CENTER FOR DRUG EVALUATION AND RESEARCH

75-105

APPLICATION NUMBER:

APPROVAL LETTER

ANDA 75-105

JUL 23 1998

Lipha Pharmaceuticals, Inc.
Attention: Anita M. Goodman, M.D.
U.S. Agent for: Alphapharm Pty. Ltd.
9 West 57th Street, Suite 3825
New York, NY 10019-2701

Dear Madam:

This is in reference to your abbreviated new drug application dated March 20, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Indapamide Tablets USP, 1.25 mg and 2.5 mg.

Reference is also made to your amendments dated September 11 and December 11, 1997; January 10 and May 29, 1998.

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 Indapamide Tablets USP, 1.25 mg and 2.5 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lozol® Tablets, 1.25 and 2.5 mg, respectively, of Rhone Poulenc Rorer Central Research). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print.

Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gordon R. Johnston for

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

7-23-98