DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-634/S-059
NDA 20-635/S-065
NDA 21-721/S-026

SUPPLEMENT APPROVAL

Ortho-McNeil-Janssen Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Melissa L. Gannon
Director, Regulatory Affairs, Established Product Support
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Gannon:

We have received your March 11, 2011, Supplemental New Drug Applications (sNDA's) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA/Supplement Number	Product name
20-634/S-059	LEVAQUIN (levofloxacin) Tablets, 250 mg, 500 mg and 750 mg
20-635/S-065	LEVAQUIN (levofloxacin) Injection, 25 mg/mL and LEVAQUIN (levofloxacin in 5% Dextrose) Injection, 5 mg/mL
21-721/S-026	LEVAQUIN (levofloxacin) Oral Solution, 25 mg/mL

We acknowledge receipt of your amendments dated April 21, 2011.

These "Prior Approval" supplemental new drug applications provide for revisions to the package insert to change information for *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control (QC) parameters for the *in vitro* susceptibility testing of organisms listed in the package insert.

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 labeling submitted April 21, 2011, with the additional minor edit of the word "weas to "was" in footnote ‡ in Table 9 on page 27.

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 submitted 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 submitted 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 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 regarding these supplements, call Maureen Dillon-Parker, Chief, Project Management Staff at (301) 796-0706. For all other issues regarding these NDAs, please contact Fariba Izadi, R.Ph., Pharm.D., Regulatory Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Sumati Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Attachment:
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
06/09/2011