NDA 208385/S-008

SUPPLEMENT APPROVAL

Sagent Pharmaceuticals, Inc.
Attention: Magdalena Pabis
Senior Associate, Regulatory Affairs
1901 N. Roselle Road, Suite 450
Schaumburg, IL, 60195

Dear Ms. Pabis:

Please refer to your supplemental new drug application (sNDA) dated and received October 13, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Daptomycin for Injection 350 mg vial.

This Prior Approval sNDA provides for the addition of pediatric patients (1 to 17 years of age) to the approved indications for the treatment of complicated skin and skin structure infections (cSSSI), and for the treatment of *Staphylococcus aureus* bloodstream infections (bacteremia) because the patent exclusivity for the listed drug has expired.

Specifically, the following sections and subsections of the prescribing information (PI) have been updated: **HIGHLIGHTS OF PRESCRIBING INFORMATION**; **FULL PRESCRIBING INFORMATION: CONTENTS**; **INDICATIONS AND USAGE (1); DOSAGE AND ADMINISTRATION (2); DOSAGE FORMS AND STRENGTHS (3); WARNINGS AND PRECAUTIONS (5), Development of Drug-Resistant Bacteria (5.12); ADVERSE REACTIONS, Clinical Trials Experience (6.1), Post-Marketing Experience (6.2); USE IN SPECIFIC POPULATIONS, Pediatic Use (8.4), Patients with Renal Impairment (8.6); CLINICAL PHARMACOLOGY (12), Pharmacokinetics (12.3); CLINICAL STUDIES (14);** and **PATIENT COUNSELING INFORMATION (17)**. In addition, minor editorial changes have been made throughout the PI,

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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

FDA.gov.[1] Content of labeling must be identical to the enclosed labeling text for the Prescribing Information 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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, PharmD, Chief Regulatory Project Manager, at 301-796-1203.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseaes
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
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