DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200327/S-013
NDA 200327/S-014
NDA 200327/S-015

SUPPLEMENT APPROVAL

Forest Research Institute, Inc.
A subsidiary of Forest Laboratories, Inc.
Attention: Patricia Pacificador, PharmD
Senior Manager, Regulatory Affairs
Harborside Financial Center, Plaza V, Suite 1900
Jersey City, NJ 07311

Dear Dr. Pacificador:

Please refer to the following Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Teflaro (ceftaroline fosamil) for Injection:

NDA	Supplement Number	Submitted Date	Received Date
200327	S-013	November 14, 2014	November 14, 2014
200327	S-014	November 21, 2014	November 21, 2014
200237	S-015	April 24, 2015	April 24, 2015

We acknowledge receipt of your amendments dated as follows:

Supplement Number	Submitted Date
S-013	December 23, 2014
	March 31, 2015
	August 21, 2015
S-014	February 5, 2015
	February 24, 2015
	August 21, 2015
S-015	May 7, 2015
	August 21, 2015

These “Prior Approval” supplemental new drug applications provide for the following:

S-013 provides for the addition of information to the Clinical Studies section (14) of the package insert regarding cases of acute bacterial skin and skin structure infections with concurrent bacteremia caused by *Staphylococcus aureus.*

S-014 provides for revisions to the Dosage and Administration section (2) to change the recommended duration of ceftaroline fosamil intravenous infusion from one hour to 5 to 60 minutes.

S-015 provides for the addition of a Postmarketing Experience subsection (6.2) and inclusion of the adverse reaction of agranulocytosis in this subsection.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. 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 August 21, 2015, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 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 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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
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/

SUMATHI NAMBIAR
08/31/2015