



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Anthony G. Amitrano
Associate Head, Regulatory Affairs
SmithKline Beecham Consumer Healthcare
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Re: Docket No. 81N-0033
Comment No. CP4

Dear Mr. Amitrano:

This letter concerns your above referenced citizen petition. The petition requests that the Agency reopen the administrative record to include the combination of benzocaine and dyclonine hydrochloride (dyclonine) at therapeutic doses in the Agency's review of OTC oral health care drug products for the relief of oral discomfort. The petition also requests the Agency to allow interim marketing of a benzocaine-dyclonine combination product during its review of this class of drug products.

For the reasons given below, the agency considers action on the petition completed.

In a March 23, 1999 letter responding to this petition, Dr. Debra L. Bowen indicated that the Agency might be able to grant a future request to accept data for benzocaine and dyclonine and consider this combination of ingredients in the review of OTC drugs for relief of oral discomfort. She stated however, that well-controlled human clinical studies will be required before the benzocaine and dyclonine hydrochloride combination can be considered for inclusion in the monograph. Clinical trials should be designed to demonstrate that there is some advantage over the single ingredients in terms of enhanced effectiveness (i.e., equal to or better than each of the ingredients used alone at its therapeutic dose) safety, patient acceptance, and/or quality of formulation.

81N-0033

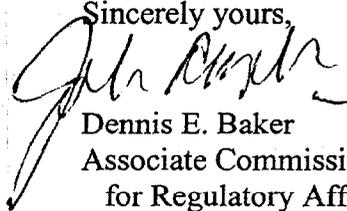
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With respect to your request to allow interim marketing of this combination during the review, our position has not changed from our March 23, 1999 letter. Accordingly, during the period that the combination is under agency review, it may not be marketed except under an approved new drug application.

Accordingly, your petition is denied.

If you have any questions regarding the petition, please refer to the docket number above and submit all inquiries in three copies, to the Dockets Management Branch, (HFA-305), Food and Drug Administration, Room 1061, 5630 Fishers Lane, Rockville, Maryland 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis E. Baker", is written over the typed name. The signature is fluid and cursive.

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs