DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct those portions that pertain to foods. This action is being taken to improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: March 31, 1997.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 101 and 102 (21 CFR parts 101 and 102) to correct certain portions that pertain to foods.

1. In the **Federal Register** of April 2, 1993 (58 FR 17328), FDA published corrections to the January 6, 1993, final rule entitled ''Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (58 FR 2079). In the April 2, 1993, document, FDA corrected the word ''Foods'' at the beginning of the fourth sentence of paragraph (j)(4) in § 101.9 to read ''Examples of foods'' (58 FR 17328 at 17331). However, in the August 18, 1993, technical corrections to § 101.9 (58 FR 44063 at 44083), the April 2, 1993, correction to § 101.9(j)(4) was inadvertently omitted. In this document, the agency is correcting the word ''Foods'' that occurs at the beginning of the fourth sentence in § 101.9(j)(4) to read ''Examples of foods''.

2. In the **Federal Register** of January 4, 1994 (59 FR 378), FDA published a final rule entitled ''Food Labeling; Requirements for Nutrient Content Claims for Dietary Supplements of Vitamins, Minerals, Herbs, and Other Similar Nutritional Substances.'' In that document, the agency amended § 101.60 by redesignating paragraphs (c)(4) and (c)(5) as paragraphs (c)(5) and (c)(6). In making this change, the agency inadvertently failed to change a reference to old § 101.60(c)(4) in the first sentence of redesignated paragraph (c)(6) to reflect that old paragraph (c)(4) had been redesignated as paragraph (c)(5). In this document, the agency is correcting that oversight.

3. In the **Federal Register** of January 6, 1993 (58 FR 2665), FDA published a final rule entitled ''Food Labeling: Health Claims; Calcium and Osteoporosis.'' This rule, among other things established the requirements that must be met for a food to bear a health claim regarding the relationship between calcium and osteoporosis. One of these requirements, § 101.72(c)(2)(ii)(A), specifies that the food shall meet or exceed the requirements for a ''high'' level of calcium. However, in § 101.72(c)(2)(ii)(A) when referencing the section in which the term ''high'' is defined in § 101.54, the agency inadvertently referred to paragraph (c), which defines the term ''good source,'' instead of paragraph (b), which defines the term ''high.'' FDA is correcting this inadvertent error.

4. In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA published a final rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food.'' This final rule, among other things, revoked § 101.25 (58 FR 2302 at 2413). In the **Federal Register** of June 3, 1996 (61 FR 27771), FDA published a final rule entitled ''Revocation of Certain Regulations Affecting Food.'' This final rule, among other things, revoked §§ 105.67 and 105.69 (21 CFR 105.67 and 105.69) (61 FR 27771 at 27779). However, in issuing these two final rules, the agency inadvertently neglected to remove the cross references to these three sections in § 101.108(a) and (b). In this document, FDA is modifying § 101.108(a) and (b) to correct this inadvertent omission.

5. In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA published a notice of proposed rulemaking entitled ''Food Labeling; Declaration of Ingredients, Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages.'' In that proposed rule, FDA proposed to, among other things, establish common or usual name requirements for beverages that contain less than 100 percent and more than 0 percent fruit or vegetable juice. In response to comments to the proposal, in the final rule, FDA acknowledged that the difference in phrasing that appeared in § 102.33(b) and (c) in the notice of proposed rulemaking of July 2, 1991; i.e., ''diluted, multiple-juice'' versus ''multiple-juice beverage'' was inadvertent, and that both should say ''diluted, multiple-juice beverage'' (58 FR 2897 at 2918, January 6, 1993). However, the agency inadvertently neglected to make the change in § 102.33(c). Additionally, in that proceeding, in response to a comment, in the final rule FDA included a new paragraph (d) in § 102.33 that contained the phrasing ''multiple-juice beverage'' instead of the preferred phrasing ''diluted, multiple-juice beverage.'' FDA is correcting these inadvertent errors.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Oils and Fats, Onions, Potatoes, Seafood.

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, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 101.9 [Amended]

2. Section 101.9 *Nutrition labeling of food* is amended in paragraph (j)(4) by removing the first word in the fourth sentence, ''Foods'', and adding in its place ''Examples of foods''.

§ 101.60 [Amended]

3. Section 101.60 *Nutrient content claims for the calorie content of foods* is amended in paragraph (c)(6) by removing the phrase ''in paragraph (c)(4)'' and adding in its place ''in paragraph (c)(5)''.

§ 101.72 [Amended]

4. Section 101.72 *Health claims: calcium and osteoporosis* is amended in paragraph (c)(2)(ii)(A) by removing the citation ''§ 101.54(c)'' and adding in its place ''§ 101.54(b)''.

§ 101.108 [Amended]

5. Section 101.108 *Temporary exemptions for purposes of conducting authorized food labeling experiments* is amended in paragraph (a) by removing the phrase ''§§ 101.9 and 101.25 and

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: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204,202–205–5483.

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 * * *.''
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> 62 FR 3584 at 3595

As the discussion of this provision in the final 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.
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> 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