DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-054
NDA 20-635/S-059
NDA 21-721/S-022

Ortho McNeil- Janssen Pharmaceutical, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Attention: Ms. Ilona Scott
Director, Regulatory Affairs
Route 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Scott:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug Product Name	**NDA Number**	**Supplement number**	**Date of supplement**	**Date of receipt**
Levaquin® (levofloxacin) Tablets	20-634	S-054	October 31, 2008	November 14, 2008
Levaquin® (levofloxacin) Injection and Levaquin® (levofloxacin in 5% dextrose) Injection	20-635	S-059	October 31, 2008	November 14, 2008
Levaquin® (levofloxacin) Oral Solution	21-721	S-022	October 31, 2008	November 14, 2008

We acknowledge receipt of your submissions dated February 6, 2009.

These supplemental applications propose the following: updating the carton and container labels to include a statement to let dispensers know that a Medication Guide must be dispensed with the product, in compliance with the Medication Guide Regulations as specified in 21 CFR 208.24 (d).

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 (immediate container and carton labels).

As soon as possible, but no later than 14 days from the date of this letter, please submit the final printed immediate container and carton labels. For administrative purposes, please designate these

submissions, "**Carton and Container Labels for approved supplements NDA 20-634/S-054, NDA 20-635/S-059, NDA 21-721/S-022.**"

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
Food and Drug Administration
Suite 12B05
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 Hyun Son, Pharm.D., Acting Safety Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
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/

Ozlem Belen

3/12/2009 10:30:55 AM