DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-874/S-016

Abbott Laboratories
Attention: Mary O'Sullivan
Associate Director, Regulatory Affairs
Hospital Products Division
200 Abbott Park Road, D-389 AP30
Abbott Park, IL 60064-6157

16 NOV 2001

Dear Ms. O'Sullivan:

Please refer to your supplemental new drug application dated January 18, 2001, received January 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Calcijex (calcitriol injection).

We acknowledge receipt of your submission dated June 4, 2001.

This supplemental new drug application proposes changes in the package insert to address the use of Calcijex in pediatric patients in response to our Pediatric Written Request dated on September 17, 1999, and amended on February 17, and September 14, 2000.

We have completed the review of this supplemental 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 supplemental 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 submitted November 15, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplement NDA 18-874/S-016." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research