DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020634/S-067
NDA 020635/S-073
NDA 021721/S-034

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Andrea Kollath, DVM
Director, Global Regulatory Affairs
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Dr. Kollath:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received June 10, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA #	Supplement #	Drug Product	Dosage
020634	S-067	Levaquin (levofloxacin) Tablets	250 mg, 500 mg, and 750 mg
020635	S-073	Levaquin (levofloxacin) Injection	25 mg/mL and 5 mg/mL
021721	S-034	Levaquin (levofloxacin) Oral Solution	25 mg/mL

We also refer to our letter dated May 12, 2016, notifying you, under Section 505(o)(4) of the FDCA, of new safety information required to be included in the labeling for the systemic fluoroquinolone class of antibacterial drugs.

These sNDAs provide for revisions to the Indications and Usage section of the package insert to include a new limitation of use statement for uncomplicated urinary tract infections, acute bacterial sinusitis, and acute bacterial exacerbation of chronic bronchitis to reserve Levaquin for treatment in patients who have no alternative treatment options. In addition, the Boxed Warning, Warnings and Precautions, and Information for Patients sections of the package insert and the Medication Guide have been revised to include information regarding the risk of disabling and potentially irreversible serious adverse reactions.

Other label changes not required under section 505(o)(4) were also provided so as to furnish adequate information for the safe and effective use of Levaquin.

These supplemental new drug applications provide for all revisions to the labeling for Levaquin consistent with our May 12, 2016 letter.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are 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 (text for the package insert, 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 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

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

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOSEPH G TOERNER
07/26/2016