ANDA 214095

ANDA APPROVAL

Apotex Corp.
U.S. Agent for Apotex Inc.
Attention: Kiran Krishnan
Senior Vice President, Global Regulatory Affairs

Dear Kiran Krishnan:

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 Emtricitabine, Rilpivirine, and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg.

Reference is also made to the complete response letter issued by this office on November 5, 2024, 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 Emtricitabine, Rilpivirine, and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Odefsey Tablets, 200 mg/25 mg/25 mg, of Gilead Sciences, Inc. (Gilead), NDA - 208351.

The RLD upon which you have based your ANDA, Gilead's Odefsey Tablets, 200 mg/25 mg/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
8,754,065 (the '065 patent)	February 15, 2033
9,296,769 (the '796 patent)	February 15, 2033

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 Emtricitabine, Rilpivirine,

and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg, under this ANDA. You have notified the Agency that Apotex Inc. (Apotex) 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 Apotex for infringement of the '065 and '796 patents in the United States District Court for the District of Delaware [Gilead Sciences, Inc. v. Apotex, Inc., et al., Civil Action No. 20-00189]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Apotex was a first ANDA applicant for Emtricitabine, Rilpivirine, and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Apotex may be eligible for 180 days of generic drug exclusivity for Emtricitabine, Rilpivirine, and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Apotex failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Apotex's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Apotex begins commercial marketing of Emtricitabine, Rilpivirine, and Tenofovir Alafenamide Tablets, 200 mg/25 mg/25 mg, or (b) at any time prior to the expiration of the '065 and '769 patent if Apotex has not begun commercial marketing. 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 Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul
Levine

Digitally signed by Paul Levine
Date: 1/30/2026 09:34:20AM
GUID: 56323ddc003554a87fad6698c2baa467