DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020634/S-066
NDA 020635/S-072
NDA 021721/S-033

SUPPLEMENT APPROVAL

Janssen Research & Development, LLC
Attention: Andrea F. Kollath, DVM
Director, Global Regulatory Affairs
1000 Route 202 South
P.O. Box 300
Raritan, NJ 08869

Dear Dr. Kollath:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received September 13, 2013, submitted under section 505(b) the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA #	Supplement #	Drug Product	Dosage
20-634	066	Levaquin (levofloxacin) Tablets	250 mg, 500 mg, and 750 mg
20-635	072	Levaquin (levofloxacin) Injection	25 mg/mL and 5mg/mL
21-721	033	Levaquin (levofloxacin) Oral Solution	25 mg/mL

These "Prior Approval" supplemental new drug applications provide for the addition of uveitis to the **ADVERSE REACTIONS Section (6), Postmarketing Experience subsection (6.3), Table 8,** Eye Disorders.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. 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), 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}

Sumathi Nambiar, M.D., M.P.H.
Director
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/

SUMATHI NAMBIAR
05/23/2014