DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-819/S-015

Abbott Laboratories
Attention: Steven F. Hoff, Ph.D.
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road; RA76, AP30-1E
Abbott Park, IL 60064-6157

Dear Dr. Hoff:

Please refer to your supplemental new drug application dated October 28, 2004, received October 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemplar (paricalcitol) Injection.

We acknowledge receipt of your submissions dated April 17, June 30, and August 30, 2005.

This supplemental new drug application provides for changes to the **DESCRIPTION, CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS**, **DOSAGE AND ADMINISTRATION,** and **HOW SUPPLIED** sections of the package insert for Zemplar Injection. In addition, the previously separate package inserts for the 2 mcg/ml and the 5 mcg/ml strengths have been combined into a single package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-819/S-015**." Approval of this submission by FDA is not required before the labeling is used.

All communications regarding this application should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 827-6416.

Sincerely,

{See appended electronic signature page}

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

Enclosure: package insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

9/2/2005 04:13:15 PM