



NDA 050207/S-074  
NDA 050611/S-036

**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 Applications (sNDAs) dated and received February 23, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ERY-PED and E.E.S. (erythromycin ethylsuccinate) (NDA 050207), and PCE Tablets (erythromycin particles in tablets) (NDA 50611).

These “Changes Being Effected” supplemental new drug applications revise the **CONTRAINDICATIONS** section as suggested in our January 29, 2018, correspondence. The following sentence was added:

Do not use erythromycin concomitantly with HMG CoA reductase inhibitors (statins) that are extensively metabolized by CYP 3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis.

**APPROVAL & LABELING**

We have completed our review of these supplemental applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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 the enclosed labeling text for the package inserts with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labelings.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 approved in these supplemental applications, 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

*{See appended electronic signature page}*

Joseph Toerner, M.D., M.P.H.  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE:

Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOSEPH G TOERNER  
04/23/2018