

FEDERALISM NOTICE TO STATES FOR VITAMIN D/CALCIUM HEALTH CLAIM REGULATION

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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 potential amendments to the health claim regulation authorizing health claims for calcium and osteoporosis (21 CFR 101.72). The agency has been petitioned to include vitamin D so that, in addition to claims for calcium and osteoporosis, additional claims can be made for calcium and vitamin D and osteoporosis, as well as to update specific requirements of the claim to reflect advancements made in the scientific community about the role of calcium and vitamin D on bone health. The agency has not yet acted upon this petition, which can be accessed at our website at docket number 2004P-0464. The agency can act upon this petition by either denying the petition, issuing a proposed rule, or issuing an interim final rule. If the agency publishes a proposed rule which later becomes final, or an interim final rule, the rule 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, we are sending this notice in advance of any action by the agency to encourage you to review the petition and to provide us with any comments you may have. Please send your comments to the docket (Docket number 2004P-0464) by March 2, 2006. You may also send comments or any questions to Dr. Jillonne Kevala, (telephone: 301-436-1848; fax: 301-436-2636; email: jillone.kevala@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).

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