



NDA 201699/S-013
NDA 213138/S-001

SUPPLEMENT APPROVAL

Cubist Pharmaceuticals LLC
c/o Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Attention: Sandra Lynn Wood, PhD
Director, Global Regulatory Affairs
P.O. Box 1000, UG2CD-48
351 North Sumneytown Pike
North Wales, PA 19454

Dear Dr. Wood:

Please refer to your supplemental new drug applications (sNDAs) dated February 13, 2020, received February 13, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DIFICID (fidaxomicin) tablets, 200 mg [NDA 201699/S-013] and DIFICID (fidaxomicin) for oral suspension, 40 mg/mL (200 mg/5 mL) [NDA 213138/S-001].

These “Changes Being Effected” supplemental new drug applications provide for the following changes: revisions to the format of the National Drug Code (NDC) in the Prescribing Information and the carton and container labels for DIFICID (fidaxomicin) for oral suspension.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.¹ 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 *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, 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 these supplemental applications, 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).

CARTON AND CONTAINER LABELING

We acknowledge your February 13, 2020 and March 24, 2020, submissions containing final printed carton and container labeling.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

NDA 201699/S-013

NDA 213138/S-001

Page 3

If you have any questions, call Kristine Park, PhD, RAC, Senior Regulatory Health Project Manager, at (301) 796-0471.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
- Carton and Container 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
05/28/2020 03:24:35 PM