



APR 16 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1101 17th St. NW, Suite 3000
Washington, DC 20036

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

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

Dear Mr. Donegan and Mr. Sedlak:

This is in response to your citizen petition dated August 6, 2001, filed on August 8, 2001, as Comment No. CP7 under Docket No. 75N-183H in FDA's Dockets Management Branch.

The petition requests that FDA reopen the administrative record for the rulemaking for the tentative final monograph (TFM) for over-the-counter (OTC) health-care antiseptic drug products (June 17, 1994, 59 FR 31402) to consider a comprehensive literature review containing the most current scientific information.

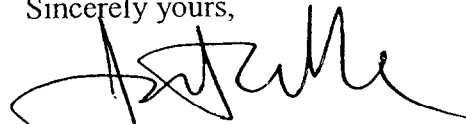
The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the agency is unable to provide a response to the petition at this time. We will respond to your petition as soon as we have made a decision on your request.

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If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'J. Woodcock', written over the printed name below.

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research