ANDA 208569

ANDA APPROVAL

Teva Pharmaceuticals USA, Inc.
400 Interpace Parkway, Building A
Parsippany, NJ 07054
Attention: Brandon Wood
Director, Regulatory Affairs, US Generics

Dear Brandon Wood:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 27, 2015, 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 complete response letter issued by this office on May 13, 2022, 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 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 Teva Pharmaceuticals USA, Inc. (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Teva within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Teriparatide Injection USP, 600 mcg/2.4 mL (250 mcg/mL) Single-Patient-Use Prefilled Pens. As a first applicant, Teva was eligible for 180 days of generic drug exclusivity. The Agency has determined, however, that Teva has forfeited its eligibility for 180-day exclusivity because Teva failed to market the drug product by April 12, 2023. See section 505(j)(5)(D)(i)(I) of the FD&C Act.

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

Sarah Kurtz

Digitally signed by Sarah Kurtz
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