DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-883/S-002

**SUPPLEMENT APPROVAL**

Durata Therapeutics International, B.V.
c/o Durata Therapeutics, Inc.
Attention: Nicole Bradley, PharmD
Director, Regulatory Affairs
Harborside Financial Center, Plaza V, Suite 1900
Jersey City, NJ 07311

Dear Dr. Bradley:

Please refer to your Supplemental New Drug Application (sNDA) dated June 26, 2015, received June 26, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DALVANCE (dalbavancin hydrochloride) 500 mg, Powder for Injection.

We also acknowledge receipt of your amendments dated October 20, November 2 and 6, 2015.

This "Prior Approval" supplemental new drug application provides for revisions to the **HIGHLIGHTS, RECENT MAJOR CHANGES** section, **DOSAGE AND ADMINISTRATION**, Preparation and Administration subsection (2.3), **DOSAGE FORMS AND STRENGTHS** section (3.0), **ADVERSE REACTIONS**, Clinical Trials Experience subsection (6.1), **DRUG INTERACTIONS**, Drug-Laboratory Test Interactions subsection (7.1), **USE IN SPECIFIC POPULATIONS**, Pregnancy subsection (8.1), Lactation subsection (8.2), **DESCRIPTION** (11) section, **NONCLINICAL TOXICOLOGY**, Carcinogenesis, Mutagenesis, Impairment of Fertility subsection (13.1) and **REFERENCES** section (15), along with other minor editorial revisions.

## APPROVAL & LABELING

We have completed our review of this supplemental application, as amended and 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 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 includes 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).

## CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on November 2, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-883/S-002**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## 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(S): Content of Labeling
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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JOSEPH G TOERNER
12/18/2015