NDA 20-819/S-003

Abbott Laboratories
Attention: Ms. Leslie Koehler
Manager Regulatory Affairs
200 Abbott Park Road
D389, Building AP30
Abbott Park, IL 60064-6154

Dear Ms. Koehler:

Please refer to your supplemental new drug application dated March 29, 1999, received April 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemplar (paricalcitol injection), 5 mcg/mL.

We acknowledge receipt of your submissions dated January 3, 7, 11, 19, and 28, 2000.

This supplemental new drug application provides for the addition of long-term (13 month) safety data to the ÁClinical Studies@ (CLINICAL PHARMACOLOGY) and ADVERSE EVENTS sections of the labeling for Zemplar.

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 draft labeling submitted on January 28, 2000.

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 supplement NDA 20-819/S-003." 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 Practitioner" 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,

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