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Richard I. Sedlak, M.D.
Vice President of Technical and International Affairs
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Re: Docket No. 75N-183H/CP10

Dear Mr. Donegan and Dr. Sedlack:

This is in reference to your citizen petition (CP10) dated November 28, 2001, filed under Docket No. 75N-183H in the Dockets Management Branch. The petition requests that the agency reopen the administrative record for the tentative final monograph for OTC Healthcare Antiseptic Drug Products, published June 17, 1994 (59 FR 31402), to allow consideration of new information relating to the agency's proposed final formulation testing methodology.

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.

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

75N-183H

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Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 9-18-02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 75N-183H

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. CP10


Charles J. Ganley, M.D.

Attachment