



ANDA 205941

ANDA APPROVAL

Amneal Pharmaceuticals LLC
50 Horseblock Road
Brookhaven, NY 11719
Attention: Janie Gwinn
Senior Director, Regulatory Affairs

Dear Janie Gwinn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 31, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Saxagliptin Tablets, 2.5 mg and 5 mg.

Reference is also made to the tentative approval letter issued by this office on September 30, 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 Saxagliptin Tablets, 2.5 mg and 5 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Onglyza Tablets, 2.5 mg and 5 mg, of AstraZeneca AB (AstraZeneca).

The RLD upon which you have based your ANDA, AstraZeneca's Onglyza Tablets, 2.5 mg and 5 mg, 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>U.S. Patent Number</u>	<u>Expiration Date</u>
7,951,400 (the '400 patent)	November 30, 2028

Your ANDA contains a paragraph IV certification to the '400 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 Saxagliptin Tablets, 2.5 mg and 5 mg, under this ANDA. You have notified the Agency that Amneal Pharmaceuticals LLC (Amneal) 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 Amneal for infringement of the '400 patent in the United States District Court for the

District of Delaware [AstraZeneca AB v. Amneal Pharmaceuticals LLC, Civil Action No. 14-00697]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Amneal was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Saxagliptin Tablets, 2.5 mg and 5 mg. Therefore, with this approval, Amneal is eligible for 180 days of shared generic drug exclusivity for Saxagliptin Tablets, 2.5 mg and 5 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

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



John
Ibrahim

Digitally signed by John Ibrahim
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