ANDA 211097

**ANDA APPROVAL**

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway
Suite 400
Weston, FL 33326
Attention: Kiran Krishnan
Senior Vice President, Global Regulatory Affairs

Dear Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 29, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Teriparatide Injection USP, 600 mcg/2.4 mL (250 mcg/mL) Single-Patient-Use Prefilled Pens.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the tentative approval letter issued by this office on November 16, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Teriparatide Injection USP, 600 mcg/2.4 mL (250 mcg/mL) Single-Patient-Use Prefilled Pens to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Forteo Injection, 600 mcg/2.4 mL (250 mcg/mL), of Eli Lilly and Company (Lilly).

The reference listed drug (RLD) upon which you have based your ANDA, Lilly's Forteo Injection, 600 mcg/2.4 mL (250 mcg/mL), is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| 7,517,334 (the '334 patent) | March 25, 2025 |

Your ANDA contains a paragraph IV certification to the '334 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Teriparatide Injection USP, 600 mcg/2.4 mL (250 mcg/mL) Single-Patient-Use Prefilled Pens, under this ANDA. You have notified the Agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Apotex for infringement of the '334 patent in the United States District Court for the Southern District of Indiana, Indianapolis Division [Eli Lilly and Company v. Apotex, Inc. and Apotex Corp., Civil Action No. 18-01037]. You have also notified the Agency that this case was dismissed. You have further notified the Agency that Apotex brought a declaratory judgment against Eli Lilly and Company in the United States District Court for the Southern District of Indiana, Indianapolis Division [Apotex, Inc. and Apotex Corp. v. Eli Lilly and Company, Civil Action No. 22-02342], and on January 27, 2023, the court decided "[t]he Apotex ANDA Product does not infringe the '334 patent."[1]

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

## REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others.

For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

*{See appended electronic signature page}*

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] Consent Judgment, Apotex, Inc. and Apotex Corp. v. Eli Lilly and Company, Civil Action No. 22-02342 (Jan. 27, 2023).

John Ibrahim

Digitally signed by John Ibrahim
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