NDA 205572/S-005

APPROVAL LETTER

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 September 27, 2018, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Moxifloxacin Injection, 400 mg/250 mL.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following changes:

1. Addition of an alternate manufacturing process for Moxifloxacin Hydrochloride, the active pharmaceutical ingredient (API) in MOXIFLOXACIN injection, as supplied by (b) (4).
2. Addendum to the Elemental Impurities Risk assessment done according to ICH Q3D and USP <232>; results of the final EI risk assessment support non-testing of the drug product for elemental impurities.

APPROVAL

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Chinedu Ebonine, Regulatory Business Process Manager, at (240) 402 - 3448.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
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