DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21883/S-007

SUPPLEMENT APPROVAL

Allergan Sales, LLC
Attention: Sandra P. Silva, MS, MBA
Director of Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Silva:

Please refer to your Supplemental New Drug Application (sNDA) dated January 16, 2018, received January 16, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dalvance (dalbavancin) for injection, 500 mg.

This Prior Approval supplemental application provides for the addition of "back pain" to the **(5) WARNINGS AND PRECAUTIONS** section, **(5.2) Infusion-Related Reactions** subsection, and the **(6) ADVERSE REACTIONS** section, **(6.2) Post Marketing Experience** subsection, based on referenced safety information from the company core data sheet (CCDS).

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 agreed-upon labeling text and with the minor editorial revision listed below:

- In the **(6.2) Post Marketing Experience** subsection, replace the braces ({}) in the reference to subsection 5.2, with square brackets (*[ ]*) as follows:

  General disorders and administration site conditions: Back pain as an infusion-related reaction *[see Warnings and Precautions (5.2)]*

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 minor editorial change listed above, and 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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

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

/s/

DMITRI IARIKOV
07/24/2018