



NDA 208385/S-001

SUPPLEMENT APPROVAL

Sagent Pharmaceuticals, Inc.
Attention: Sheeja George
Senior Manager, Regulatory Affairs
1901 N. Roselle Road, Suite 450
Schaumburg, IL 60195

Dear Ms. George:

Please refer to your Supplemental New Drug Application (sNDA) dated February 27, 2018, received February 27, 2018, 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 per vial.

This Changes Being Effected supplemental new drug application provides for revisions to the package insert. The following sections and subsections have been updated:

INDICATIONS AND USAGE section (1); *Staphylococcus aureus* **Bloodstream Infections (Bacteremia) in Adult Patients, Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates** subsection (1.2)
WARNINGS AND PRECAUTIONS section (5); **Eosinophilic Pneumonia** subsection (5.3)
ADVERSE REACTIONS section (6); **Post Marketing Experience** subsection (6.2)
USE IN SPECIFIC POPULATIONS section (8); **Pediatric Use** subsection (8.4)
CLINICAL PHARMACOLOGY section (12); **Microbiology** subsection (12.4)
CLINICAL STUDIES section (14); **Complicated Skin and Skin Structure Infections** subsection (14.1)

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 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 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 Naseya Minor, Regulatory Project Manager, at (301) 796-0756.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, Ph.D.
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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
08/30/2018