



NDA 020634/S-062, 064
NDA 020635/S-068, 070
NDA 021721/S-029, 031

SUPPLEMENT APPROVAL

Ortho-McNeil-Janssen Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research and Development, LLC
Attention: Melissa L. Gannon
Director, Regulatory Affairs
920 Route 202 South, PO Box 300
Raritan, NJ 08869-0602

Dear Ms. Gannon:

Please refer to your supplemental New Drug Applications (sNDAs) for the following:

NDA Number	Drug Name	Supplement Number	Submission Date	Date Received
020634	LEVAQUIN (levofloxacin) Tablets	S-062, 064	August 25, 2011	August 26, 2011
020635	LEVAQUIN (levofloxacin) Injection	S-068, 070	August 25, 2011	August 26, 2011
021721	LEVAQUIN (levofloxacin) Oral Solution	S-029, 031	August 25, 2011	August 26, 2011

The “Prior Approval” supplemental applications, 062, 068, and 029 provide for the addition of pseudotumor cerebri to the WARNINGS, Central Nervous System Effects/Disorders Subsection, of the package insert, as noted in our June 24, 2011, supplement request letter.

The “Prior Approval” supplemental applications 064, 070, and 031 provide for revisions to the Medication Guide according to our July 20, 2011, Risk Evaluation and Mitigation Strategy (REMS) modification notification letter.

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, submitted on August 25, 2011.

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

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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 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 submissions, 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, MD, Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, 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: Package Insert

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
10/11/2011