DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-110/S-10

SUPPLEMENT APPROVAL

Theravance Biopharma Antibiotics, Inc.
Attention: Rebecca Coleman, PharmD
Vice President, Regulatory Affairs and Quality
901 Gateway Boulevard
South San Francisco, CA 94080

Dear Dr. Coleman:

Please refer to your Supplemental New Drug Application (sNDA) dated July 2, 2014, received, July 2, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIBAIV (telavancin) for Injection, 250 mg and 750 mg.

We acknowledge receipt of your amended risk evaluation and mitigation strategy (REMS) on October 30, 2014.

This "Prior Approval" supplemental new drug application provides for updated REMS materials, reflecting the change in ownership for NDA 22-110.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for VIBATIV was originally approved on September 11, 2009, and REMS modifications were approved on July 27, 2011 and June 21, 2013. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS. As indicated above, your proposed modification to the REMS consist of updated REMS materials, reflecting the change in ownership for NDA 22-110.

APPROVAL OF REMS MATERIALS

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 REMS documentation.

The timetable for submission of assessments of the REMS will remain the same as that approved on June 21, 2013.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 22-110 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 22110 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 22110
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 22110
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: REMS

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
11/12/2014