DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-207/S-073

SUPPLEMENT APPROVAL

Arbor Pharmaceuticals, LLC
Attention: Briana Warren
Manager, Regulatory Affairs, Labeling
6 Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Warren:

Please refer to your Supplemental New Drug Application (sNDA) dated May 24, 2017, received May 24, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EES (erythromycin ethylsuccinate) Granules for Oral Suspension.

This Prior Approval supplemental new drug application proposes to update the **CLINICAL PHARMACOLOGY** and **REFERENCES** sections and **Microbiology** subsection of the labeling with changes made to the approved label for ANDA 61905 EES 400 (erythromycin ethylsuccinate).APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below. (Deletions –Strikethrough and additions underlined). The attached label contains the changes listed below.

Microbiology

Interactions with other (b) (4) -Antimicrobials (b) (4)
Antagonism exists in vitro between erythromycin and clindamycin, lincomycin, and chloramphenicol.

REFERENCES

1. Clinical and Laboratory Standards Institute (CLSI). *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria ~~that~~That Grow Aerobically, Approved Standard – Tenth Edition.* CLSI document M07-A10. Wayne, PA: Clinical and Laboratory- Standards Institute; 2015.
2. Clinical and Laboratory Standards Institute (CLSI). *Performance Standards for Antimicrobial Susceptibility Testing.* 27th ed. CLSI ~~document~~ supplement M100.Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions listed, the enclosed labeling text for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Acting Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DMITRI IARIKOV
08/17/2017