DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-030
NDA 20-635/S-030

Ortho McNeil Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Robyn S. Thomas
Manager, Regulatory Affairs
US Highway 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Thomas:

Please refer to your supplemental new drug applications dated December 24, 2003, received March 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LEVAQUIN® (levofloxacin) Tablets (NDA 20-634/S-030); LEVAQUIN® (levofloxacin) Injection and LEVAQUIN® (levofloxacin in 5% dextrose) Injection (NDA 20-635/S-030).

We acknowledge receipt of your submissions dated:

January 9, 2004	February 10, 2004 (2)	June 21, 2004
January 29, 2004	March 31, 2004	July 7, 2004

These supplemental new drug applications provide for the use of LEVAQUIN® (levofloxacin) Tablets, LEVAQUIN® (levofloxacin) Injection, and LEVAQUIN® (levofloxacin in 5% dextrose) Injection for the treatment of Community Acquired Pneumonia caused by Multi-Drug Resistant *Streptococcus pneumoniae*.

We 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 submitted July 7, 2004).

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 should be submitted in *pdf* format. To assist in our review, 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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for ages 0 to 18 years until August 1, 2010.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of Community Acquired Pneumonia caused by Multi-Drug Resistant *Streptococcus pneumoniae* in pediatric patients ages 0 to 18 years.

   Final Report Submission: August 1, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Susan Peacock, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

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

Enclosure (labeling)

PROPOSED TEXT OF THE LABELING FOR LEVAQUIN ANNOTATED

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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