ANDA 218383

ANDA TENTATIVE APPROVAL

Lupin Pharmaceuticals, Inc
U.S. Agent for Lupin Limited
111 South Calvert Street
Harborplace Tower, 21st Floor
Baltimore, MD 21202
Attention: Debashis Mohanty
Associate Director- Regulatory Affairs

Dear Debashis Mohanty:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 31, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Abacavir, Dolutegravir and Lamivudine Tablets for Oral Suspension, 60 mg/5 mg/30 mg.

Reference is also made to the complete response letter issued by this office on May 6, 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. We have determined your Abacavir, Dolutegravir and Lamivudine Tablets for Oral Suspension, 60 mg/5 mg/30 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Triumeq PD Tablets for Oral Suspension, 60 mg/5 mg/30 mg, of ViiV Healthcare Company (ViiV) NDA - 215413.

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**. 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, ViiV's Triumeq PD Tablets for Oral Suspension, 60 mg/5 mg/30 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
8,129,385 (the '385 patent)	April 5, 2028
9,242,986 (the '986 patent)	June 8, 2030

Your ANDA contains a paragraph III certification to the patent '385 under section 505(j)(2)(A)(vii)(III) of the FD&C Act stating that Lupin Limited (Lupin) will not market Abacavir, Dolutegravir and Lamivudine Tablets for Oral Suspension, 60 mg/5 mg/30 mg prior to the expiration of the patent. 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 '385 patent has expired, currently April 5, 2028.

Your ANDA contains a paragraph IV certification to the '986 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Abacavir, Dolutegravir and Lamivudine Tablets for Oral Suspension, 60 mg/5 mg/30 mg, under this ANDA. You have notified the Agency that Lupin complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Lupin within the statutory 45-day period.

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 April 5, 2028[1], 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 Paula Oriaku, PharmD, MS, Regulatory Project Manager, at (301) 796 - 1644.

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] We note that this ANDA currently is eligible for approval the day after expiration of the pediatric exclusivity period. See Section 505A(b)(1)(B) of the FD&C Act. If this day falls on a Saturday, Sunday, or Federal holiday, it will be eligible for approval the next business day.

Paul Levine

Digitally signed by Paul Levine
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