ANDA 75-220 August 28, 2000

Abbott Laboratories
Attention: Kenneth Oh
200 Abbott Park Road, D-389, AP30
Abbott Park, IL 60064-6157

Dear Sir:

This is in reference to your abbreviated new drug application dated September 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Desmopressin Acetate Injection, 4 mcg/mL, packaged in 1 mL ampules.

Reference is also made to your amendments dated June 2, July 14, and July 27, 2000.

Your application contains patent certifications to patent 5,500,413 and patent 5,763,407 under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Abbott Laboratories has complied with the requirements of Section 505(j)(2)(B) of the Act. No action for patent infringement was brought against Abbott Laboratories within the statutory forty-five day period.

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 Desmopressin Acetate Injection, 4 mcg/mL to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (DDAVP® Injection, 4 mcg/mL of Aventis Pharmaceutical Products, 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.

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.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies which may be identified.

Sincerely yours,

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