NDA 20634/S-073

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Tamara Mazza, PhD
Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Dr. Mazza:

Please refer to your supplemental new drug application (sNDA) dated and received April 03, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Levaquin Tablets (250 mg, 500 mg, and 750 mg).

This Prior Approval supplemental new drug application provides for revisions to the prescribing information (PI) as follows:

The **HIGHLIGHTS OF PRESCRIBING INFORMATION** and the **USE IN SPECIFIC POPULATIONS (8)** section, **Lactation (8.2)** subsection were revised to provide for the risk benefit assessment of Levaquin tablets for ihhalational anthrax (post-exposure).

The Medication Guide has also been updated to be in agreement with the revisions made to the PI.

Minor editorial changes were made throughout the PI.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 and 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 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, Safety Regulatory Project Manager at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
• Content of Labeling
  o Prescribing Information
  o Medication Guide:

[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.

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
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