

This communication is part of our outreach to state and local officials in response to the President's Executive Order 13132, "Federalism." In accordance with federalism principles, we want to provide you with the opportunity for meaningful input to the regulatory policies that have, or may have, substantial direct effects: (1) on the states; (2) on the relationship between the national government and the states; or (3) on the distribution of power and responsibilities among the various levels of government. The Food and Drug Administration (FDA) has adopted this process to enhance state and local government input by sending state and local officials and their organizations notice of upcoming Federal Register publications. These publications are those that FDA thinks will be of particular interest to state and local governments. FDA is seeking your input before these documents are published in the Federal Register.

This notice concerns FDA's intended amendment to the health claim regulation authorizing health claims for noncariogenic carbohydrate sweeteners and dental caries (21 CFR 101.80), which will add sucralose as a sweetener to this health claim. The proposed rule was published on May 13, 2005, at 70 Federal Register 25496. When published as a final rule, this amended regulation would preempt State law in accordance with section 403A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1). Because of the statutory preemption implications of the rule when effective, we are sending this notice in advance of publication of the final rule to encourage you to review this notice and to provide us with any comments you may have. Please send your comments to the docket (docket number 2004P-0294), as provided in the Federal Register notice). You may also send comments or any questions to the contact person listed in the Federal Register notice, Dr. James E. Hoadley, (telephone: 301-436-1458; fax: 301-436-2636; email: James.Hoadley@fda.hhs.gov), or to Mr. Richard Barnes of the FDA's Division of Federal-State Relations (fax: 301-443-2143; email: Richard.Barnes@fda.hhs.gov).

Please be advised that FDA intends to move forward with this rulemaking in the very near future and would appreciate your feedback by **Monday January 23, 2006.**