



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Thomas J. Donegan, Jr.
Vice President-Legal and General Counsel
The Cosmetic, Toiletry, and Fragrance Association
Suite 300
1101 17th Street, N.W.
Washington, D.C. 20036-4702

Richard I. Sedlak, M.D.
Vice President of Technical and International Affairs
The Soap and Detergent Association
Suite 300
1500 K Street, N.W.
Washington, D.C. 20005

Re: Docket No. 75N-183H/CP5

Dear Mr. Donegan and Dr. Sedlak:

This is in reference to your citizen petition (CP5) dated April 2, 2001, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that the June 17, 1994 Tentative Final Monograph for OTC Healthcare Antiseptic Drug Products (59 FR 31401) be amended to include: 1) Revised labeling for OTC healthcare personnel handwash, surgical handscrub, and patient preoperative skin preparation drug products, 2) labeling for consumer hand and body and food handler topical antibacterial OTC drug products, 3) a modified "Keep out of reach of children" warning for consumer hand and body OTC topical antimicrobial drug products, and 4) reduced content and format alternatives for small packages of these products.

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.

75N-183H

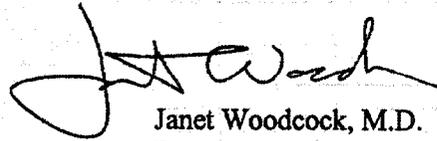
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If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janet Woodcock". The signature is fluid and cursive, with a large initial "J" and "W".

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research