DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205572 /S-06

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Attention: John McNally
Senior Regulatory Specialist
Three Corporate Drive
Lake Zurich, IL 60047

Dear Mr. McNally:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 10, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Moxifloxacin Injection, 400 mg/250 mL.

We also refer to our letter dated December 20, 2018, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for the systemic fluoroquinolone class of antibacterial drugs. This information pertains to the risk of aortic aneurysm and dissection.

We also refer to our February 13, 2019 letter that informed you of an additional extension of the discussion period to allow us to complete our review and reach agreement on the content of the labeling.

This supplemental new drug application provides for the inclusion of new safety information describing the risk of aortic aneurysm and dissection in the following sections of the labeling.

- **WARNINGS AND PRECAUTIONS (5)** section, **Risk of Aortic Aneurysm and Dissection (5.9)** subsection
- **USE IN SPECIFIC POPULATIONS (8)** section**, Geriatric Use (8.5)** subsection.
- **PATIENT COUNSELING INFORMATION (17)**
- **MEDICATION GUIDE**

In addition, minor editorial revisions have been made throughout the labeling to reflect these changes.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended during the discussion period. 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 (Medication Guide), 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, Acting Safety Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Joseph G. Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/

JOSEPH G TOERNER
05/03/2019 11:16:00 AM