ANDA 214226

ANDA APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Limited
400 Campus Drive
Somerset, NJ 08873
Attention: Kalpana Vanam
Senior Vice President, Regulatory Affairs

Dear Kalpana Vanam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 5, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tenofovir Alafenamide Tablets, 25 mg.

Reference is also made to the tentative approval letter issued by this office on April 14, 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 Tenofovir Alafenamide Tablets, 25 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vemlidy Tablets, 25 mg, of Gilead Sciences, Inc. (Gilead).

The RLD upon which you have based your ANDA, Gilead's Vemlidy Tablets, 25 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) 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
7,390,791 (the '791 patent)	October 17, 2025
8,754,065 (the '065 patent)	February 15, 2033
9,296,769 (the '769 patent)	February 15, 2033

With respect to the: 1) ‘791 patent and 2) ‘065 and ‘769 patents including those portions as they pertain to the use code U-1275 (Treatment of chronic hepatitis B in adults), your ANDA contains paragraph IV certifications to each of the patents, 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 Tenofovir Alafenamide Tablets, 25 mg, under this ANDA. You have notified the Agency that Lupin Limited (Lupin) 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 Lupin for infringement of the '791, '065 and '769 patents in the United States District Court for the District of Delaware [Gilead Sciences, Inc. v. Lupin Limited, et al., Civil Action No. 20-00189]. You have also notified the Agency that this case was dismissed.

With respect to the ‘065 and ‘769 patents excluding those portions as they pertain to the use code U-1275 (Treatment of chronic hepatitis B in adults), your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim an indication or other condition of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Lupin was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Tenofovir Alafenamide Tablets, 25 mg. Therefore, with this approval, Lupin is eligible for 180 days of shared generic drug exclusivity for Tenofovir Alafenamide Tablets, 25 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.

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
Date: 3/30/2023 01:40:38PM
GUID: 54078879000a1b9e15dd31ed6f0343ca