ANDA 205981

ANDA APPROVAL

Mylan Pharmaceuticals Inc.
3711 Collins Ferry Road
Morgantown, WV 26505
Attention: Beth Britton
Head, Regulatory Affairs US Generic

Dear Beth Britton:

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 and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg.

Reference is also made to the complete response letter issued by this office on May 27, 2021, 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 and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Kombiglyze XR Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg, of AstraZeneca AB (AstraZeneca).

The RLD upon which you have based your ANDA, AstraZeneca's Kombiglyze XR Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,628,799 (the '799 patent)	July 13, 2025
9,339,472 (the '472 patent)	July 13, 2025

Your ANDA contains paragraph IV certifications to each of the patents[1] under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Saxagliptin and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg, under this ANDA. You have notified the Agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) 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

[1] The Agency notes that the '799 and '472 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Sarah Kurtz

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