DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-679/S-034

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Fred Fantozzi, M.S.
Product Manager, Global Regulatory Affairs
275 N. Field Drive
Dept. 0389, Bldg. H2-2N
Lake Forest, IL 60045

Dear Mr. Fantozzi:

Please refer to your Supplemental New Drug Application (sNDA) dated August 12, 2010, received August 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MAXIPIME (cefepime hydrochloride, USP) for Injection, USP.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the package insert, as requested in our June 8, 2010, supplement request letter:

- Addition of "non-convulsive status epilepticus" in the **WARNINGS** section, **Neurotoxicity** subsection, **PRECAUTIONS** section, **Information for Patients** subsection, **ADVERSE REACTIONS s**ection, **Postmarketing Experience** subsection and in the **OVERDOSAGE** section.

- Addition of a paragraph regarding the risk of hypersensitivity reactions in the **PRECAUTIONS** section, **Information for Patients** subsection.

- Addition of "erythema" and "anemia" in the **ADVERSE REACTIONS** section, **Clinical Trials** subsection, Table 10.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor formatting revision listed below and indicated in the enclosed labeling:

- Addition of a hard return at line 623 to set off the paragraph beginning with the term "Encephalopathy."

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 revisions listed.

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 via 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 with the revisions listed **or** indicated above 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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

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
03/15/2013