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NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

February 26, 1999

Debra L. Bowen, M.D.
Acting Director, Division of OTC
Drug Products (HFD-560)
Deputy Director, Office of Drug
Evaluation V
Center for Drug Evaluation and Research
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: FDA Docket No. 81N-0114

Dear Dr. Bowen:

Enclosed for FDA review is an "Update on Safety Studies with Benzoyl Peroxide" submitted by the NDMA Benzoyl Peroxide Study Group. Included in the update are reports of the interim (1 year) sacrifices in the 2-year dermal carcinogenicity studies in F344 rats and B6C3F1 mice and the final report for the 1-year photo co-carcinogenicity study. In addition, we have included reports from investigative studies with benzoyl peroxide conducted to further understand relative species differences in skin penetration and potential interactions with ultraviolet radiation.

Topical benzoyl peroxide has been used for over 30 years in the treatment of acne with no reports of adverse effects that could be related to skin cancer. This positive clinical experience is supported by the results of epidemiological studies and chronic animal carcinogenicity studies. And now the results from the chronic safety studies in animals presented in this update further uphold the conclusions from earlier studies.

Three copies of this entire submission are being sent to the FDA Dockets Management Branch.

Please let me know if you or others at FDA have questions about this submission.

Sincerely yours,

Lorna C. Totman, Ph.D., DABT
Director of Scientific Affairs

Enclosures: Nine (9) volumes (in submission NB)

LT/ct

Update on Safety Studies
with
Benzoyl Peroxide

Submission to FDA Docket No. 81N-0114
February 26, 1999

Nonprescription Drug Manufacturers Association
Benzoyl Peroxide Study Group
1150 Connecticut Avenue
Washington, DC 20036

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