DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-606

Abbott Laboratories
Attention: Steve Hoff, Ph.D.
Associate Director, Global Pharmaceutical Regulatory Affairs
RA-76, AP 30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Dr. Hoff:

Please refer to your new drug application (NDA) dated July 28, 2004, received July 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zemplar (paricalcitol) Capsules, 1 mcg., 2mcg., and 4 mcg.

We acknowledge receipt of your submissions dated August 18, October 21, November 4, 22, and 24, December 10, and 15, 2004, and January 26, March 2, 7, 8, and 14, and May 13, 24, and 25, 2005.

This new drug application provides for the use of Zemplar (paricalcitol) Capsules for the treatment of secondary hyperparathyroidism associated with Stage 3 and Stage 4 chronic kidney disease (CKD).

We completed our review of this application, as amended. It 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, immediate container and carton labels). 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 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 NDA 21-606**." Approval of this submission by FDA is not required before the labeling is used.

All communications regarding this application that contain electronic media or a combination of electronic and paper media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Rd.
Beltsville, Md. 20705-1266

Paper communications regarding this application that **DO NOT** contain electronic media should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 8B45
5600 Fishers Lane
Rockville, Maryland 20857

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. We are waiving the pediatric study requirement for birth to eleven years and deferring pediatric studies for ages twelve to sixteen years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of Stage 3 and Stage 4 chronic kidney disease in pediatric patients ages twelve to sixteen years.

   Final Report Submission: December 31, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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, immediate container labels and cartons

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

/s/

Mary Parks
5/26/05 03:05:36 PM
for Dr. Orloff