

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2006–P–0404] (formerly Docket No. 2006P–0487)

Food Labeling: Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries

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 that amended the regulation authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include isomaltulose as a substance 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 [*insert date of publication in the Federal Register*].

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 September 17, 2007 (72 FR 52783), FDA published an interim final rule to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between noncariogenic carbohydrate sweeteners and dental caries (§ 101.80) to include

the noncariogenic sugar isomaltulose. Under section 403(r)(3)(B)(i) and section 403(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 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 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.

On August 31, 2006, Cargill, Inc. (petitioner), submitted a health claim petition to FDA requesting that the agency amend the “dietary noncariogenic carbohydrate sweeteners and dental caries” claim at § 101.80 to authorize a noncariogenic dental health claim for isomaltulose. FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on December 8, 2006. The petitioner requested that FDA grant an interim final rule by which foods containing isomaltulose could bear the health claim prior to publication of the final rule. FDA and the petitioner mutually agreed to

extend the deadline for the agency's decision on the petition to September 5, 2007.

As part of its review of the scientific literature on isomaltulose and dental caries, FDA considered the scientific evidence presented in the petition as well as information previously considered by the agency on the etiology of dental caries and the effects of slowly fermentable carbohydrates. The agency summarized this evidence in the interim final rule (72 FR 52783 at 52784 to 52786). Based on the available evidence, FDA concluded that isomaltulose, like other noncariogenic carbohydrate sweeteners listed in § 101.80(c)(2)(ii), does not promote dental caries. Consequently, FDA amended § 101.80(c)(2)(ii) to broaden the health claim to include isomaltulose as an additional substance 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 December 3, 2007. The agency received four letters of response, three from consumers and one from a manufacturer. The manufacturer supported the interim rule. Two of the consumers' comments addressed issues that are outside the scope of this rulemaking and will not be addressed here. The remaining comment suggested that there had been insufficient testing to demonstrate the safety of isomaltulose, but did not provide any information or analysis to support revision of the agency's conclusion.

Given the absence of contrary evidence on the agency's decisions announced in the interim final rule, FDA is adopting as a final rule, without change, the interim final rule that amended § 101.80 to include isomaltulose as a substance eligible for the dental caries health claim.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, 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 interim final rule (72 FR 52783 at 52787 to 52788) are adopted without change in this final rule. By now affirming that interim final rule, 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 isomaltulose and the nonpromotion of dental caries 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—* * *(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) * * *

On September 17, 2007, FDA published an interim final rule which imposed requirements under section 403(r) of the act. This final rule affirms the September 17, 2007, amendment to the existing food labeling regulations to add isomaltulose to the authorized health claim for noncariogenic carbohydrate sweeteners and dental caries. Although this rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for isomaltulose and the nonpromotion of dental caries 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 August 1, 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 noncariogenic carbohydrate sweeteners and dental caries (§ 101.80). FDA received no comments from any States in response to this notice.

In addition, the agency sought input from all stakeholders through publication of the interim final rule in the **Federal Register** on September 17, 2007 (72 FR 52783). FDA received no comments from any States on the interim final rule.

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 § 101.80 that was published in the **Federal Register** of September 17, 2007 (72 FR 52783), is adopted as a final rule without change.

Dated: May 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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