

Alternative Methods of Compliance (AMOCs)

(k) You must request AMOCs as specified in 14 CFR 39.19. All AMOCs must be approved by the Manager, Chicago Aircraft Certification Office, FAA.

Special Flight Permits

(l) We will not issue special flight permits for propellers with fewer than 10 hours TIS since return to service by T and W Propellers, Inc.

Material Incorporated by Reference

(m) None.

Related Information

(n) The applicable propeller manufacturer's service documents contain instructions for performing the required overhaul actions.

Issued in Burlington, Massachusetts, on June 26, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 03-16689 Filed 7-2-03; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. 02P-0177]

Food Labeling: Health Claims; D-tagatose 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 sugar alcohols and dental caries, i.e., tooth decay, to include the sugar D-tagatose as a substance eligible for the dental caries health claim. FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective July 3, 2003.

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 2, 2002 (67 FR 71461), the agency

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 sugar alcohols and dental caries (§ 101.80) to include the sugar D-tagatose, a novel food ingredient. Under section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)), 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 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.

On January 9, 2002, Arla Foods Ingredients a/s, DK-8260 Viby, Denmark (the petitioner) filed a petition requesting that the agency: (1) Amend § 101.80 to include the sugar D-tagatose as one of the substances eligible to bear the dental caries health claim; (2) amend § 101.9, the nutrition labeling regulation, to exclude D-tagatose from the definition of "sugars" (§ 101.9(c)(6)(ii)), thereby allowing a "sugar free" nutrient content claim; and (3) modify the text of § 101.80 because D-tagatose is not a sugar alcohol (Ref. 1). FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on April 19, 2002.

FDA considered the scientific evidence presented in the petition as part of its review of the scientific literature on D-tagatose and dental caries, 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 (67 FR 71461 at 71463). Based on the available evidence, FDA concluded that dental caries is a disease for which the U.S. population is at risk; D-tagatose is a food, because it contributes taste and other technical effects listed in 21 CFR 170.3(o) to food; the use of D-tagatose in food is safe and lawful; and there is significant scientific agreement among

qualified experts that D-tagatose does not promote dental caries (67 FR 71461 at 71462 through 71464). Consequently, FDA published an interim final rule amending § 101.80 to authorize a dental caries health claim for D-tagatose.

As discussed in the interim final rule, the agency believes that it would be false and misleading for D-tagatose containing foods to bear a "sugar free" claim because D-tagatose is a sugar (67 FR 71461 at 71466). Consequently, rather than exempting D-tagatose from the definition of "sugars" as requested by the petitioner, the agency instead exempted D-tagatose from the "sugar free" requirement of § 101.80. To address the incongruity of a sugar-containing food bearing the dental caries health claim and to inform consumers about the uniqueness of D-tagatose as a noncariogenic sugar, we added the requirement that the claim identify D-tagatose as a sugar that, unlike other sugars, does not promote the development of dental caries. Accordingly, although products containing D-tagatose are not permitted to be labeled as "sugar-free," they are authorized to state that D-tagatose sugar does not promote, or may reduce the risk of, tooth decay.

II. Summary of Comments and the Agency's Response

The agency received one comment in support of the petition from a manufacturer prior to publication of the interim final rule. Comments from seven consumers were sent to this docket during the comment period, none of which were relevant to this rulemaking.

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 D-tagatose as a substance eligible for the dental caries health claim.

III. 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.

IV. Analysis of Impacts**A. Regulatory Impact Analysis**

We have examined the economic implications of this final rule as required by Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates