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 amba, 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

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).

With this final rule, FDA is adopting without change the provisions of the interim final rule published in the **Federal Register** of December 2, 2002. The interim final rule amended the regulation authorizing a health claim on the relationship between sugar alcohols and dental caries to include the sugar D-tagatose as a substance eligible for the health claim. We assessed the costs and benefits of the interim final rule in that **Federal Register** document (67 FR 71461 at 71468 and 71469). By now reaffirming that interim final rule, FDA has not imposed any new requirements. There are, therefore, no additional costs and benefits associated with this final rule.

B. 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 impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

Because this final rule does not impose any new costs on firms, we certify that this final rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before issuing any final 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). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $113 million.

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 D-tagatose 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 has 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, 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. That section 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'' certain food labeling requirements, unless an exemption is provided by the Secretary of Health and Human Services (and by delegation, FDA). Relevant to this final rule, one such requirement that States and political subdivisions may not adopt is ''any requirement respecting any claim of the type described in section 403(r)(1) of the act made in the label or labeling of food that is not identical to the requirement of section 403(r) * * *'' (section 403A(a)(5) of the act (21 U.S.C. 343–1(a)(5)). Prior to the effective date of this final rule and the interim rule that preceded it, this provision operated to preempt States from imposing health claim labeling requirements concerning D-tagatose and reduced risk of dental caries because no such requirement had been imposed by FDA under section 403(r) of the act. Under this final rule and the interim rule that preceded it, States are preempted from imposing any health claim labeling requirements for D-tagatose and reduced risk of dental cares that are not identical to those required by this rule. 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). Although this rule has preemptive effect in that it would preclude States from issuing regulations or adopting or enforcing any requirements, including state tort-law imposed requirements, for health claims about D-tagatose and reduced risk of dental caries that are not identical to the requirements of the interim final rule as adopted by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

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.'' Similarly, section 6(c) of the Executive order states that ''to the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts state law, unless the agency, prior to the formal promulgation of the regulation * * * consulted with State and local officials early in the process of developing the proposed regulation.'' This requirement, that FDA provide the States with an opportunity for appropriate participation in this rulemaking, has been met. FDA sought input from all stakeholders through publication of the interim final rule in the **Federal Register**. No comments from State or local government entities were received.

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

VII. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Arla Foods Ingredients amba, ''Petition to Amend the Regulation for 21 CFR Sec. 101.80 to Authorize a Noncariogenicity Dental Health Claim for D-tagatose,'' CP–1, Docket No. 02P–0177, January 9, 2002.

■ Accordingly, the interim final rule amending 21 CFR 101.80 that was published in the **Federal Register** of December 2, 2002 (67 FR 71461), is adopted as a final rule without change.

Dated: June 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16949 Filed 7–1–03; 10:06 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[TTB T.D.–3; Re: Notice No. 957]

RIN 1512–AC70

Seneca Lake Viticultural Area (99R–260P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This Treasury decision establishes the ''Seneca Lake'' viticultural area located in upstate New York. The Seneca Lake viticultural area encompasses about 204,600 acres of land surrounding Seneca Lake within the established Finger Lakes viticultural area. We take this action under the authority of the Federal Alcohol Administration Act and our wine labeling and advertising regulations.

EFFECTIVE DATE: This final rule is effective on September 2, 2003.

FOR FURTHER INFORMATION CONTACT: Kristy Colón, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 650 Massachusetts Avenue, NW., Washington, DC 20226; (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

What Is Treasury's and TTB's Authority To Establish a Viticultural Area?

The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity and prohibits the use of deceptive information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out the Act's provisions.

Regulations in 27 CFR part 4, Labeling and Advertising of Wine, allow the establishment of definitive viticultural areas. The regulations allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements. Title 27 CFR Part 9, American Viticultural Areas, contains the list of approved viticultural areas.

What Is the Definition of an American Viticultural Area?

Section 4.25a(e)(1), title 27 CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been delineated in subpart C of part 9. The establishment of viticultural areas allows the identification of regions where a given quality, reputation, or other characteristics of the wine is essentially attributable to its geographic origin. The establishment of viticultural areas is intended to help wineries to accurately describe the origin of their wines to consumers and to help consumers identify the wines they purchase. Establishment of a viticultural area is neither an approval nor endorsement of the wine produced there.

What Is Required To Establish a Viticultural Area?

Section 4.25a(e)(2) outlines the procedure for proposing an American viticultural area. Any interested person may petition TTB to establish a grape-growing region as a viticultural area. The petition must include:

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that the boundaries of the proposed viticultural area are as specified in the petition;
- Evidence that the proposed area's growing conditions, such as climate, soils, elevation, physical features, etc., distinguish it from surrounding areas;
- A description of the proposed viticultural area's specific boundaries, based on features found on United States Geological Survey (USGS)-approved maps; and
- A copy of the appropriate USGS-approved map(s) with the boundaries prominently marked.

Impact on Current Wine Labels

With the establishment of this viticultural area, bottlers who use brand names like Seneca Lake may be affected. If you fall in this category, you must ensure that your existing products are eligible to use the name of the viticultural area as an appellation of origin. For a wine to be eligible, at least 85 percent of the grapes in the wine must have been grown within the viticultural area.

If the wine is not eligible for the appellation, you must change the brand name and obtain approval of a new label. Different rules apply if you label a wine in this category with a label approved prior to July 7, 1986. *See* 27 CFR 4.39(i) for details. Additionally, if you use the viticultural area name on a wine label in a context other than appellation of origin, the general prohibitions against misleading representation in part 4 of the regulations apply.

Rulemaking Proceeding

ATF–TTB Transition

Effective January 24, 2003, the Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms (ATF) into two new agencies, the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury and the Bureau of Alcohol, Tobacco, Firearms, and Explosives in the Department of Justice. The regulation and taxation of alcohol beverages remains a function of the Department of the Treasury and is the responsibility of TTB. References to the former ATF and the new TTB in this document reflect the time frame, before or after January 24, 2003.

Seneca Lake Petition

ATF received a petition from Ms. Beverly Stamp of Lakewood Vineyards in Watkins Glen, New York, proposing to establish the ''Seneca Lake'' viticultural area. The petitioned area included portions of Schuyler, Yates, Ontario, and Seneca counties in upstate New York and covers approximately 204,600 acres of primarily rural agricultural and forestland. Of that total, 3,756 acres are planted to grapes. There are currently 33 wineries on or near Seneca Lake, one of New York's eleven Finger Lakes. The Cayuga Lake viticultural area lies to the east of the area, and both are entirely within the established Finger Lakes viticultural area.

Notice of Proposed Rulemaking

ATF published a notice of proposed rulemaking regarding the Seneca Lake viticultural area in the October 21, 2002, **Federal Register** as Notice No. 957 (67 FR 64575). In that notice, ATF requested comments by December 21, 2002, from