



NDA 20-634/S-039  
NDA 20-635/S-042  
NDA 21-721/S-006

Ortho McNeil Pharmaceutical, Inc.  
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.  
Attention: Mrs. Alysia Baldwin-Ferro  
Director, Regulatory Affairs  
1000 U.S. Highway 202 South, P.O. Box 300  
Raritan, NJ 08869-0602

Dear Mrs. Baldwin-Ferro:

Please refer to your supplemental new drug applications, dated May 9, 2005 and received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Product
20-634	039	Levaquin <sup>®</sup> (levofloxacin) Tablets, 250 mg, 500 mg, and 750 mg
20-635	042	Levaquin <sup>®</sup> (levofloxacin) Injection and Levaquin <sup>®</sup> (levofloxacin in 5% dextrose) Injection
21-721	006	Levaquin <sup>®</sup> (levofloxacin) Oral Solution, 25 mg/mL

We acknowledge receipt of your submissions dated November 18, 2005 and January 20, 2006.

Your submissions of November 18, 2005 constituted a complete response to our November 10, 2005 action letter.

These supplemental new drug applications provide for the addition of information pertaining to false-positive urine screening results for opiates caused by levofloxacin in a new subsection under **PRECAUTIONS** as well as to the **Patient Information About Levaquin<sup>®</sup>** section of the labeling.

These supplemental new drug applications provide for the following revisions to the package insert:

1. In the **PRECAUTIONS** section, a new subsection and text were added to the labeling:

*Interaction with Laboratory or Diagnostic Testing*

Some quinolones, including levofloxacin, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

2. The following paragraph was added to the **Patient Information About Levaquin<sup>®</sup>** section of the labeling:

Some quinolones, including levofloxacin, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: ***Providing Regulatory Submissions in Electronic Format - NDAs*** (January 1999) and ***Providing Regulatory Submissions in Electronic Format – Content of Labeling*** (February 2004). The guidances specify that labeling be submitted in *pdf* format. To assist in our review of the FPL and future submissions, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, these submissions should be designated "**FPL for approved supplements NDA 20-634/S-039, NDA 20-635/S-042, and NDA 21-721/S-006.**"

Approval of these submissions by the FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Rebecca D. Saville, Pharm.D., Regulatory Project Manager, at (301) 796-1600.

Sincerely,

*{See appended electronic signature page}*

Renata Albrecht, M.D.  
Director  
Division of Special Pathogen and Transplant Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Renata Albrecht  
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