CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 75-241

APPROVAL LETTER

ANDA 75-241

MAY 28 1999

Abbott Laboratories
Hospital Products Division
Attention: Jessie Y. Lee,Ph.D.
200 Abbott Park Road, D-389 AP30
Abbott Park, Illinois 60064

Dear Madam:

This is in reference to your abbreviated new drug application dated October 31, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Furosemide Injection USP, 10 mg/mL, packaged in Ansyr® Plastic Syringes [4 mL (40mg) and 10 mL (100mg)].

Reference is also made to your amendments dated March 5, April 14, May 14, and May 21, 1999.

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 Furosemide Injection USP, 10 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lasix® Injection, 10 mg/mL, of Hoechst-Marion Roussel Inc.).

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,

/S/

Douglas L. Sporn 5/28/99
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc:

5/27/99

5/28/99

APPROVAL

5/27/99