



NDA 201699/S-010

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp  
Agent for Cubist Pharmaceuticals, LLC  
Attention: Sandra Lynn Wood, Ph.D.  
Director, Global Regulatory Affairs  
PO Box 1000 Mailstop UG2CD-48  
351 North Sumneytown Pike  
North Wales, PA 19454

Dear Dr. Wood:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 26, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Difucid (fidaxomicin) 200 mg Tablet.

This Prior Approval supplemental new drug application provides for the following revisions:

The prescribing information (PI) was updated in accordance with the Pregnancy and Lactation Labeling Rule (PLLR) [21 CFR 201.57(c)(9)(i) through (iii)].

The **CLINICAL PHARMACOLOGY (12)** section, **Clinical Microbiology subsection (12.4)**, was updated to be consistent with the FDA Guidance for Industry: Systemic Antibacterial and Antifungal Drugs: Susceptibility Test Interpretative Criteria Labeling for NDAs and ANDAs <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM588747.pdf>

The **INDICATION AND USAGE (1)** section, **Usage subsection (1.2)**, was updated to be consistent with regulatory required statement 21 CFR 201.204.

The **CONTRAINDICATIONS (4)** section, and **WARNINGS AND PRECAUTIONS (5)** section, **Lack of Effectiveness for Infections other than C. difficile-Associated Diarrheas subsection (5.1)** were revised for clarity.

The **HIGHLIGHTS OF PRESCRIBING INFORMATION** has also been updated to reflect the changes made to the Full Prescribing Information (FPI).

Additionally, minor editorial changes have been made throughout the labeling.

## **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 with minor editorial revisions.

## **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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 Fariba Izadi, PharmD, Regulatory Project Manager, at (301) 796-0563.

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(S):

Content of Labeling  
Prescribing Information

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**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.**  
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/s/  
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DMITRI IARIKOV  
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