ANDA 062621/S-043

CHANGES BEING EFFECTED
SUPPLEMENT APPROVAL

Arbor Pharmaceuticals, LLC
Suite 1800
6 Concourse Parkway
Atlanta, GA 30328

Attention: Cassie Alexander
Manager, Regulatory Affairs

Dear Ms. Alexander:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on August 17, 2018, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Erythromycin Tablets USP, 250 mg and 500 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

This Changes Being Effected supplemental abbreviated new drug application provides for updated package insert labeling based on updated labeling for NDA 050611/S-036, approved 04/23/2018. The amendment further provides for updated package insert labeling to align with the most recent annual report (30) submission dated May 31, 2019 which includes the100-count bottles in the How Supplied section, update to the Contraindication section, update to the Microbiology section to comply with the STIC guidance, removal of pregnancy category to comply with the PLLR guidance and minor editorial changes.

We have completed the review of this supplemental application. It is approved, effective on the date of this letter.

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.

Sincerely yours,

{See appended electronic signature page}

For CAPT Thuyanh Vu, RPh, MBA
Acting Director
Divison of Labeling Review
Office of Regulatory Operations
Office of Generic Drugs

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

Carrie Lemley

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