DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-606/S-004

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Jennifer Doney
Senior Regulatory Affairs Specialist
Dept. PA 76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Doney:

Please refer to your supplemental new drug application dated May 11, 2006, received May 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zemplar (paricalcitol) Capsules 1 mcg, 2 mcg, and 4 mcg.

We acknowledge receipt of your submissions dated May 7, 2008, and January 19, June 8 and 15, 2009.

Your submission of May 7, 2008, constituted a complete response to our March 9, 2007, action letter.

This Prior Approval supplemental new drug application provides for the use of Zemplar Capsules for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5 in patients on hemodialysis or peritoneal dialysis.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text for the package insert (PI) submitted June 15, 2009.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the package insert, which was submitted on June 15, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 21-606/S-004."**

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

1. You are required to develop an age-appropriate formulation; therefore we are deferring submission of your pediatric studies for ages 0 to 9 years in patients receiving peritoneal dialysis for this application until April 2014.

2. We are deferring submission of your pediatric studies for ages 10 to 16 years in patients receiving peritoneal dialysis for this application until January 2012, because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81(For NDAs) and section 505B(a)(3)(B) of the FDCA. These required studies are listed below.

1. Deferred pediatric study under PREA for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5 for patients receiving peritoneal dialysis in pediatric patients ages 0 to 9.

   Final Protocol Submission: May 2012
   Study Completion: November 2013
   Final Report Submission: April 2014

2. Deferred pediatric study under PREA for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 5 for patients receiving peritoneal dialysis in pediatric patients ages 10 to 16 years.

   Final Protocol Submission: January 2011
   Study Completion: January 2012
   Final Report Submission: April 2012

Submit final study reports to this NDA. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated "**Required Pediatric Assessments**".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac

LETTERS TO HEALTH CARE PROFESSIONALS

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Haley Seymour, Regulatory Project Manager, at (301) 796-2443.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology 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/

Mary Parks

6/29/2009 04:49:19 PM