DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021318/S-051

**SUPPLEMENT APPROVAL**
**RELEASE FROM REMS REQUIREMENT**

Eli Lilly & Company
Attention: Ash Rampersaud, MS, PMP
Manager, Global Regulatory Affairs-US
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Mr. Rampersaud:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 8, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Forteo [teriparatide (rDNA origin) injection].

We also refer to our REMS modification notification letter dated March 2, 2017.

This prior approval supplemental application provides for proposed modification to the approved REMS and proposes to eliminate the requirement for the approved REMS for Forteo.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

## 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 indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Forteo was originally approved on July 22, 2009, and the most recent modification was approved on August 30, 2013. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modifications consist of elimination of the communication plan and the Medication Guide, and therefore, release from the requirement for a REMS for Forteo.

As communicated in the March 2, 2017, REMS Modification Notification Letter, we determined a communication plan is no longer necessary to include as an element of the approved REMS because the communication plan has been completed, and the most recent assessment demonstrates that the communication plan has met its goals.

We have also determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Forteo outweigh its risks. The Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

Therefore, because the Medication Guide and communication plan are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Forteo.

## 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 Meredith Alpert, MS, Safety Regulatory Project Manager, at (301) 796-1218.

Sincerely,

*{See appended electronic signature page}*

Christine P. Nguyen, M.D.
Deputy Director for Safety
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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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.**

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/s/

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CHRISTINE P NGUYEN
04/28/2017