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February 16, 2001

Daniel A. Kracov
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VIA COURIER

Charles Ganley, M.D.
Director, Division of Over-the-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd., Room S-205
Rockville, MD 20850

Re: Meeting Request
Topical Antimicrobial Drug Products for Over-the-Counter Human Use
Docket Number 75N-183H
Ingredient: Benzethonium Chloride
Company: Lonza Inc.

Dear Dr. Ganley:

On behalf of Lonza Inc., I would like to schedule a meeting with you and your staff to discuss the status of benzethonium chloride, one of the active ingredients listed in the 1994 Tentative Final Monograph (TFM) for topical antimicrobial drug products.

Since 1994, Lonza has submitted an extensive safety database on benzenthonium chloride to support a Category I designation for this ingredient. The data submissions have included carcinogencity bioassays in both the rat and mouse, a developmental toxicity study and a mutagenicity battery. After reviewing these data, FDA scientists asked Lonza to provide dermal absorption and pharmacokinetic data with aqueous and ethanol formulations of benzethonium chloride. These studies were submitted to FDA on October 10, 2000.

Lonza is now requesting a meeting for two reasons: (i) to obtain feedback from FDA regarding the October 10th submission and to learn whether any additional data are needed to support a Category I designation for benzethonium chloride; and (ii) if FDA concludes that the database on benzethonium chloride is complete, options for notifying the regulated community that benzethonium chloride has been reclassified into Category I.

75N-183H

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If possible, we would like to meet as soon as possible. I will call you to discuss potential dates that may be convenient for you and your staff.

Sincerely,

Daniel A. Kracov

Counsel to Lonza, Inc.

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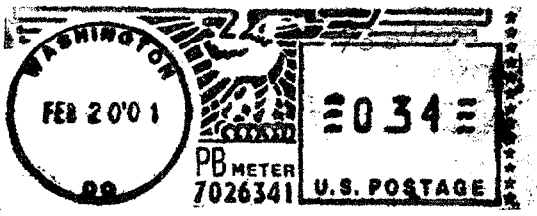


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