualifying levels of oatmeal, oat bran, and β -glucan were overly restrictive and prevented a number of important oat-containing foods from bearing the claim. These comments requested that the qualifying levels of oat bran, oatmeal, or β -glucan be lowered so that more products could qualify to bear the claim. Several suggested that Americans are more likely to increase their consumption of soluble fiber if they are presented with a wide variety of whole-grain oat-containing foods that may be eaten over the course of the day. The comments suggested various qualifying levels for a food to bear the claim, ranging from 6 to 15 g of oatmeal or from 4 to 11 g of oat bran.

Some comments recommended setting only a level of β -glucan soluble fiber that must be contained in the food to qualify for this claim, rather than a level of oat bran or oatmeal as well as a level of β -glucan soluble fiber. These comments argued that the level of the β -glucan soluble fiber in the product is a marker of the product's usefulness in reducing the risk of CHD, and that if a product contains the appropriate amount of β -glucan soluble fiber, it should qualify to bear the claim no matter how much oat bran or oatmeal it contains. The comments suggested a range of qualifying β -glucan levels from 0.5 g β -glucan to 3 g β -glucan per serving. A number of different rationales were presented in the comments to justify these varying qualifying levels of β -glucan per serving.

One comment recommended a level of 0.6 g β -glucan soluble fiber per serving as the qualifying level instead of the proposed 1 g β -glucan soluble fiber because 0.6 g is more readily achievable and thus would encourage the development of new soluble fiber-containing products. According to the comment, this level is at least twice the level of existing oatmeal-based bakery products such as cookies and crackers. Some comments suggested that a qualifying level of 0.6 g β -glucan per serving would make the qualifying criteria for this claim consistent with the authorized health claim for fruits, vegetables, and grain products and CHD.

Many comments stated that the qualifying level of β -glucan soluble fiber per serving should not be based on three servings of oat products per day but rather on FDA's usual basis of four eating occasions (three meals and a snack) a day. The comments stated that the agency did not adequately justify its reliance on three eating occasions per day, rather than on four. A few comments questioned whether consumers would consume oatmeal and other oat products three or four times a day. One comment asked for evidence that consumers will eat oat products three times a day every day.

As discussed earlier in this final rule, FDA has been persuaded that the subject of the claim is appropriately β -glucan soluble fiber from whole oats. Thus, to be eligible to bear the claim, a food must contain the requisite amount of β -glucan soluble fiber from whole oat sources, rather than a specified amount of oat bran or rolled oats that provide a specific amount of β -glucan soluble fiber.

Given the changed focus of the final regulation, the issues raised in the comments that addressed the levels of oat bran and oatmeal are moot. FDA has

deleted the requirement in proposed § 101.81(c)(2)(iii)(A) that the food must contain no less than 20 g oatmeal or 13 g of oat bran that provides, without fortification, at least 1.0 g of β -glucan soluble fiber and replaced it with a requirement that focuses on the β -glucan level.

The agency has reviewed the discussions from the comments concerning the levels of β -glucan in a food. The agency disagrees with the comments that suggested that the qualifying level of β -glucan soluble fiber be low as 0.5 or 0.6 g per RACC to permit many more oat-containing products, e.g., crackers and cookies, to qualify to bear the claim. As discussed previously, an intake of 3 or more g of β -glucan soluble fiber from whole oat products is necessary to make a significant impact on serum lipid levels. Using the minimum levels of β -glucan soluble fiber for oat bran (5.5 percent) and rolled oats and whole oat flour (4 percent) that the agency now specifies in new § 101.81(c)(ii)(A)(1) through (3) (see comment 8 in section II.B.1. of this document), products that contain a minimum of 0.5 g β -glucan soluble fiber would contain about 9 g of oat bran or 12.5 g rolled oats or whole oat flour, or a level between 9 and 12 g if a blend of whole oats is used. To obtain a daily intake of 3 g β -glucan from whole oats, it would require the consumption of six or more servings. Similarly, if the oat products qualified with 0.6 g β -glucan soluble fiber, consumers would have to consume five or more servings of oat-containing products daily. The agency finds that these levels of consumption, five or six or more servings per day, highly unlikely. As mentioned in some of the comments, consumers should be able to consume a beneficial amount of the nutrient based on typical American eating patterns, i.e., four eating occasions per day.

In the proposal, the agency considered the number of eating occasions at which consumers might consume oat bran and rolled oats. The agency tentatively agreed with the petitioner's arguments that it was unlikely that consumers would eat oat bran or rolled oats 4 times a day, in order to consume a daily intake of about 40 g oat bran or 60 g rolled oats, but that consumers should be able to consume this amount over three eating occasions a day (61 FR 296 at 309). Based on the petitioner's submission, the agency considered that β -glucan soluble fiber would come from only two sources, oat bran and rolled oats, which would limit the number and types of products available.

In this final rule, however, the agency has expanded the sources of whole oats to include whole oat flour. Thus, many more whole oat-containing products will be available to qualify to bear this claim. This development increases the likelihood that whole oat products will be consumed at four, instead of three, eating occasions. Moreover, based on consumption data provided in a comment submitted by the petitioner, whole oat products (including all oat cereals, baked products, and snack foods) are consumed at four eating occasions a day, with breakfast being the most popular time to consume oat products (see Sup-1 to Docket No. 95P-0197). Therefore, based on the expanded focus of this final regulation (to include whole oat flour) and on the additional evidence from comments, the agency is persuaded that the determination of the qualifying level of β -glucan for a food to bear a claim should be based on four eating occasions a day (three meals plus a snack) rather than on the proposed three.

The agency proposed a qualifying level of 1 g β -glucan soluble fiber per serving based on the consumption of 3 g per day (see comment 6 in section II.A.6. of this document) distributed over three eating occasions per day. Based on the same approach as that used in the proposal, but adjusting it for the increase in the number of servings consumed per day, the intake of 3 g of β -glucan is distributed over four servings per day as part of four eating occasions (3 g divided by 4) and results in a criterion of 0.75 g per serving (i.e., RACC).

In providing for this qualifying level, the agency wishes to point out that the approach used to derive the qualifying level is somewhat different from that used in authorizing other health claims. Specifically, the guiding principle for other health claims is to use the established definitions for "good source" or for "high" which characterize the amount of a nutrient based on a percentage of the Daily Value (DV) for the nutrient in a serving of food. In this way, products that qualify to bear the claim contain a meaningful level of the substance per serving compared to the recommended intake of the substance from all food sources. In the case of this final rule, there is no DV for β -glucan soluble fiber or for soluble fiber.

FDA has revised § 101.81(c)(2)(iii)(A) to state "[T]he food shall contain at least 0.75 gram (g) per reference amount customarily consumed of whole oat soluble fiber from the eligible sources listed in paragraph (c)(2)(ii) of this section." The statement in proposed

§ 101.81(c)(2)(iii)(A) regarding the method for determining β -glucan soluble fiber has been deleted because it now appears under section new section § 101.81(c)(2)(ii)(A) of this final rule, as discussed previously.

No comments were received on proposed § 101.81(c)(2)(iii)(B) which requires that the food meet the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food. Therefore this paragraph is adopted without change, although it has been renumbered as § 101.81(c)(2)(iii)(C).

2. Mixtures of Oat Products

(Comment 11)

Some comments stated that the agency should allow a mixture of oat products that together within a single food product provide the total qualifying level of β -glucan soluble fiber to bear this claim. The comments stated that as long as the requisite amount of β -glucan soluble fiber is present, it should not matter if it is derived from a mixture.

The agency agrees with this suggestion and notes that it never intended not to allow a mixture of whole oats to qualify for the proposed claim. To clarify this fact, the agency has revised § 101.81(c)(2)(iii) (Nature of the food eligible to bear the claim) to state that the product must provide the required level of soluble fiber per RACC from the eligible sources of whole oat soluble fiber listed in § 101.81(c)(2)(ii). Therefore, a mixture of oat bran, rolled oats, and whole oat flour may be used in a product that bears a claim so long as the product contains the requisite amount of β -glucan soluble fiber per RACC.

3. Nutrient Declaration for Soluble Fiber and β -glucan Soluble Fiber

The agency proposed in § 101.81(d)(4) that if the claim uses the term "soluble fiber," which was to be optional, the total soluble fiber content must be declared in the nutrition label, consistent with § 101.9(c)(6)(i)(A). (Comment 12)

One comment suggested that the final rule require that the soluble fiber and β -glucan contents of a food product bearing the health claim be declared in nutrition labeling. The comment stated that, because β -glucan is the marker nutrient in a qualifying product, it should be included in the nutrition label. The comment cited other health claim regulations specific to foods (rather than nutrients) (§§ 101.76 to 101.78) as precedents for requiring declaration of the amount of the marker nutrient in the nutrition label. In

suggesting that β -glucan be declared as a subcomponent of soluble fiber, the comment also cited as precedent the regulation permitting β -carotene to be declared as a subcomponent of vitamin A (§ 101.9(c)(8)(vi)). In addition, the comment stated that the final regulation should also permit optional declaration of these nutrients elsewhere on the label, consistent with § 101.13(i)(3).

The agency has considered this comment in view of the previously discussed conclusions concerning the food substance that is the subject of this claim, specifically β -glucan soluble fiber from whole oats. The suggestion in the comment that soluble fiber be declared within the nutrition label is consistent with the change in focus of the claim from oat bran and oatmeal to β -glucan soluble fiber from whole oats. Since β -glucan is a soluble fiber, and the claim requires use of the term "soluble fiber," FDA is requiring the declaration of the amount of soluble fiber per RACC or labeled serving (which would include the declaration of the amount of β -glucan) in the nutrition label in accordance with § 101.9(c)(6)(i)(A). In this document, FDA is adding § 101.81(c)(2)(iii)(B), which reflects this requirement. As a result of this action, FDA, as stated previously, is redesignating proposed § 101.81(c)(2)(iii)(B) as § 101.81(c)(2)(iii)(C).

FDA does not agree with the comment that the specific amount of β -glucan should also be declared in the nutrition label. Declarations for β -carotene, which the comment uses as an analogy, are made in terms of a percentage of the DV for vitamin A. In this case, there is no DV for soluble fiber or for β -glucan soluble fiber. More importantly, use of the term "beta-glucan" as a subcategory of soluble fiber would likely be confusing to the consumer as " β -glucan" is primarily a technical term with which consumers are not familiar. Therefore, FDA is not providing for the declaration of β -glucan on the nutrition label.

It should be noted that the agency is making provision for optional label statements in the claim relative to the amount of β -glucan considered useful in reducing the risk of CHD (i.e., 3 g per day) and to the contribution that one serving of the food makes toward reaching the specified amount. As explained in section II.D.4. of this document, provision of this information is optional because of the agency's concerns about requiring long messages and the possibility of consumer information overload. Moreover, given the potential for the broad range of soluble fibers that may be eligible to

bear the claim in the future, it is questionable whether requiring that the consumers' attention be drawn to a specific type of soluble fiber would be helpful. The comment provided no information on how consumers would use and interpret such a declaration for β -glucan. In the absence of such data, it is difficult to conclude that declaration of β -glucan soluble fiber in the nutrition label would assist consumers to any greater degree than the declaration of soluble fiber.

Further, FDA notes that, as suggested in the comment, declaration of soluble fiber and β -glucan soluble fiber on the label other than in the Nutrition Facts panel, is permitted by § 101.13(i)(3). No additional authorization is needed for such declarations.

D. Provisions for Abbreviated and Full Claims

In addition to providing for a full claim on the relationship between oat bran and rolled oats as part of a diet low in saturated fat and cholesterol and risk of CHD, the agency proposed an optional abbreviated claim. FDA proposed in § 101.81(c)(2)(ii), "Presentation of the claim," to provide that if a full statement of the claim appears on a label or in labeling, other presentations of the claim may appear on the label or in labeling that do not include the information required in proposed § 101.81(c)(2)(i)(C)(2) as long as there is a referral statement from the shortened to the full claim. The agency was concerned, however, about the possibility that consumers may not read the complete claim, and thus that they will not have all the facts necessary to fully understand the significance of the claim and to comprehend the claim in the context of the daily diet. FDA asked for data on whether the shortened claim will affect the extent to which consumers read the full claim (61 FR 296 at 307). The agency also requested comments on whether consumers will be misled if the multifactorial nature of CHD is not stated as part of the claim (61 FR 296 at 307). The agency proposed making optional the statement "a disease caused by many factors."

1. Appropriateness of Abbreviated Claim and Wording of Full Claim (Comment 13)

Many comments expressed concern about the omission of reference to the diet in the proposed abbreviated claim. Some comments suggested that the proposed abbreviated claim, which stated that "Diets high in [oat bran/oatmeal] may reduce the risk of heart disease," will mislead consumers to think that the oat products will

compensate for a diet that is high in saturated fat and cholesterol. The comments stated that other authorized health claims reinforce that overall diets, not individual foods, can reduce the risk of disease. Many comments stated that the abbreviated claim is misleading without the reference to a total diet that is low in saturated fat and cholesterol. A few of the comments stated that the effects of oat bran or rolled oats on reducing the risk of CHD, in the absence of a low saturated fat and cholesterol diet, is modest, so the abbreviated claim may mislead consumers to think that eating oat products daily, without consuming a low saturated fat and cholesterol diet, will significantly effect their risk of CHD.

Some of the comments discussed diet as one of the more important modifiable risk factors for CHD. Many stated that a reference to the total diet should be a mandatory part of the abbreviated claim. The comments suggested that including reference to the diet in the claim will help prevent oat bran and rolled oats from appearing to be "magic bullets." However, there were comments that stated that consumers are aware that no one food is a "magic bullet" in reducing the risk of disease.

Some of the comments stated that the agency did not present any data to show that consumers will read the full claim, which includes the statement on the total diet, when it is located elsewhere on the food label relative to the abbreviated claim. They concluded that consumers would be misled by the limited information in the abbreviated claim. Several comments stated that by removing the qualifying portion of the health claim (i.e., information about total diet) from the most prominent location on the label, there was less likelihood this critical information would be read by consumers.

Some comments supported FDA's proposal to permit use of an abbreviated health claim because it provided flexibility and consumer-friendly language. Several comments in support of the shortened claim mentioned its advantages in communicating information to consumers because it was easily readable, compelling, and direct. The shortened claim was seen as playing the role of a reminder to consumers about the core diet-disease relationship that is the subject of the health claim. One comment cited findings from FDA health claims focus groups (Ref. 53), which reported that consumers perceived full health claims as "too wordy, too vague, too academic, and much too long." One comment stated the use of the abbreviated claim

as a referral (see § 101.14(d)(2)(iv)) to the full claim would serve both consumer information needs and the motivational goals of the 1990 amendments to encourage industry to use health claims on appropriate food products.

The agency proposed the abbreviated claim because the petitioner requested it, and because the agency tentatively concluded that the information could be more effectively communicated with an abbreviated claim in a prominent place with a referral to the full claim. The agency did not intend for the abbreviated message to suggest to consumers that adding oats to the diet was the only dietary modification necessary to help them reduce the risk of CHD.

The agency agrees with the comments that the dietary component of this health claim is important for a complete understanding of the relationship between the type of soluble fiber from whole oats and reduced risk of heart disease. FDA has been persuaded that there is the possibility that consumers may be misled if reference to the total diet were to be omitted in an abbreviated version of this claim. Diets low in saturated fat and cholesterol are considered by expert groups to be the most effective dietary means of reducing heart disease risk (Ref. 5). While soluble fiber from whole oats can contribute to this effect, its role is generally recognized as being of smaller magnitude (Refs. 4 and 5). Selection of foods with soluble fiber from whole oats is seen as a useful adjunct to selection of diets low in saturated fat and cholesterol (Ref. 5). Therefore, the agency concludes that it would not be in the best interest of public health or consistent with the scientific evidence to imply that selecting diets with soluble fiber from whole oats is a substitute for consuming diets low in saturated fat and cholesterol, and has FDA revised § 101.81 to emphasize the importance of the diet.

Proposed § 110.81(b)(2) stated, "* * * Scientific evidence demonstrates that diets high in oat bran and oatmeal and low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels." FDA has revised that sentence to state:

* * * Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels. Soluble fiber from whole oats, when added to a low saturated fat and cholesterol diet, also helps to lower these blood levels and thus the risk of CHD. The revised statement emphasizes that consumption of a diet low in saturated fat and cholesterol is an important factor

in reducing the risk of CHD and is consistent with FDA's conclusions in authorizing the health claim for dietary saturated fat and cholesterol and heart disease (58 FR 2739, January 6, 1993).

Relative to the concerns about the appropriateness of the abbreviated claim, the agency was mindful of those comments that focused on concerns about health claims being too wordy and too lengthy. This concern has been raised to the agency in various ways, including by a petition submitted by the National Food Processors Association (NFPA) (Docket No. 94P-0390). In response to the NFPA petition, the agency proposed several changes to the requirements for health claims in the Federal Register of December 21, 1995 (60 FR at 66206) (the 1995 proposal). At that time, FDA stated that it had no desire for its regulations to unnecessarily stand in the way of the use of health claims and the presentation of the important information contained therein. The agency stated that, while health claims are being used on the label and in labeling, they could be used more extensively. The agency, therefore, proposed to provide for shorter health claims by making optional some of the elements that are presently required. If FDA finalizes the 1995 proposal as it was proposed, many of the current full claims will be brief enough to permit their use on the principal display panel.

FDA is reviewing the comments received in response to the 1995 proposal on changing the requirements for health claims, but it has not completed its work on the final rule. Given that this proposal is pending, and given its relevance to many of the issues raised as a result of the proposal that is the subject of this rulemaking, FDA has decided to defer a decision on allowing for an abbreviated claim on β -glucan soluble fiber from whole oats and the risk of CHD. The agency intends to resolve this matter in the context of the rulemaking based on the NFPA petition. Thus, at this time, the agency is making provision only for a full claim. Thus, FDA has deleted proposed § 101.81(c)(2)(ii), "Presentation of the claim," which provided for an abbreviated claim, in this final rule.

2. Research Study on the Abbreviated Claim

(Comment 14)

A comment from the petitioner included results from a consumer research study that compared an abbreviated oatmeal claim ("A diet high in oatmeal may help reduce the risk of heart disease") with a full fiber-heart disease health claim ("Diets low in

saturated fat and cholesterol and high in grains, fruits and vegetables that contain fiber, particularly soluble fiber, may reduce the risk of heart disease, a condition associated with many factors.”) The data were from a national shopping mall intercept study of 826 consumers. Participants saw one of three mocked-up cereal packages that contained either the abbreviated claim, the long claim, or no claim (control condition).

The comment suggested that results showed that the presence of either health claim, compared to the control condition, increased the number of participants who recognized that a diet high in oatmeal may help reduce the risk of heart disease. There were no significant differences in terms of the impact of the claims on consumers' perceptions of the product or their beliefs about the diet-disease relationship.

The data submitted by the petitioner address issues related to the interpretation of a specific abbreviated claim and are intended to provide support for an abbreviated claim on the relationship that is the subject of this rulemaking. Because the FDA rulemaking that responds to the NFPA petition is pending, the agency is deferring a final decision on whether to make provisions for an abbreviated claim to describe this relationship. FDA finds that there is nothing in this evidence that is sufficiently compelling to persuade the agency that it is not appropriate to defer this decision. Therefore, the agency is forwarding the petitioner's comment and supporting data as a comment to the 1995 proposal (i.e., to Docket No. 94P-0390) so that FDA can consider these results as part of that rulemaking.

3. Use of “Low Fat” to Replace “Low in Saturated Fat and Cholesterol” (Comment 15)

Two comments suggested that the statement “low in saturated fat and cholesterol” might be shortened to “low fat” for the abbreviated claim only. These comments did not provide any data to show that consumers interpret the statement “low fat” to mean “low in saturated fat and cholesterol.”

Another comment cautioned against referring to a “low fat” diet because the scientific evidence showed that a low fat diet was not associated with reduced blood total cholesterol levels and hence a reduced risk of CHD, while a diet low in saturated fat and cholesterol did affect cholesterol levels.

The agency finds that there is not sufficient evidence to support simplifying the term “low saturated fat

and cholesterol” to the term “low fat.” No data were submitted to show that consumers would not be misled by such a simplification, and, as pointed out by comments, there is evidence that low fat diets do not necessarily result in the benefits of low saturated fat diets. The term “low fat” is defined in § 101.62(b)(iii)(2) as low in total lipid fatty acids. It therefore takes into account not only saturated fat but also polyunsaturated and monounsaturated fat. Further, the term does not include cholesterol. Therefore, the term “low fat” is not sufficiently specific.

4. Modifications of § 101.81

In light of the changes in this final rule to authorize a claim for diets low in saturated fat and cholesterol that include soluble fiber from whole oats, a number of additional modifications to the proposed requirement for the claim are required.

The agency is revising § 101.81(c)(2)(i)(A) to state that: “The claim states that diets low in saturated fat and cholesterol that include soluble fiber from whole oats ‘may’ or ‘might’ reduce the risk of heart disease.”

New § 101.81(c)(2)(i)(C) states: “In specifying the substance, the claim uses the term ‘soluble fiber’ qualified by either the use of the name of the eligible source of whole oat soluble fiber (provided in (c)(2)(ii)) or the name of the food product.” Examples of such statements are: “Soluble fiber from whole oats * * *” and “Soluble fiber from oatmeal * * *” In each case, the inclusion of information about the source or the product qualifies the term soluble fiber so that the consumer is not misled to believe that all soluble fiber may reduce the risk of CHD. The manufacturer may also clarify the information for those product names that do not indicate the name of the soluble fiber source, for instance: “Soluble fiber from the oat bran in this product * * *”

The agency is also adding new paragraph (c)(2)(i)(D), which states: “In specifying the fat component, the claim uses the terms ‘saturated fat’ and ‘cholesterol.’” This terminology is consistent with the authorized CHD health claims, §§ 101.75 and 101.77, regarding diets low in saturated fat and cholesterol and risk of disease.

After careful consideration of the comments about claim wording and in view of the change in focus of the claim in response to comments, FDA has modified the model health claim statements in § 101.81(e) to reflect the changes it is making. Thus, FDA has deleted proposed paragraph (e)(1), which provided an example of a full

claim, and replaced it with the following model claim: “Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section or name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.” FDA has also deleted proposed § 101.81(e)(2) and (e)(2)(A) and (B), which provided examples of the shortened claim with the referral statement, and replaced it with new paragraph (e)(2), which gives another example of a full claim.

Section 101.81(d) provides for optional information that the manufacturer may use to elaborate on the substance-disease relationship. New § 101.81(d)(4) states that the manufacturer may identify the specific type of soluble fiber that is the subject of claim. For instance, the claim may state: “Beta-glucan soluble fiber from whole oats, as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease.” The agency believes that the specification of β -glucan soluble fiber in the wording of the claim is appropriate as an option for the manufacturer but need not be a required component of the claim, because while scientifically correct, it may be information that is too technical for many consumers and thus contrary to the agency's desire to keep the claim simple, concise, and easy for consumers to understand.

Proposed § 101.81(b)(2) stated, “Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels * * *.” Based on recent data on cholesterol intakes reported in the “Third Report on Nutrition Monitoring in the United States” (Ref. 77), which shows a reduction in some cholesterol intake levels, the agency has reconsidered including of the second sentence and has decided to delete it.

5. Multifactorial Nature of Disease (Comment 16)

Several comments responded to FDA's question as to whether consumers will be misled if the multifactorial nature of CHD is not stated in the claim. These comments supported the proposal to make optional the statement “a disease caused by many factors.” Several comments cited FDA Health and Diet Survey data that showed “American consumers understand that serious diseases like cancer and heart disease have multiple causes, including factors such as diet, heredity, smoking and stress” (Ref. 54). One comment stated that consumers are

sufficiently knowledgeable to appreciate that many factors affect risk of CHD, and that a mandatory statement of this fact would detract from the communication of the core message because it would make the claim longer, which would in turn deter manufacturers from using the claim.

For the reasons set out in the proposal and in the absence of any objections to the agency doing so, FDA has concluded that the statement "a disease caused by many factors" should remain optional. FDA is adopting proposed paragraph (d)(1) without change.

6. Dietary "Context" of Claim

(Comment 17)

Some comments stated that the proposed claim would be misleading to consumers because it provided no indication of how much of the oat-containing food would have to be consumed to reduce the risk of CHD. One comment stressed the need for explicit information in the health claim about how much oat bran or oatmeal to eat daily to affect the risk of disease, for example in terms of number of servings. The comment emphasized the need to make it clear that the consumer should eat a certain amount every day in order to benefit from consumption of these foods.

The agency agrees that consumers may find "contextual" information, as well as additional information that specifies the nature of the relationship, helpful. However, in the absence of a DRV for soluble fiber, the agency cannot identify an amount of whole oat soluble fiber that represents a "good source" or that is "high" in soluble fiber. Until the agency takes action to establish a DRV for soluble fiber, it considers such information to be more appropriate as optional information.

The agency does not agree that consumers would be misled if such information were not provided, and the mandatory inclusion of such optional information would be inconsistent with the approach taken for other claims. For the other authorized health claims, §§ 101.72 through 101.80, the agency has not required the level of detail suggested by these comments in the wording of the claim. For example, the regulation authorizing health claims on the relationship between diets low in saturated fat and cholesterol and CHD does not require that the claim statement specify that saturated fat should be less than 10 percent of calories on a daily basis, or that cholesterol should be limited to less than 300 mg per day. FDA allows for the optional provision of this information.

FDA, therefore, concludes that the information described in proposed § 101.81(d)(8) be retained as optional information, but the agency is modifying the statement to reflect the change in the focus of the claim to β -glucan soluble fiber from whole oats. Proposed paragraph (d)(8) has been replaced with new § 101.81(d)(6), which states:

A claim based on β -glucan soluble fiber from whole oats may state that 3 g or more per day of β -glucan soluble fiber from whole oats may reduce the risk of CHD, provided that the claim also states the contribution one serving of the product makes to this specified intake level for β -glucan soluble fiber.

The amount of β -glucan per serving is required here because without it, consumers may be misled to believe that the food contributes 3 g of β -glucan soluble fiber per serving. In making this provision, FDA wishes to point out that if a variety of soluble fibers become eligible to make this claim, it may be necessary to review and revise the appropriateness of such "contextual."

As a result of this change, FDA has renumbered proposed paragraphs (d)(6) and (d)(7) in the final regulation as paragraphs (d)(7) and (d)(8), respectively. In the absence of comments on paragraphs (d)(7) and (d)(8), FDA has adopted these paragraphs without change.

Proposed paragraph (d)(5) states: "The claim may state that a diet low in saturated fat and cholesterol and high in oatmeal or oat bran is consistent with 'Nutrition and Your Health, Dietary Guidelines for Americans,' * * *." In light of the change in focus of this claim to soluble fiber from whole oats and in the absence of dietary guidelines specific for soluble fiber, the agency is revising this statement to keep it consistent with "Dietary Guidelines for Americans." Therefore, § 101.81(d)(5) now states "* * * a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats" is consistent with the dietary guidelines.

E. Other Comments

1. Implied Claims

(Comment 18)

Some comments expressed concern that, if FDA authorizes a health claim that specifically mentions an oat ingredient, e.g., oat bran, oatmeal, or whole oats, these terms will imply, wherever they appear, that the food provides the effect described in the claim. One comment suggested specific limitations on how label statements about oat ingredients in a food could be used, depending on the nature and amount of soluble fiber in the food.

Another comment noted that in the regulation on implied nutrient content claims (§ 101.65(c)(3)) and FDA's discussion of implied claims in the January 6, 1993, final rule on nutrient content claims (58 FR at 2374), the agency had provided that in some contexts terms like "made with oat bran" or "oat bran muffins" would be considered to imply that the food was a good source of dietary fiber. This comment stated that once the health claim appears on food labels, consumers will interpret the terms as implying the presence of a significant amount of β -glucan soluble fiber consistent with the message of the claim. The comment stated that, therefore, any such oat ingredient implied nutrient content claim should be regulated as a claim about the amount of β -glucan soluble fiber rather than as a more general claim about dietary fiber.

Recognizing that current FDA regulations do not permit "good source" or "high in" claims about soluble fiber in general or about β -glucan in particular, the comment suggested that FDA provide advice in this final rule that such claims could be made using the soluble fiber intake recommendations cited in the regulation authorizing health claims about soluble-fiber containing fruits, vegetables, and grain products and CHD (§ 101.77). In the preamble to the final rule establishing § 101.77 (58 FR 2573 through 2574), FDA had explained that the 0.6 g soluble fiber eligibility criterion for bearing the claim derives from 10 percent of the Life Science Research Organization (LSRO) recommended daily intake of soluble fiber, i.e., about 6 g (Ref. 7).

Another comment disagreed with this suggestion, however, stating that it would require decisions that are outside the scope of this proposal. The comment stated that the proposal made no mention of the possibility of a nutrient content claim regulation arising from the proposed health claim rule. In addition, the comment stated that it would be speculative to conclude that any declaration (outside the ingredient list) on the label of the whole oat substance identified in the health claim regulation would constitute a nutrient content claim. The comment stated that the impact of label references to oats will depend on a variety of factors: The extent of the market penetration of the oats/CHD claim; the manner in which consumers who became aware of the claim perceive that claim; whether the claim leads consumers to become aware of β -glucan at all; and whether they consider it beyond its role as a marker for measuring the effectiveness of oats

in improving serum cholesterol levels. On the basis that this kind of information is not available at this time, the comment opined that FDA should not adopt any final rules until it has more information on these issues.

The agency agrees that a final regulation defining a nutrient content claim is outside the scope of the proposal. FDA also agrees with the comment that it would be premature for the agency to conclude that all declarations of relevant oat ingredients on a food label (other than in the ingredient list) are implied claims. The regulation establishing general principles for health claims states that implied health claims "include those statements, * * * that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition" (§ 101.14(a)(1)). In the preamble for that regulation (58 FR 2478 at 2483), FDA stated that it could not establish a bright line definition of implied health claims, and that labeling claims needed to be considered in their entirety and in context to determine whether the elements of a health claim are present. The agency took a similar position in the preamble of the final rule establishing regulations for nutrient content claims (58 FR 2370 through 2374). In that document, FDA stated that whether a label statement is a nutrient content claim will depend on the context in which it is presented, taking the entire label into consideration.

To change this position and find that terms such as "oat bran," "rolled oats," or "whole oat flour" are always in a context that constitutes a nutrient content or health claim, FDA would need information that it does not have. The agency would need data showing that consumers consistently interpret these terms as implying the presence of a significant amount of β -glucan, or that consumption of the food will affect the risk of CHD. The comments did not provide this or any other kind of information that FDA could use as a basis for the requested policy.

While FDA remains concerned that label statements not be misleading, it agrees with the comment that its policy of evaluating label statements on a case-by-case basis provides adequate control. The agency reviews the entire label to assess what emphasis is being placed on the specific ingredients named. However, if experience with label statements about oat ingredients or other information persuades FDA that additional regulatory controls are

needed, the agency can take action to establish appropriate regulations.

In addition, FDA advises that, as discussed previously in response to comment 5 in section II.A.5. of this document, the agency intends to propose to establish a DRV for soluble fiber, which will provide the basis for nutrient content claims like "good source of soluble fiber" and "high in soluble fiber." The information in the comment recommending use of 6 g as the DV can be fully evaluated in the rulemaking to establish the DV for soluble fiber.

2. Reference to Authoritative Bodies (Comment 19)

One comment suggested permitting reference to third party authoritative bodies, including FDA, as part of the health claim. It was noted that in the FDA health claims study (Ref. 53), consumers expressed skepticism about health claims on food packages, in large part because they did not realize health information on the front of the package was regulated.

The agency advises that issues related to making specific provision for reference to authoritative bodies as part of health claims statements is outside the scope of this rulemaking. Under the statute, FDA evaluates the relationship between a nutrient or food and a disease being advanced as the subject of a health claim. FDA authorization reflects a determination that there is significant scientific agreement that the relationship is supported by the totality of publicly available data. Once a health claim has been authorized by the agency, specific claims on labels are not subject to prior review or approval because the agency does not approve specific claims (see section 3(b)(1)(A)(vii) of the 1990 amendments). Therefore, the agency does not agree that citing FDA as an authoritative body is appropriate. Under the general principles for health claims, § 101.14(a)(1), the agency defines a health claim as including "third party" references, so it does not object to the use of other third party endorsements, provided the food complies with all requirements of the claim, and the statement of endorsement is not false or misleading.

3. RACC

(Comment 20)

One comment requested that FDA reevaluate its established RACC for flavored instant oat products. The comment suggested that the RACC for flavored sweetened hot cereals should be lowered from 55 g to 40 g which is the RACC for regular rolled oats.

This issue is outside the scope of this rulemaking. This rulemaking addresses the question of whether to authorize a claim regarding the association between oat bran and rolled oats and the risk of CHD. The process for amending a reference amount is set forth in § 101.12.

4. Oat Gum Product

(Comment 21)

One comment stated that, in the proposal, the agency incorrectly concluded that the oat gum product used in the study by Braaten et al. (Ref. 12), had not been characterized. The comment stated that the gum was thoroughly described and characterized in other studies that were cited in the Braaten et al. study, and requested that FDA correct this statement to make clear that the gum had in fact been characterized. The comment included a copy of the studies but made no other request relative to consideration of these data.

The agency acknowledges that the oat gum used in the study by Braaten and coworkers was characterized in the information and studies submitted with the comment (Refs. 56, 59, and 76). The agency notes, however, that this additional information was not submitted with the petition and was, therefore, not part of the administrative record available to the agency at the time of the proposal. The studies submitted with the comment do not alter the outcome of this final rulemaking because oat gum, a purified extract of oat bran, is not a whole grain oat product and was not one of the substances that was the subject of the petition. Although whole oat flour was not one of the substances in the petition, the agency has included it in this final rule because it is a whole grain oat product with similar nutritional properties to rolled oats, and there were sufficient data in the administrative record from which to evaluate its physiological effectiveness. This type of evidence for purified oat gum is not available in the administrative record. A manufacturer may petition to amend § 101.81 to include oat gum by submitting such data.

III. Decision to Authorize a Health Claim on the Relationship Between Soluble Fiber From Whole Oats and CHD

FDA has considered all of the comments that it received in response to its proposal to authorize a claim to describe the relationship between oat bran and rolled oats and the risk of CHD. The agency is authorizing this claim although, based on comments, FDA has been persuaded to make a

number of changes in the proposed provisions for the health claim.

FDA concludes that, rather than oat bran and rolled oats, the food substance that is the subject of the claim is β -glucan soluble fiber from whole oats. FDA further determines that the relationship is scientifically valid in that there is significant scientific agreement based on the totality of publicly available scientific evidence that β -glucan soluble fiber from whole oats, as part of a diet low in saturated fat and cholesterol, may reduce the risk of CHD. Decisions relating to provisions for an abbreviated version of the claim have been deferred and will be handled in a separate rulemaking.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (61 FR 296). At that time, the agency determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity).

Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of that rule on small entities. FDA finds that this final rule is not a significant rule as defined by Executive Order 12866 and finds under the Regulatory Flexibility Act that the final rule will not have a significant

impact on a substantial number of small entities.

The authorization of health claims about the relationship between β -glucan soluble fiber from whole oats and CHD results in benefits and in costs only to the extent that food manufacturers elect to take advantage of the opportunity to use the claim. This rule will not require that any labels be redesigned, or that any product be reformulated.

The benefit of authorizing this type of health claim is to provide for new information in the market in the form of a claim linking consumption of soluble fiber from whole oats to the risk of CHD.

Costs will be incurred by small entities only if they opt to take advantage of the marketing opportunity presented by this regulation. FDA cannot predict the number of small entities that will choose to use the claim. However, no firm, including small entities, will choose to bear the cost of redesigning labels unless they believe the claim will result in increased sales of their product. Therefore, this rule will not result in either a decrease in revenues or a significant increase in costs to any small entity. Accordingly, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VI. Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. References

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

1. The Quaker Oats Company, "Petition for Health Claim—Oat Products and Coronary Heart Disease," March 22, 1995 [CP1].
2. Scarbrough, F. Edward, CFSAN, FDA, Letter to Ted Moeller, Quaker Oats Company, June 29, 1995.
3. DHHS, Public Health Service (PHS), "The Surgeon General's Report on Nutrition and Health," U.S. Government Printing Office, Washington, DC, 1988.
4. National Research Council, National Academy of Sciences, "Diet and Health," National Academy Press, Washington, DC, 1989.
5. DHHS, PHS and the National Institutes of Health (NIH), "National Cholesterol Education Program: Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," NIH, Bethesda, MD, 1989.

6. DHHS, PHS and the National Institutes of Health, "National Cholesterol Education Program: Population Panel Report," Bethesda, MD, 1989.

7. LSRO, FASEB, "Physiological Effects and Health Consequences of Dietary Fiber," Bethesda, MD, 1987.

8. Anderson, J. W., N. H. Gilinsky, D. A. Deakins, S. F. Smith, D. S. O'Neal, D. W. Dillon, and P. R. Oeltgen, "Lipid Responses of Hypercholesterolemic Men to Oat-bran and Wheat Bran Intake," *American Journal of Clinical Nutrition*, 54:678-83, 1991.

9. Anderson, J. W., D. B. Spencer, C. C. Hamilton, S. F. Smith, J. Tietzen, C. A. Bryant, and P. Oeltgen, "Oat-bran Cereal Lowers Serum Total and LDL Cholesterol in Hypercholesterolemic Men," *American Journal of Clinical Nutrition*, 52:495-499, 1990.

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List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, 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 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 348, 351, 352, 355, 371).

2. New § 101.81 is added to subpart E to read as follows:

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

(a) *Relationship between diets low in saturated fat and cholesterol that include soluble fiber from whole oats and risk of coronary heart disease*—(1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 mmol/L) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that

are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from whole oats to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol that include soluble fiber from whole oats and risk of CHD*—(1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels. Soluble fiber from whole oats, when added to a low saturated fat and cholesterol diet, also helps to lower blood total and LDL-cholesterol levels.

(c) *Requirements*—(1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements—(i) Nature of the claim. A health claim associating diets low in saturated fat and cholesterol that include soluble fiber from whole oats with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol that include soluble fiber from whole oats "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soluble fiber" qualified by either the use of the name of the eligible source of whole oat

soluble fiber (provided in paragraph (c)(2)(ii) of this section or the name of the food product;

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets low in saturated fat and cholesterol that include soluble fiber from whole oats; and

(F) The claim does not imply that consumption of diets low in saturated fat and cholesterol that include soluble fiber from whole oats is the only recognized means of achieving a reduced risk of CHD.

(ii) Nature of the substance. Eligible sources of soluble fiber.

(A) Beta (β) glucan soluble fiber from the whole oat sources listed below. β -glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the Association of Official Analytical Chemists International," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC;

(1) Oat bran. Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb)) β -glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber;

(2) Rolled oats. Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of β -glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(3) Whole oat flour. Whole oat flour is produced from 100 percent dehulled,

clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of β -glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(B) [Reserved]

(iii) Nature of the Food Eligible to Bear the Claim.

(A) The food shall contain at least 0.75 gram (g) per reference amount customarily consumed of whole oat soluble fiber from the eligible sources listed in paragraph (c)(2)(ii) of this section;

(B) The amount of soluble fiber shall be declared in the nutrition label, consistent with § 101.9(c)(6)(i)(A).

(C) The food shall meet the nutrient content requirements in § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

(d) *Optional information*—(1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets low in saturated fat and cholesterol that include soluble fiber from whole oats and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol;"

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in saturated fat and cholesterol that include soluble fiber from whole oats and coronary heart disease and the significance of the relationship;

(4) The claim may specify the name of the eligible soluble fiber;

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats

is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) A claim based on β -glucan soluble fiber from whole oats may state that an intake of 3 g or more per day of β -glucan soluble fiber from whole oats may help reduce the risk of CHD, provided that the claim also states the contribution one serving of the product makes to this specified intake level for β -glucan soluble fiber;

(7) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(8) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO;

(e) *Model health claim*. The following model health claims may be used in food labeling to describe the relationship between diets low in saturated fat and cholesterol that include soluble fiber from whole oats and reduced risk of heart disease:

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section or name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.

(2) Diets low in saturated fat and cholesterol that include soluble fiber from [name of soluble fiber source from paragraph (c)(2)(ii) of this section or name of food product] may reduce the risk of heart disease.

Dated: January 9, 1997.
William B. Schultz,
Deputy Commissioner for Policy.
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