



NDA 50-207/S-071
NDA 50-611/S-035

SUPPLEMENT APPROVAL

Arbor Pharmaceuticals, Inc.
Attention: Anita Fauchier
Director, Quality and Regulatory Affairs
980 Hammond Drive, Suite 1250
Atlanta, GA 30363

Dear Ms. Fauchier:

Please refer to your Supplemental New Drug Applications (sNDAs) dated January 13, 2012, received January 13, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50-207/S-071	EES (erythromycin ethylsuccinate) Granules for Oral Suspension Ery-Ped (erythromycin ethylsuccinate) Liquid
NDA 50-611/S-035	PCE (erythromycin particles in tablets) Film Coated Tablets, 333 mg and 500 mg

These “Prior Approval” supplemental new drug applications were submitted in response to an Agency supplemental request letter dated November 15, 2011 to add wording concerning QT prolongation to the **WARNINGS** section of the label.

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

We note that your January 13, 2012, submission includes final printed labeling (FPL) for your package inserts. We have not reviewed this FPL. You are responsible for assuring that the wording in these printed labeling are identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 test for 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 from 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 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}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
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/

SUMATHI NAMBIAR
02/02/2012