NDA 21-117

Abbott Laboratories Inc.
Attention; Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road D-389 AP30
Abbott Park IL 60064-6137

Dear Dr. Lee:

Please refer to your new drug application (NDA) dated March 26, 1999, received March 29, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 10% Calcium Chloride Injection, USP, in 10 mL Plastic Syringe.

We acknowledge receipt of your submissions dated April 9(2), July 30, and December 16, 1999, and January 12, 14, 21, and 24, 2000.

This new drug application provides for the use of 10% Calcium Chloride Injection, USP, in 10 mL Plastic Syringe for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, immediate container and carton labels) submitted January 21, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-117." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55. We are deferring submission of your pediatric dosing information until April 29, 2000.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and
Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research