DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021606/S-009

GENERAL ADVICE -
CORRECTION TO APPROVAL LETTER

Abbott Laboratories
Attention: Janette Meyer
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Dept. PA76/Bldg. AP30-1E
Abbott Park, IL 60064-6157

Dear Ms. Meyer:

Please refer to your Supplemental New Drug Application (sNDA) dated October 20, 2010, received October 20, 2010, submitted under section 505(b) the Federal Food, Drug, and Cosmetic Act (FDCA) for Zemplar (Paricalcitol) Capsule.

We also refer to our approval letter for this supplement dated April 6, 2011.

This letter corrects an error in our approval letter. The labeling attached to our approval letter was incorrect.

The correct approved labeling is attached to this letter. We apologize for any inconvenience this may have caused.

If you have any questions, please call Pooja Dharia, Pharm.D., Regulatory Project Manager, at (301) 796-5332.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Agreed Upon Labeling

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

/s/

MARY H PARKS
04/08/2011