DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-318/S-016

Eli Lilly and Company
Attention: Jean Wright, DVM
Manager, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

**SUPPLEMENT APPROVAL**

Dear Dr. Wright:

Please refer to your supplemental new drug application dated October 30, 2007, received October 31, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Forteo (teriparatide) 3ml Cartridge.

We acknowledge receipt of your submissions dated February 12, March 28, and June 20, 2008.

This supplemental new drug application provides for a new pre-filled pen-injector for use with teriparatide cartridges manufactured with a lower nominal fill volume at the currently approved facility in Fegersheim, France.

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.

## 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)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. 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 21-318/S016**."

## CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your June 20, 2008, submission containing final printed carton and container labels.

## LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
HFD-001, Suite 5100

5515 Security Lane
Rockville, MD 20852

**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 Oluchi Elekwachi, PharmD, MPH, Regulatory Project Manager, at (301) 796-1207.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, MD
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Approved Labeling for Forteo PI, Medguide, User Manual, Carton and Container

---

**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

6/25/2008 05:19:45 PM