



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

9046 '01 NOV -7 A10 53

NOV 5 2001

Daniel A. Kracov, Esquire
Patton Boggs LLP
2550 M Street, NW
Washington, DC 20037-1350

Dear Mr. Kracov:

I am responding to your letters of September 17, and October 3, 2001, on behalf of Lonza, Inc., requesting a meeting to discuss the status of benzethonium chloride under the over-the-counter (OTC) monograph for health care antiseptic drug products.

I want to thank you for the detailed history you provided in your September 17th letter. I want to assure you that the agency intends to fully consider all relevant data on benzethonium chloride available to us before making a decision on the ingredient's status in the final rule.

Our evaluation of the data submitted on benzethonium chloride will be presented as part of the final rule for this class of OTC drug products. Because we are currently developing that final rule, our regulations (see 21 CFR 10.80) limit the communication we may have with interested persons outside the executive branch of the Government. This limitation includes providing feedback at this time (prior to the issuance of the final rule) on the status of benzethonium chloride and the data submitted on this ingredient. Accordingly, I am sorry but we are unable to meet with you at this time.

Sincerely yours,

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V

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

DATE: NOV 5 2001

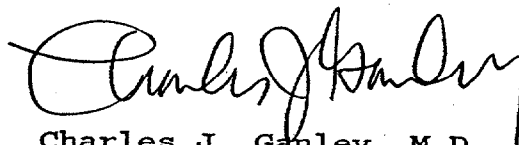
FROM: Director
Division of OTC Drug Products, HFD-560

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

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. RPT 4


Charles J. Ganley, M.D.

Attachment