CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-751

APPROVAL LETTER

ANDA 76-751

SEP 17 2004

Clay-Park Labs, Inc.
Attention: Candis Edwards
U.S. Agent for: Agis Industries (1983), Ltd.
1701 Bathgate Avenue
Bronx, NY 10457

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mesalamine Rectal Suspension, USP (Enema), 4 g/60 mL unit-dose bottle).

Reference is also made to your amendments dated April 6, May 5, June 17, July 23, and September 7, 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 Mesalamine Rectal Suspension, USP (Enema), 4 g/60 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Rowasa® Rectal Suspension, USP (Enema), 4 g/60 mL, of Solvay Pharmaceuticals. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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,

Gary Buehler 9/17/04
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 76-751
Division File
Field Copy
HFD-610/R. West
HFD-330
HFD-205
HFD-610/Orange Book Staff

Endorsements:
HFD-640/S.Read/ Read 5/13/04
HFD-645/B.Arnwine/5/13/04 B Arnwine 5/25/04
HFD-617/N.Lee/ NLee 5/14/04
HFD-613/K.Lee/ [illegible] 5/17/04
HFD-613/L.Golson/ [illegible] for L. Golson 5/17/04

[illegible] 6/25/04

Robert L. West 9/17/2004

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F/T by: EW 5/13/04

APPROVAL