

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 caries 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.