DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 079246

ANDA APPROVAL

Teva Pharmaceuticals USA
425 Privet Road
Horsham, PA 19044
Attention: Rich Leone
Senior Director, Regulatory Affairs, US Generics

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Abacavir and Lamivudine Tablets USP, 600 mg/300 mg.

Reference is also made to the tentative approval letter issued by this office on July 17, 2014, and to your amendments dated January 13, January 29, April 28, July 22, July 28, and August 31, 2016.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the **ANDA is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Abacavir and Lamivudine Tablets USP, 600 mg/300 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Epzicom Tablets, 600 mg/300 mg, of ViiV Healthcare Company (ViiV). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, ViiV's Epzicom Tablets, 600 mg/300 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,905,082 (the '082 patent) and 6,294,540 (the '540 patent) are scheduled to expire (with pediatric exclusivity added) on November 18, 2016, and November 14, 2018, respectively.

With respect to the '540 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Abacavir and Lamivudine Tablets USP, 600 mg/300 mg, under this ANDA. You have notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Teva within the statutory 45-day period.

As noted above, the pediatric exclusivity period associated with the '082 patent is scheduled to expire on November 18, 2016. You have notified the agency that ViiV has granted a selective

waiver to Teva with respect to the pediatric exclusivity period associated with the '082 patent, effective as of September 28, 2016. With this waiver, the Office of Generic Drugs is able to approve your ANDA prior to expiration of the pediatric exclusivity period associated with the '082 patent.

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Abacavir and Lamivudine Tablets USP, 600 mg/300 mg. Therefore, with this approval, Teva is eligible for 180 days of generic drug exclusivity for Abacavir and Lamivudine Tablets USP, 600 mg/300 mg. It is noted that this ANDA was not tentatively approved within the 30-month period described in section 505(j)(5)(D)(i)(iv) of the FD&C Act. Nevertheless, the agency has determined that Teva has not forfeited its eligibility for 180-day generic drug exclusivity.[1] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

[1] ANDA 079246 was received on September 27, 2007. On June 27, 2016, Teva submitted a correspondence to the agency asserting on several grounds that the applicant has not forfeited its eligibility for exclusivity. The agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed. Accordingly, the agency has not considered any alternative grounds asserted by Teva in support of its position.

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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