



DEC 13 2004

Frederick O. Cope, Ph.D., FACN, CNS
Hy-Gene Biomedical Corporation
Executive and Clinical Office
1660 Northwest Professional Plaza, Suite E
Columbus, OH 43220

Re: Docket No. 75N-183H
Comment No. CP17

Dear Dr. Cope:

This is in response to your citizen petition dated June 9, 2004, filed on June 10, 2004, as Comment No. CP17 under Docket No. 75N-183H in FDA's Division of Dockets Management.

The petition requests that FDA find benzalkonium chloride and benzethonium chloride safe and effective (Category I) for use as an active ingredient in leave-on hand antiseptic products (products which are used without water and are not rinsed off the skin).

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 your petition at this time. We will respond to your petition as soon as we have made a decision on your request.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Division of Dockets Management (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 "S. Galson".

Steven K. Galson, M.D., M.P.H.
Acting Center Director
Center for Drug Evaluation and Research