DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-874/S-019 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Kelly Kaleck-Schlinsog
Manager, Global Pharmaceutical Regulatory Affairs
Dept. RA76, Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Dear Ms. Kaleck-Schlinsog:

Please refer to your supplemental new drug application dated December 29, 2006, received January 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Calcijex (calcitriol injection), 1 mcg/mL.

This supplemental application provides for the following change to the ADVERSE REACTIONS section of the package insert: Addition of a new subsection, "***Post-Marketing Experience,***" containing the following phrase: *Rare cases of hypersensitivity reactions have been reported, including anaphylaxis.*

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

We note your December 29, 2006, submission includes the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format. This labeling submission has not been reviewed. We will review this labeling postapproval to confirm it is identical to the agreed upon labeling text. Prior approval of this labeling in SPL format by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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
Officer of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

7/1/2007 08:37:55 PM