DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

SEP 2 2 2003

Rec'd 10/16/03 TP

Tish E. Pahl
Jur T. Strobos, M.D.
Olsson, Frank and Weeda, P.C.
Suite 400
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220

Re: Docket No. 81N-033A
Comment No. CP1

Dear Ms. Pahl and Dr. Strobos:

This is in reference to your citizen petition (CP1) on behalf of Sinofresh Research Labs, LLC, dated March 24, 2003, filed under Docket No. 81N-033A in the Division of Dockets Management. The petition requests that the agency reopen the administrative record for the tentative final monograph for over-the-counter oral antiseptic drug products to allow for additional safety and efficacy data to support 0.05 percent cetylpyridinium chloride as a Category I (safe and effective) oral antiseptic in the oro- and naso-pharyngeal cavity.

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 3 copies of all inquiries to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Janet Woodcock
Director
Center for Drug Evaluation and Research

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