DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 15 2003

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1500 K Street, NW, Suite 300
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Re: Docket No. 75N-183H
Comment No. CP15

Dear Mr. Donegan and Mr. Sedlak:

This letter is in response to your citizen petition dated January 17, 2003, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requested that FDA amend the June 17, 1994 Tentative Final Monograph for OTC Healthcare Antiseptic Drug Products (59 FR 31401) to: (1) amend relevant sections of 21 CFR 333 including, § 333.450, § 333.455 and § 333.470 to include additional organisms, specifically viruses, and appropriate test methods, performance criteria and anti-viral labeling for health-care personnel hand products, food handler products, and consumer hand products in the monograph and (2) amend § 333.470 to establish and maintain efficacy methods indicative of anti-viral activity in the monograph by incorporating the most current voluntary consensus standards set by the American Society for Testing and Materials (ASTM), specifically the finger pad method (ASTM E 1838) and the hand method (ASTM E 2011).

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,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research