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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P-0512]

Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a

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final rule, without change, the provisions of the interim final rule that amended the regulation authorizing a health claim on the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of coronary heart disease (CHD) by adding barley as an additional source of beta-glucan soluble fiber eligible for the health claim. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective May 22, 2006. The Director of the Office of the Federal Register approved the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.81(c)(2)(ii)(A)(5) as of December 23, 2005.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, 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 December 23, 2005 (70 FR 76150), FDA published an interim final rule to amend the regulation that authorizes a health claim on the relationship between soluble fiber from certain foods and CHD risk (Sec. 101.81 (21 CFR 101.81)) to include beta-glucan soluble fiber from barley. Under sections 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 (r)(7)), FDA issued this interim final rule in response to a petition filed under section 403(r)(4) of the act. 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 only if FDA ``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 21 CFR 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition. Section 403(r)(7) of the act permits FDA to make proposed regulations 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 (70 FR 76150 at 76157).

On August 3, 2004, the National Barley Foods Council (petitioner), submitted a health claim petition to FDA requesting that the agency amend the ``Soluble fiber from certain foods and coronary heart disease health claim'' at Sec. 101.81 to include barley and barley products as an additional source of beta-glucan soluble fiber eligible for the health claim. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on November 10, 2004. The petitioner requested that FDA grant an interim final rule by which labeling of barley-containing foods could bear the health claim prior to publication of a final rule.

FDA considered the scientific evidence presented in the petition as part of its review of the scientific literature on barley beta-glucan soluble fiber and CHD risk, as well as information previously

considered by the agency on the relationship of consumption of beta-glucan containing oat foods and blood (serum or plasma) cholesterol levels. The agency summarized this evidence in the interim final rule (70 FR 76150 at 76153--76155). Based on the available evidence, FDA concluded that consuming whole grain barley and dry milled barley products that provide at least 3 grams of beta-glucan soluble fiber per day, is effective in lowering blood total and LDL cholesterol; and that the cholesterol-lowering effects of beta-glucan soluble fiber in dry milled barley products is comparable to that of the oat sources of beta-soluble glucan fiber now listed in Sec. 101.81(c)(2)(ii)(A). Consequently, FDA amended Sec. 101.81 to broaden the health claim to include whole grain barley and dry milled barley products as an additional source of beta-glucan soluble fiber eligible for the health claim.

II. Summary of Comments and the Agency's Response

FDA solicited comments on the interim final rule. The comment period closed on March 8, 2006. The agency received no comments related to the requirements in the interim final rule. Therefore, FDA is adopting, without change, as a final rule, the interim final rule that amended Sec. 101.81 to include dry milled barley products as an eligible source of beta-glucan soluble fiber for the soluble fiber from certain foods and CHD health claim.

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 costs and benefits of available regulatory alternatives analyzed in the interim final rule (70 FR 76150) are adopted without change in this final rule. By now reaffirming that interim final rule, FDA has not imposed any new requirements. Therefore, there are no additional costs and benefits associated with this final rule.

A. Regulatory Flexibility Analysis

We have examined the economic implications of this final rule, as

required by the Regulatory Flexibility Act (5 U.S.C. 601-612). 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 the rule on small entities. As this final rule does not make any changes to the interim final rule or our analysis included therein, this final rule does not impose any new costs on firms. Accordingly, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

B. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq., 1532) requires that agencies prepare a written statement, of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 in any one year (adjusted annually for inflation). This final rule does not create such a mandate. The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Environmental Impact

FDA 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

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environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act

FDA has concluded 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 beta-glucan soluble fiber and CHD risk is a ``public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (see 5 CFR

1320.3(c)(2)).

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 pre-emptive 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 pre-emption provision. Section 403A (a) (5) of the act (21 U.S.C. 343-1(a)(5)) provides that * * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce-- * * * (5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r). * * *

Currently, this provision operates to pre-empt States from imposing health claim labeling requirements concerning barley beta-glucan soluble fiber and reduced risk of CHD. On December 23, 2005, FDA published an interim final rule which imposed requirements under section 403(r) of the act. This final rule affirms the December 23, 2005, amendment of food labeling regulations to add whole grain barley and dry milled barley products as eligible sources of beta-glucan fiber to the soluble fiber from certain foods and CHD health claim. Although this rule has a pre-emptive effect, in that it would preclude States from issuing any health claim labeling requirements for barley and reduced risk of CHD that are not identical to those required by this final rule, this pre-emptive 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. *Medtronic v. Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548-49 (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the pre-emptive effect of the 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.' ' FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the interim final rule in the Federal Register on December 23, 2005. FDA received no comments from any States on the interim rulemaking.

In addition, on January 13, 2006, 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 intended amendment to add barley beta-glucan soluble fiber to the soluble fiber from certain foods and CHD health claim (Sec. 101.81). The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the interim final rule and encouraged State and local governments to review the notice and to provide any comments to the docket (Docket No. 2004P-0512), opened in the December 23, 2005 Federal Register notice, by the close of the comment period indicated in the Federal Register notice (i.e., by March 8, 2006), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the above numbered docket.

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

List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by Reference, Nutrition, Reporting and recordkeeping requirements.

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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

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Accordingly, the interim final rule amending 21 CFR part 101 which was published at 70 FR 76150 on December 23, 2005, is adopted as a final rule without change.

Dated: May 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-4703 Filed 5-19-06; 8:45 am]

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