DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022106/S-012

SUPPLEMENT APPROVAL

Shionogi, Inc.
Attention: Jairo A. Ussa
Senior Manager, Regulatory Affairs, CMC
300 Campus Drive, Suite 300
Florham Park, NJ 07932

Dear Mr. Ussa:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DORIBAX (doripenem) for Injection.

We acknowledge receipt of your amendments dated February 7 and February 10, 2012, March 26, April 3, April 29, June 12, 2013, and January 13, 2014.

This "Prior Approval" supplemental new drug application provides for the following changes:

1. **HIGHLIGHTS** section

   RECENT MAJOR CHANGES
   Addition of the following:
   Warnings and Precautions
   - Increased Mortality in Ventilator-Associated Bacterial Pneumonia (5.1)

   WARNINGS AND PRECAUTIONS
   Addition of new information regarding increased mortality in ventilator-associated bacterial pneumonia

2. **FULL PRESCRIBING INFORMATION**

   WARNINGS AND PRECAUTIONS section: Addition of a new subsection, **Increased Mortality in Ventilator-Associated Bacterial Pneumonia** (5.1).

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 (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 includes 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
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/

SUMATHI NAMBIAR
01/17/2014