

with §§ 105.66, 105.67, and 105.69" and adding in its place "§§ 101.9 and 105.66" and in paragraph (b) by removing the phrase "§§ 101.9 and 101.25 and §§ 105.66, 105.67, and 105.69" and adding in its place "§§ 101.9 and 105.66".

## PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

6. The authority citation for 21 CFR part 102 continues to read as follows:

**Authority:** Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

### § 102.33 [Amended]

7. Section 102.33 *Beverages that contain fruit or vegetable juice* is amended in paragraphs (c) and (d) by adding the word "diluted," before the phrase "multiple-juice beverage".

Dated: March 24, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

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## 21 CFR Part 101

[Docket No. 95P-0197]

RIN 0910-AA19

### Food Labeling: Health Claims; Soluble Fiber From Whole Oats and Risk of Coronary Heart Disease

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulation that authorizes health claims about the relationship between soluble fiber from whole oats and coronary heart disease (CHD) to clarify and correct its provisions. This action is being taken in response to inquiries that FDA has received since it issued this regulation.

**EFFECTIVE DATE:** March 31, 1997.

#### FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

### I. Background

In the *Federal Register* of January 23, 1997 (62 FR 3584), FDA published a final rule announcing its decision to authorize the use of health claims on the relationship between soluble fiber from whole oats (i.e., oat bran, rolled oats,

and whole oat flour) and the risk of CHD (§ 101.81 (21 CFR 101.81)). Since then, questions have been raised regarding the meaning of the regulation. Therefore, FDA is amending § 101.81 to correct and clarify the regulation.

### II. Nature of the Claim (§ 101.81(c)(2)(i))

Section 101.81(c)(2)(i)(C) states that "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."

The agency is amending § 101.81(c)(2)(i)(C) to clarify that the claim must state the name of the source of eligible soluble fiber, and that it may state the name of the food product that contains the source of the soluble fiber. In the preamble to the whole oats final rule (62 FR 3584 at 3595), the agency gave examples of statements that complied with § 101.81(c)(2)(i)(C). Those examples were: "Soluble fiber from whole oats \* \* \*" and "Soluble fiber from oatmeal \* \* \*." The agency stated that:

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 \* \* \*."

62 FR 3584 at 3595

As the discussion of this provision in the final rule tried to make clear, it was the agency's intention that the claim use the name of the whole oat food, i.e., oat bran, rolled oats, or whole oat flour, that is the source of soluble fiber, so that the consumer would not be misled to believe that all soluble fibers that may be present in the food may reduce the risk of CHD. However, the agency has come to recognize that a claim such as "Soluble fiber from Today's Cereal as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease," which does not identify the source of the soluble fiber that provides the basis for the claim, satisfies § 101.81(c)(2)(i)(C) in that it uses the term "soluble fiber" qualified by the name of the product. Thus, the regulation does not set out the rule the agency intended to embody in the regulation.

Consequently, FDA finds it necessary to amend § 101.81(c)(2)(i)(C) to make clear that the food source of the beta (β)-glucan soluble fiber in the product that bears the claim must be identified in the health claim, and that use of the product name is optional. Therefore, in this

document, the agency is correcting § 101.81(c)(2)(i)(C) to state:

In specifying the substance, the claim uses the term 'soluble fiber' qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii) of this section). Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber.

### III. Nature of the Food Eligible to Bear the Claim (§ 101.81(c)(2)(iii))

Section 101.81(c)(2)(iii)(A) states that, "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." Section 101.81(c)(2)(ii) lists three whole oat foods that are eligible sources of β-glucan soluble fiber: Oat bran (§ 101.81(c)(2)(ii)(A)(1)), rolled oats or oatmeal (§ 101.81(c)(2)(ii)(A)(2)), and whole oat flour (§ 101.81(c)(2)(ii)(A)(3)).

Questions have been raised regarding whether an extract of whole oat β-glucan soluble fiber, such as an extract of β-glucan from oat bran, could be used to fortify a product and thus qualify for the health claim.

FDA intended to make clear in § 101.81 that an extract of an eligible oat food could not justify the use of the authorized health claim. In the preamble to the whole oat final rule, the agency stated that the β-glucan soluble fiber in whole oat products is the primary, but not the only, component in whole oats that affects serum lipids (62 FR 3584 at 3585). The agency also stated that:

Other food sources of β-glucan soluble fiber (such as oat gum and non-oat sources) have not been carefully reviewed by the agency, 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. 62 FR 3584 at 3587

It was the agency's intention that the provisions in § 101.81(c)(2)(iii)(A) define the nature of the whole oat foods that are eligible sources of β-glucan soluble fiber, and not to suggest that β-glucan soluble fiber by itself could be used to fortify a product for purposes of making a claim.

The inquiries that FDA has received, however, stated that FDA needs to make its meaning even clearer in § 101.81(c)(2)(iii)(A). Therefore, in this document, the agency is amending this provision to state: "The food product shall include one or more of the whole oat foods from § 101.81(c)(2)(ii), and the

whole oat foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product.”

**IV. Model Health Claim (§ 101.81(e))**

In light of the revision to § 101.81(c)(2)(i)(C) in section II of this document, the agency is making minor changes to the model claims in § 101.81(e)(1) and (e)(2). In current paragraphs (e)(1) and (e)(2) in the model claims, the name of the soluble fiber source from § 101.81(c)(2)(ii) or the name of the food product may be provided. In this document, the agency is revising the model claims to clarify that the name of the soluble fiber source from § 101.81(c)(2)(ii) must be presented and, if desired, the name of the food product may also be provided. For example, FDA is amending § 101.81(e)(1) to state, “Soluble fiber from foods such as [name of soluble fiber source from section (c)(2)(ii) and, if desired, the name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.” Therefore, a claim for an oat bran-containing food may state, “Soluble fiber from foods such as oat bran in Brand Name Cereal, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.”

**List of Subjects in 21 CFR Part 101**

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

**PART 101—FOOD LABELING**

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

**Authority:** Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.81 is amended by revising paragraphs (c)(2)(i)(C), (c)(2)(iii)(A), (e)(1), and (e)(2) to read as follows:

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

\* \* \* \* \*

- (c) \* \* \*
- (2) \* \* \*
- (i) \* \* \*

(C) In specifying the substance, the claim uses the term “soluble fiber” qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii) of this section).

Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber;

\* \* \* \* \*

(iii) \* \* \*

(A) The food product shall include one or more of the whole oat foods from paragraph (c)(2)(ii) of this section, and the whole oat foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product;

\* \* \* \* \*

(e) \* \* \*

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the 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 and, if desired, the name of food product] may reduce the risk of heart disease.

Dated: March 25, 1997.

**William B. Schultz,**  
*Deputy Commissioner for Policy.*  
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