



NDA 50-207/S-064

**SUPPLEMENT APPROVAL**

Arbor Pharmaceuticals, Inc.  
Attention: Anita Fauchier  
Director, Quality and Regulatory Affairs  
980 Hammond Drive, Suite 1250  
Atlanta, GA 30328

Dear Ms. Fauchier:

Please refer to your Supplemental New Drug Application (sNDA) dated September 29, 2006, received October 2, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50-207/S-064 EES (erythromycin ethylsuccinate) Granules for Oral Suspension  
Ery-Ped<sup>®</sup> (erythromycin ethylsuccinate) Liquid

We acknowledge receipt of your amendments dated March 19, 2009 and November 30, 2010. The November 30, 2010, submission constitutes a complete response to our June 25, 2010 action letter.

This supplemental new drug application proposes changes to the **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS** sections. The changes provide additional information on drug interactions, interstitial nephritis, and animal toxicology studies.

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.

We ask that you submit a supplemental application updating NDA 50-297 Ery-Ped (erythromycin ethylsuccinate) Chewable Tablets incorporating the approved changes.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling text for the package insert and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements and any 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.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

## **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}*

Katherine A. Laessig, MD  
Deputy Director  
Division of Ant-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure:

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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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KATHERINE A LAESSIG  
01/26/2011