

9/1/06

Docket # 1978N-0065

0014 6 SEP -1 P2:40

Dear Colleague:

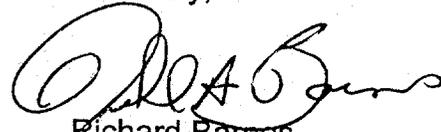
This communication is part of the Food and Drug Administration's (FDA) outreach to state and local officials, as required by the President's Executive Order 13132, "Federalism." In accordance with the Executive Order, we want to provide you with the opportunity for meaningful input into FDA regulatory 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. In order to accomplish this, we send state and local officials notices of upcoming Federal Register publications that we believe will be of particular interest to them.

This notice concerns the safety of hydroquinone, the only ingredient proposed for inclusion in FDA's over-the-counter drug monograph for skin bleaching drug products. The proposed rule (titled, **Docket No. 1978N-0065, Skin Bleaching Drug Products For Over-The-Counter Human Use; Proposed Rule**) published on August 29, 2006; at 71 FR 51146. You will find this proposed rule on the FDA's website at: www.fda.gov/OHRMS/DOCKETS/98fr/E6-14263.htm

When published as a final rule, this regulation would preempt state law in accordance with section 751 of the Federal Food, Drug, and Cosmetic Act (21 u.s.c. 379r). Because of the statutory preemption implications of the rule when effective, we are sending you this notice to encourage you to review the proposed rule and provide us with any comments you may have concerning the impact this rule may have (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. Please send your written comments to the Division of Dockets Management, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 10-61, Rockville, MD 20852. Please identify your comments with Docket No. 1978N-0065 (formerly Docket No. 78N-0065). You may distribute this notice to any office or organization within your state or local government that you believe might be interested.

FDA would appreciate your feedback by December 27, 2006.

Sincerely,



Richard Barnes
Director, Federal State Relations
Food and Drug Administration

1978N-0065

LET 17