



Food and Drug Administration
Rockville, MD 20857

Richard I. Sedlack
Vice President of Technical and International Affairs
Soap and Detergent Association
1500 K Street NW, Suite 300
Washington, DC 20005

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Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1107 17th Street NW, Suite 300
Washington, DC 20036-4702

RE: Docket No. 75N-183H
Comment No. CP7

Dear Mr. Sedlack and Mr. Donegan, Jr.:

This letter is in response to your letter of August 6, 2001, in which you requested a reopening of the administrative record of the tentative final monograph (TFM) for Over-the-Counter (OTC) Health Care Antiseptic Drug Products to include current scientific information regarding healthcare professional products. Your August 6, 2001, letter was filed as CP7 under Docket No. 75N-183H in the Dockets Management Branch.

In the Federal Register of May 29, 2003 (copy enclosed), the Food and Drug Administration (FDA) published a reopening of the comment period for the rulemaking for OTC topical antimicrobial drug products to accept comments and data concerning OTC healthcare antiseptic drug products. While this reopening of the record was not specifically in response to your August 6, 2001, CP, it serves to grant your request and completes the FDA's action on your request. The comment period will be open until August 27, 2003.

I hope this information will be helpful.

Sincerely yours,

Charles J. Ganley, M.D.

Director

Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

Enclosure

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