DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-049
NDA 20-635/S-053
NDA 21-721/S-017

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

Dear Ms. Baldwin-Ferro:

Please refer to your supplemental new drug applications dated October 8, 2007, received October 9, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Product
20-634	049	Levaquin® (levofloxacin) Tablets, 250 mg, 500 mg, and 750 mg
20-635	053	Levaquin® (levofloxacin) Injection and Levaquin® (levofloxacin in 5% dextrose) Injection, 5 mg/mL
21-721	017	Levaquin® (levofloxacin) Oral Solution, 25 mg/mL

These "Changes Being Effected" supplemental applications propose revising the **DOSAGE AND ADMINISTRATION/2.4 Administration Instructions/Food and Levaquin Tablets and Oral Solution** subsection of the package insert to correct the administration instructions for levofloxacin oral solution as follows (~~strikethrough~~ = deleted):

> LEVAQUIN® Tablets ~~and Oral Solution~~ can be administered without regard to food. It is recommended that LEVAQUIN® Oral Solution be taken 1 hour before or 2 hours after eating.

We have completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "**SPL for approved NDA 20-634/S-049, NDA 20-635/S-053, and NDA 21-721/S-017**."

LETTERS TO HEALTH CARE PROFESSIONALS

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 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

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

/s/

Renata Albrecht

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