DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NOV 14 2001

Lorna C. Totman, Ph.D.
Director of Scientific Affairs
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036-4193

Re: Docket No. 81N-0114
Comment RPT3

Dear Dr. Totman:

This letter concerns your submission dated March 1, 1999 regarding benzoyl peroxide, an active ingredient in over-the-counter (OTC) topical acne drug products. Your submission contained, among other things, an interim (1 year) report of a 2-year dermal carcinogenicity study in F344 rats and B6C3F1 mice. During subsequent telephone conversations with members of my staff in 1999 and 2000, you indicated that the final report on the completed dermal carcinogenicity studies would be forthcoming. As of the date of this letter, we have not received a final report for these studies.

In the Federal Register of August 7, 1991 (56 FR 37622), the agency reclassified benzoyl peroxide for use in topical acne drug products from Category I (generally recognized as safe and effective) to Category III (available data are insufficient). This action was taken due to information indicating that benzoyl peroxide may be a tumor promoter in mice. Labeling for all OTC topical acne drug products containing benzoyl peroxide was also proposed in the Federal Register of February 17, 1995 (60 FR 95540), pending the results of studies undertaken by the Consumer Healthcare Products Association Benzoyl Peroxide Study Group. The agency stated that the final status of benzoyl peroxide in OTC drug products and the continued need for the additional labeling would be determined when these additional studies were completed and evaluated.

We wish to inform you of our intentions to proceed with completion of the rulemaking for OTC topical acne drug products with respect to the present status of the active ingredient benzoyl peroxide. Unfortunately, without a final report of a completed study, we will not be able to adequately assess and utilize the results from the 2-year dermal carcinogenicity study. Please respond in writing within the next 10 days. The final

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report should be submitted in three copies, identified with the docket number shown at the beginning of this letter, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. I would also appreciate your sending me a desk copy of your response.

Thank you for your assistance concerning this matter. If you have any questions, please contact Tia Frazier, Regulatory Health Project Manager, at 301-827-2222.

Sincerely yours,

Charles J. Ganley, MD
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research