



NDA 050786/S-016

SUPPLEMENT APPROVAL

Forest Laboratories, LLC
Attention: Linda Kunka, MA
Director, Regulatory Affairs
Harborside Financial Center
Plaza V Suite 1900
Jersey City, NJ 07311

Dear Ms. Kunka:

Please refer to your Supplemental New Drug Application (sNDA) dated April 10, 2017, received April 10, 2017, and your amendment dated May 19, 2017, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pylera (bismuth subcitrate potassium, metronidazole, tetracycline HCl) Capsules.

The submission provides for changes to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, as well as, **WARNINGS AND PRECAUTIONS (5)** that describe metronidazole-associated adverse event monitoring for patients with hepatic impairment (in subsection **5.10**) and **Hepatic Impairment (8.7)**

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.

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, 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 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 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 Deepak Aggarwal, Regulatory Project Manager, at (301) 796-0746.

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(S):
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
05/30/2017