

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**ANDA 75-570**

**APPROVAL LETTER**

ANDA 75-570

JUN 23 2004

Clay-Park Labs, Inc.  
Attention: Candis Edwards  
1700 Bathgate Avenue  
Bronx, NY 10457

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 27, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ammonium Lactate Lotion, 12% (base).

Reference is also made to your amendments dated September 16, 1999; July 11, July 14, October 15, and December 19, 2003; and June 21, 2004.

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 labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Ammonium Lactate Lotion, 12% (base) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lac-Hydrin<sup>®</sup> Lotion, 12% (base) of Westwood Squibb Pharmaceuticals, Inc.).

Under Section 506A 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in

draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Division of Drug Marketing, Advertising, and Communications, HFD-42  
5600 Fishers Lane  
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler", followed by the date "6/23/2004". The signature is written in a cursive style.

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research