**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

**[Docket No. FDA–2008–P–0090] (formerly Docket No. 2006P–0393)**

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

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule (IFR) that amended the regulation authorizing a health claim on soluble fiber from certain foods and risk of coronary heart disease (CHD), to add barley betafiber as an additional eligible source of beta-glucan soluble fiber. FDA is taking this action to complete the rulemaking initiated with the IFR.

**DATES:** This final rule is effective August 15, 2008.

**FOR FURTHER INFORMATION CONTACT:** Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of February 25, 2008 (73 FR 9938), FDA published an IFR to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between soluble fiber from certain foods and CHD (§ 101.81), to include barley betafiber as an additional eligible source of beta-glucan soluble fiber. Under section 403(r)(3)(B)(i) and (r)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i) and 343(r)(7)), FDA issued the IFR in response to a petition filed under section 403(r)(4) of the act. On June 20, 2006, Cargill Inc. (the petitioner), submitted a health claim petition to FDA requesting that the agency expand the ''Soluble fiber from certain foods and coronary heart disease'' health claim (§ 101.81) to include barley betafiber as an eligible food ingredient source of beta-glucan soluble fiber. The petitioner requested that FDA grant an IFR by which foods containing barley betafiber could bear the health claim prior to publication of the final rule.

Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue a regulation authorizing a health claim 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).) Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition. Section 403(r)(7) of the act permits FDA to make a proposed regulation issued under section 403(r) effective upon publication pending consideration of public comment and publication of a final regulation if the agency determines that such action is necessary for public health reasons. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on September 28, 2006.

As part of its review of the scientific literature on barley betafiber and CHD, FDA considered the scientific evidence presented in the petition as well as information previously considered by the agency on CHD risk reduction and the effects of beta-glucan soluble fiber containing food ingredients on lowering serum total and low density lipoprotein (LDL) cholesterol. The agency summarized this evidence in the IFR (73 FR 9938 at 9941 to 9943). Based on the available evidence, FDA concluded that barley betafiber, like the other whole oat and barley products listed in § 101.81(c)(2)(ii)(A), lowers serum total and LDL cholesterol. Consequently, FDA amended § 101.81(c)(2)(ii)(A) to broaden the health claim to include barley betafiber as an additional eligible source of beta-glucan soluble fiber.

### II. Summary of Comments and the Agency's Response

FDA solicited comments on the IFR. The comment period closed on May 12, 2008. The agency received five letters of response, three from consumers, one from academia, and one from the Commonwealth of Kentucky. One consumer comment and the comment from academia supported the IFR. The Commonwealth of Kentucky advised the agency that FDA's ruling on the health claim would not adversely affect the State's actions or conflict with any State laws. The remaining consumer comments addressed issues that are outside the scope of this rulemaking and will not be addressed here.

Given the absence of contrary evidence on the agency's decisions announced in the IFR, FDA is adopting as a final rule, without change, the IFR that amended § 101.81 to include barley betafiber as an additional eligible source of beta-glucan soluble fiber.

### III. 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), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

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

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

FDA received no comments relevant to economic impact. The costs and benefits of available regulatory alternatives analyzed in the IFR (73 FR 9938 at 9944 and 9945) are adopted, without change, in this final rule. By now affirming that IFR, FDA has not imposed any new requirements. Therefore, there are no additional costs and benefits associated with this final rule.

**IV. Environmental Impact**

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

**V. Paperwork Reduction Act**

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claim on the association between consumption of barley betafiber and reduced risk of coronary heart disease is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

**VI. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a)(5) of the act provides that ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—* * * any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r). * * *''

On February 25, 2008, FDA published an IFR which imposed requirements under section 403(r) of the act. This final rule affirms the February 25, 2008, amendment to the existing food labeling regulations to add barley betafiber to the authorized health claim for soluble fiber from certain foods and CHD. Although this rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for barley betafiber and reduced risk of CHD that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties (*Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)).

FDA believes that the preemptive effect of this final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' On December 12, 2007, FDA's Division of Federal and State Relations provided notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors, as well as FDA field personnel, of FDA's intent to amend the health claim regulation authorizing health claims for soluble fiber from certain foods and CHD (§ 101.81).

In addition, the agency sought input from all stakeholders through publication of the IFR in the **Federal Register** on February 25, 2008. FDA received one comment from the Commonwealth of Kentucky, which noted that FDA's ruling on the health claim would not adversely affect the State's actions or conflict with any State laws.

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

**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

■ Accordingly, the interim final rule amending § 101.81 that was published in the **Federal Register** of February 25, 2008 (73 FR 9938), is adopted as a final rule, without change.

Dated: August 7, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–18863 Filed 8–14–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF STATE

**22 CFR Part 94**

**[Public Notice: 6320]**

**RIN 1400–AC45**

## Procedures for Children Abducted to the United States; Interim Final Rule

**AGENCY:** Department of State.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** This interim final rule amends regulations regarding incoming parental abduction cases pursuant to the Hague Convention on the Civil Aspects of International Child Abduction. Incoming cases will be processed by the United States Central Authority (USCA), the Office of Children's Issues in the Bureau of Consular Affairs within the U.S. Department of State or an entity designated by the USCA.

**DATES:** This rule is effective August 15, 2008.

The Department will accept written comments from the public through September 15, 2008.

**ADDRESSES:** You may submit comments, identified by RIN 1400–AC45, by either of the following methods:

• *Electronic comments:* Submit through the Federal eRulemaking Portal; *http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Address all written submissions to Corrin M. Ferber, CA/OCS/PRI, U.S. Department of State, 2100 Pennsylvania Ave., NW., 4th Floor, Washington, DC 20037, fax 202–736–9111.

*Instructions:* Please submit one copy of your comments by only one method. All submissions must include the agency name and Regulatory Information Number (RIN) identification above for this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** Corrin M. Ferber, CA/OCS/PRI, U.S. Department of State, Room 4039, 2201 C Street, NW., Washington, DC 20520; telephone: (202) 736–9172 (this is not a toll free number). Hearing-or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service at 1–800–877–8339.