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August 13, 2003

Daniel A. Kracov
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VIA FACSIMILE AND MAIL

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**
Docket Number 75N-183H
Ingredient: Benzethonium Chloride
Company: Lonza Inc.

Dear Dr. Ganley:

I am writing to follow up on my letter dated June 19, 2003 (Attachment A), on behalf of Lonza Inc. ("Lonza"), and several recent discussions with your office. In my letter, we reinitiated our request for a meeting with you and your staff to discuss the status of Benzethonium Chloride under the over-the-counter (OTC) monograph for health care antiseptic drug products.[1]

Although not technically applicable to this meeting request, your staff has requested that we submit information in accordance with the *Guidance on Formal Meetings with Sponsors and Applicants for PDUFA Products.* The information requested by that guidance is as follows:

1. Product Name and Application

   Benzethonium Chloride

   Docket No. 75N-183H

[1] As you are well aware, the docket for that monograph is now open. 68 *Federal Register* 32003 (May 29, 2003).

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2. Chemical Name and Structure

Benzethonium Chloride (see original submissions to docket for further descriptive information).

3. Proposed Indications

Health Care Antiseptic

4. Type of Meeting

Not technically applicable. Equivalent of Type B meeting.

5. Dosage Form, Point of Administration and Dosing Regimen

Topical. Dosing to be determined.

6. Purpose of Meeting

See Attachment A.

7. Objectives/Outcomes

a. To obtain guidance as to the sufficiency of the data submitted to FDA to support Category I safety and efficacy status for Benzethonium Chloride.

b. To identify and agree upon further requirements, if any, in support of Category I status for Benzethonium Chloride.

8. Proposed Agenda

See Attachment B.

9. Specific Questions

a. What are the data gaps, if any, in the safety and efficacy data submitted in support of Benzethonium Chloride?

b. If gaps exist, what studies/protocols should be undertaken to fulfill such data requirements?

c. What is the plan for finalization of the above-referenced monograph? Will it be finalized in one final rule or multiple final rules? What is the timing for finalization of such rules?

d. What is the status, if any, of Benzalkonium Chloride under the above-referenced monograph?

10 Clinical Data Summary

See prior Lonza submissions to above-referenced docket.

11. Preclinical Data Summary

See Attachment A and prior Lonza submissions to above-referenced docket.

12. Chemistry, Manufacturing and Controls

See prior Lonza submissions to above-referenced docket.

Given the May 29, 2003, *Federal Register* notice, which would appear to eliminate prior concerns regarding holding a meeting while the administrative record was closed, we believe a meeting is now warranted.

Lonza attendees would include Daniel Kracov, Joseph Robinson, Eliot Harrison, Jerry Schoenig, and Howard Cash.

Thank you for your attention to this matter. We would like to schedule this meeting as soon as possible.

Sincerely,

Daniel A. Kracov

Counsel to Lonza, Inc.

cc: Debbie L. Lumpkins
Michelle M. Jackson

ATTACHMENT A

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June 19, 2003

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Charles Ganley, M.D.
Director, Division of Over-the-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research
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Re: **Meeting Request**
Docket Number 75N-183H
Ingredient: Benzethonium Chloride
Company: Lonza Inc.

Dear Dr. Ganley:

On behalf of Lonza Inc. ("Lonza"), and in light of the recent reopening of the administrative record in the above-referenced docket[1], I would like reinitiate our request for a meeting with you and your staff to discuss the status of Benzethonium Chloride under the over-the-counter (OTC) monograph for health care antiseptic drug products.

As you know, Lonza has submitted an extensive safety database on Benzethonium Chloride to support a Category I designation for this ingredient. After review of those data, FDA scientists asked Lonza to provide dermal absorption and pharmacokinetic data with aqueous and ethanol formulations of Benzethonium Chloride. Those studies were submitted to FDA on October 10, 2000. On February 16, 2001, I submitted a request for a meeting regarding Benzethonium Chloride, which was denied as premature. On September 17, 2001, I wrote to you again to provide our perspective on the status of Benzethonium Chloride relative to the health care antiseptic drug products monograph, and on October 3, 2001, we reiterated our request for a meeting to review the status of the ingredient. Finally, in a May 15, 2002, Citizen Petition, we specifically requested a reopening of the administrative record, resubmitted our prior studies, and submitted efficacy and skin and eye irritation studies.

[1] 68 *Federal Register* 32003 (May 29, 2003).

Given the May 29, 2003, *Federal Register* notice, which would appear to eliminate prior concerns regarding meeting while the administrative record was closed, we believe a meeting is now warranted in order to: (1) obtain feedback from FDA regarding Lonza's prior submissions; and (2) discuss next steps with respect to the monograph status of Benzethonium Chloride.

Thank you for your attention to this matter. We would like to schedule this meeting as soon as possible, and I will call you to discuss dates that are convenient for you and your staff.

Sincerely,

Daniel A. Kracov

Counsel to Lonza, Inc.

cc: Debbie L. Lumpkins
Michelle M. Jackson

ATTACHMENT B

AGENDA

Proposed Meeting:
Division of Over-the-Counter Drug Products
and Lonza, Inc.

[Docket # 75N-183H (Benzethonium Chloride Status
Under Health Care Antiseptic Monograph)]

Date/Time: TBD

1. Introduction
2. Review of General Monograph Status
3. Review of Lonza Benzethonium Chloride Submissions
4. Discussion of Benzethonium Chloride Data Gaps (If Any)
5. Status of Benzalkonium Chloride
6. Next Steps in Monograph Development
7. Other Issues