FDA U.S. FOOD & DRUG ADMINISTRATION

RECEIVED
5/31/18

ANDA 091144/S-012

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Cipla USA, Inc.
U.S. Agent for Cipla Limited
1560 Sawgrass Corporate Parkway
Suite 130
Sunrise, FL 33323
Attention: Michele Crawley

Digitally signed by Margină Veaceslav
Date: 2019.03.04 12:45:47 EET
Reason: MoldSign Signature
Location: Moldova

Dear Madam:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on December 19, 2017, 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 any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as "Changes Being Effected in 30 Days", provides for:

- Addition of Cipla Limited, Goa, India as an alternate drug product manufacturing, packaging, labeling, warehousing and testing site.

We have completed the review of this sANDA, as amended, and it is approved.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Office of Generic Drugs should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Office of Generic Drugs in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions [1] 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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

If you have any questions regarding the resubmission of this supplement as a PAS, please call Yajun (Jason) Tu, Regulatory Business Process Manager, at (240) 402-4202.

Sincerely yours,

{See appended electronic signature page}

For:
Paul Schwartz, Ph.D.
Director, Division of Post Marketing Activities II
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

[1] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Andrew
Langowski

Digitally signed by Andrew Langowski
Date: 5/23/2018 05:27:52PM
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