CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75014

APPROVAL LETTER

ANDA 75-014

MAR 28 2000

Alpharma, U.S. Pharmaceuticals Division
Attention: Martin Levy
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

Dear Sir:

This is in reference to your abbreviated new drug application dated December 3, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Permethrin Lotion, 1%. This application was accepted for filing on January 4, 1999.

Reference is also made to your amendment dated February 29, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Permethrin Lotion, 1%, to be bioequivalent to the listed drug (Nix® Crème Rinse, 1%, of Warner Lambert Company, Consumer Products Division).

Under Section 505(A) of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

/S/ 3/28/00

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research