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LEWIS & HARRISON

Consultants in Government Affairs

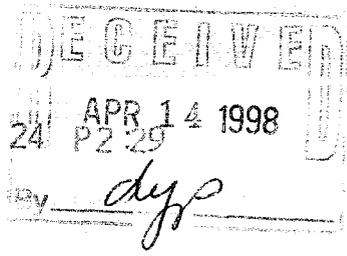
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April 6, 1998

Stephanie Mason
Division of OTC Products
Office of Drug Evaluation V
Center for Drug Evaluation & Research
Food & Drug Administration
5600 Fishers Lane, HFD-560
Rockville, MD 20857-001

re: "Feedback" Meeting on Benzethonium Chloride

Dear Ms. Mason:

On behalf of Lonza Inc., I want to thank you and other members of the Division of OTC Products (DOTCP) for meeting with Lonza representatives on April 1. Even though the meeting was brief, we believe the meeting was productive.

It is Lonza's understanding that DOTCP scientists found the data package submitted by Lonza to be adequate to assess the safety of benzethonium chloride (BZC) for use as an antimicrobial agent in handsoaps and that the only concern raised by the data is the use of ethanol as the delivery solvent in the chronic/oncogenicity studies conducted on BZC under the auspices of the National Toxicology Program. According to Dr. Peters of DOTCP, the use of ethanol is an issue since BZC will be formulated into water-based rather than ethanol-based antimicrobial handsoap products. Therefore, information regarding the potential toxicity and toxicokinetics of BZC, when applied in a representative water-based antimicrobial handsoap formulation, is needed to complete the safety assessment. The study that DOTCP requested to provide these data is a six-month dermal toxicity study in the rat.

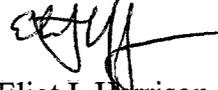
DOTCP encouraged Lonza to conduct and submit this study as soon as possible. DOTCP also encouraged Lonza to submit a protocol for the study prior to initiating any work.

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Please let me know if the above statements are consistent with DOTCP's position at the meeting.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Harrison', with a long horizontal stroke extending to the right.

Eliot I. Harrison
Agent for Lonza

cc: J. Robinson (Lonza)
G. Schoenig (TRS)