ANDA 217037

ANDA TENTATIVE APPROVAL

Laurus Generics Inc.
U.S. Agent for Laurus Labs Limited
400 Connell Drive, Suite 5200
Berkeley Heights, NJ 07922
Attention: Sharath Koripally
Senior Director RA, QA, & PV

Dear Sharath Koripally:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 7, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Bictegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg.

Reference is also made to the complete response letter issued by this office on August 21, 2023, 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. We have determined your Bictegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Biktarvy Tablets, 50 mg/200 mg/25 mg, of Gilead Sciences, Inc. (Gilead).

However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**.[1] This determination is based upon information available to the Agency at this time (e.g., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C Act.

The RLD upon which you have based your ANDA, Gilead's Biktarvy Tablets, 50 mg/200 mg/25 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
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*
9,216,996 (the '996 patent)	December 19, 2033
9,732,092 (the '092 patent)	December 19, 2033
9,708,342 (the '342 patent)	June 19, 2035
10,385,067 (the '067 patent)	June 19, 2035
10,548,846 (the '846 patent)	November 8, 2036
11,744,802 (the '802 patent)	November 8, 2036

* with pediatric exclusivity added

With respect to the '791, '065, '769, '996, and '092 patents, your ANDA contains paragraph III certifications to each of the patents under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Laurus Labs Limited (Laurus) will not market Bictegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg prior to the expiration of the patents. Therefore, final approval of your ANDA may not be granted pursuant to section 505(j)(5)(B)(ii) of the FD&C Act until the '996 and '092 patents have expired, currently December 19, 2033.

Your ANDA contains paragraph IV certifications to the '342, '067, '846, and '802 patents[2] 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 Bictegravir, Emtricitabine, and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg, under this ANDA. You have notified the Agency that Laurus 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 Laurus for infringement of the '342, '067, and '846 patents in the United States District Court for the District of Delaware [Gilead Sciences, Inc. v. Laurus Labs Limited, et. al., Civil Action No. 22-00615].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 7.5-year period provided for in sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the FD&C Act,

   b. the date the court decides[3] that the '342, '067 and '846 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the FD&C Act), or

   c. the '791, '065, '996, '769, '092, '342, '067 and '846 patents have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

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, if your ANDA receives final approval, it 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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will be eligible for final approval. A request for final approval that contains no new data, information, or other changes to the ANDA generally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturing and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review available Agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review the changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after tentative approval, including changes in labeling, patent or exclusivity information, or marketing status. The

submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information as specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book. Should you believe that there are grounds for issuing the final approval letter prior to December 19, 2033, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Parth Soni, PharmD, MBA, PMP, Regulatory Project Manager, at (301) 796-7673.

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

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[1] With this Tentative Approval letter, the Agency informs you that FDA is continuing to evaluate whether one or more supplements to NDA No. 210251, which is the RLD cited as the Basis of Submission for this ANDA, is eligible for three-year exclusivity under section 505(c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(iii), and (j)(5)(F)(iv) of the FD&C Act. Upon making its decision, the Agency will identify any period of exclusivity for which NDA No. 210251 is eligible in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book. Please note that any determination that a supplement to NDA No. 210251 qualifies for exclusivity may affect the date on which your ANDA is eligible for Final Approval. Please also note that if you seek to omit any exclusivity-protected indication or aspect of labeling under 21 CFR 314.94(a)(8)(iv), FDA will need to evaluate the acceptability of your proposed labeling. FDA recommends that you request Final Approval in a manner consistent with recommendations in the *Guidance for Industry: ANDA Submissions-Amendments and Request for Final Approval to Tentatively Approved ANDAs* taking into account when you believe all barriers to final approval will be extinguished.

[2] The Agency notes that the '802 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

[3] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

Sarah Kurtz

Digitally signed by Sarah Kurtz
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