DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-048
NDA 20-635/S-052
NDA 21-721/S-016

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 September 21, 2007, received on September 21, 2007 (NDA 20-634/S-048) and September 24, 2007 (NDA 20-635/S-052 and NDA 21-721/S-016), and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Product
20-634	048	Levaquin® (levofloxacin) Tablets, 250 mg, 500 mg, and 750 mg
20-635	052	Levaquin® (levofloxacin) Injection and Levaquin® (levofloxacin in 5% dextrose) Injection, 5 mg/mL
21-721	016	Levaquin® (levofloxacin) Oral Solution, 25 mg/mL

These supplemental applications propose revising the first paragraph of the **FULL PRESCRIBING INFORMATION/8. Use in Specific Populations/8.5. Geriatric Use** section of the package insert as follows (~~strikethrough~~ = deleted and double-underlined = added):

> In phase 3 clinical trials, ~~1,190~~1,945 LEVAQUIN®-treated patients (~~25~~26 %) were ≥ 65 years of age. Of these, ~~675~~1,081 patients (14%) were between the ages of 65 and 74 and ~~515~~864 patients (~~11~~12 %) were 75 years or older.

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-048, NDA 20-635/S-052, and NDA 21-721/S-016**."

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

11/15/2007 11:35:29 AM