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## CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

March 22, 2002

Linda M. Katz, M.D., M.P.H.  
Deputy Director, Division of OTC Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research/  
Food and Drug Administration  
Rockville, MD 20857

RE: Docket No. 81N-003 Comment no. PR5

Dear Dr. Katz:

We are in receipt of your letter of January 8 and have considered the comments that the agency provided to our letter dated April 22, 1999 and coded by the Docket Management Branch as Comment PR5 under Docket 81N-003.

The agency has raised a number of significant issues concerning which our Oral Discomfort Task Group would like to seek resolution, so that it may move forward with studies on the effectiveness of benzocaine. We ask for a meeting with FDA in order to facilitate development of a mutually agreeable approach to studying clinically the benefits and use patterns of benzocaine.

Among the issues that we would like to discuss at the meeting are the designs for our proposed studies. A Background Document will be sent to you at least 2 weeks prior to the meeting. This document will consist of the rationale for the study designs, a table summarizing the key concerns outlined in FDA's letter of January 8th and our response to those concerns, and synopses for the proposed studies. We are hoping for a meeting by the end of April. The issues raised regarding eugenol will be addressed separately.

I look forward to your reply. Should you wish clarification on this matter, please feel free to contact me directly.

Sincerely yours,

R. William Soller, Ph.D.  
Senior Vice President and  
Director of Science & Technology

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