

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 21-572/S-052

Trade Name: Cubicin® RF

Generic Name: daptomycin for injection

Sponsor: Cubist Pharmaceuticals LLC

Approval Date: July 6, 2016

Indications: For complicated skin and skin structure infections, *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis.

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APPROVAL LETTER



NDA 21-572/S-052

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp., agent for Cubist Pharmaceuticals, LLC
Attention: Sandra Lynn Wood, PhD
Director, Global Regulatory Affairs
351 North Sumneytown Pike
P.O. Box 1000, Mailstop UG-2D48
North Wales, PA 19454-2505

Dear Dr. Wood:

Please refer to your Supplemental New Drug Application (sNDA) dated February 9, 2016, received February 9, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cubicin RF (daptomycin for injection), 500 mg/vial.

This Prior Approval supplemental new drug application provides for a re-formulated Cubicin product, Cubicin RF. The package insert (PI) and carton and container labels have been revised accordingly, the former including changes to the **HIGHLIGHTS OF PRESCRIBING INFORMATION** section, **DOSAGE AND ADMINISTRATION (2)**, **Preparation of CUBICIN RF for Administration (2.5)**, **Compatible Intravenous Solutions (2.6)**, and **Incompatibilities (2.7)** subsections, **DESCRIPTION (11)** section, and the **HOW SUPPLIED/STORAGE AND HANDLING (16)** section.

Additionally, the following has been added to the **ADVERSE REACTIONS (6)**, **Postmarketing Experience (6.2)** subsection:

- *Blood and lymphatic system disorders:* anemia
- *General and administration site conditions:* pyrexia
- *Renal and urinary disorders:* acute kidney injury, renal insufficiency, and renal failure
- *Skin and Subcutaneous Tissue Disorders:* acute generalized exanthematous pustulosis

Further, the term “single-use” has been replaced with “single-dose” throughout the package insert, cartons and containers.

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 (text for the package insert), 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 carton and immediate container labels submitted on June 22, 2016, 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 21-572/S-052.**” 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.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

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