ANDA 214414

ANDA APPROVAL

Syneos Health, LLC
U.S. Agent for Alembic Pharmaceuticals Limited
1030 Sync Street
Morrisville, NC 27560
Attention: Shawna Richards
Manager

Dear Shawna Richards:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 23, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg.

Reference is also made to the tentative approval letter issued by this office on December 7, 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 Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Uptravi Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg, of Actelion Pharmaceuticals US, Inc. (Actelion).

The RLD upon which you have based your ANDA, Actelion's Uptravi Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg, 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
7,205,302 (the '302 patent)	October 31, 2026
8,791,122 (the '122 patent)	August 1, 2030
9,173,881 (the '881 patent)	August 12, 2029

9,284,280 (the '280 patent)	June 25, 2030
10,821,108 (the '108 patent)	December 1, 2036
10,828,298 (the '298 patent)	December 1, 2036

Your ANDA contains paragraph IV certifications to the '302, '122, '280, '108 and '298 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 Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg, under this ANDA. You have notified the Agency that Alembic Pharmaceuticals Limited (Alembic) 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 Alembic for infringement of the '122 and '280 patents in the United States District Court for the District of New Jersey [Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd., v. Alembic Pharmaceuticals Limited, Alembic Pharmaceuticals, Inc., Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc., Civil Action No. 20-03859] and for infringement of the '302 patent in the United States District Court for the District of Delaware [Actelion Pharmaceuticals US, Inc., Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd., v. Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc., Civil Action No. 23-00383]. You have also notified the Agency that these cases were dismissed.

With respect to the '881 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Alembic was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg. Therefore, with this approval, Alembic is eligible for 180 days of shared generic drug exclusivity for Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg. 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

[1] The Agency notes that the '108 and '298 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.

Catherine Poole

Digitally signed by Catherine Poole
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