



Consumer Healthcare
Products Association

December 17, 2004

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Director, Division of OTC Drug Products
Office of Drug Evaluation V, Center for Drug
Evaluation and Research
Food and Drug Administration
5600 Fishers Lane (HFD-560)
Rockville, MD 20857

RE: Docket No. 81N-0033

Dear Dr. Ganley

Reference is made to the 10 September 2004 meeting minutes from the 28 June 2004 feedback meeting on the proposed labeling and clinical data supporting the OTC status of benzocaine-containing products for the temporary relief of toothache pain. Reference is also made to the background package for the June 2004 feedback meeting which contained a draft protocol for a benzocaine gel toothache dose-response study.

Based upon the feedback provided by the Agency in the 10 September 2004 meeting minutes and at the June 2004 the feedback meeting, we have revised the protocol for the benzocaine gel toothache dose-response study (Attachment I). Specifically we have:

- Defined a dose-response if there is at least a 5% difference in the percentage of responders between the 10% and 20% benzocaine treatment groups, or alternatively between the 10% and 20% groups of those subjects enrolling with severe toothache pain.
- Included subjects down to the age of 12 years old and will encourage the clinical investigators to enroll a sufficient number of these subjects to comprise at least 20% of the total enrollment population.
- Defined the purpose of the VAS measurement.
- Included a question, for subjects applying more than 1 gram of product, to understand why they did so.

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We are submitting this protocol for review so that both the Agency and CHPA are in agreement on the study design prior to the initiation of the clinical study. To aid in the review process, we have highlighted those sections of the protocol to which significant changes have been made. We are hopeful that the Agency will expedite review of this protocol, as our clinical sites are prepared to start the study in early March 2005.

We believe that the changes we have made address the comments from the Agency, and that the study design will establish the efficacy of 10% and 20% benzocaine for the temporary relief of toothache pain. Pending a successful outcome of this dose-response study and based on our discussions with the Agency, it is our understanding that no additional clinical studies will be necessary to establish the efficacy and labeling of 10% and 20% benzocaine-containing oral care products for the temporary relief of toothache pain.

We look forward to your agreement to this protocol. Please do not hesitate to contact me at 202-429-9260 should you have any questions.

Sincerely,



Douglas Ws. Bierer, Ph.D.
Vice President, Regulatory and Scientific Affairs

cc: Elaine G. Abraham (HFD-560)

DB/mm