DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-634/S-025
NDA 20-635/S-022

Johnson & Johnson Pharmaceutical Research and Development
Attention: Robyn S. Keown, Sr. Regulatory Associate, Regulatory Affairs
920 Rte. 202 South, PO Box 300
Raritan, N J 08869-0602

Dear Ms. Keown:

Please refer to your supplemental new drug applications dated December 28, 2001, received December 31, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levaquin (levofloxacin) Tablets (NDA 20-634/S-025); Levaquin (levofloxacin) Injection and Levaquin (levofloxacin in 5% dextrose injection) Injection (NDA 20-635/S-022).

We acknowledge receipt of your submissions dated:

January 29, 2002	March 27, 2002	August 7, 2002	October 29, 2002
February 8, 2002	May 29, 2002	August 12, 2002	
March 4, 2002	July 23, 2002	August 30, 2002	
March 25, 2002	July 24, 2002	September 17, 2002	

These supplemental new drug applications provide for the use of Levaquin Tablets and Injection for the treatment of nosocomial pneumonia.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted on October 29, 2002).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-634/S-025, NDA 20-635/S-022." Approval of these submissions by FDA is not required before the labeling is used.

The text in italics below addresses the application of FDA's Pediatric Rule at [21 CFR 314.55/21 CFR 601.27] to these supplemental NDAs. The Pediatric Rule has been challenged in court. On October

17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. The government has not yet decided whether to seek a stay of the court's order. In addition, the government has not yet decided whether to appeal the decision; an appeal must be filed within 60 days. **Therefore, this letter contains a description of the pediatric studies that would be required under the Pediatric Rule, if the Pediatric Rule remained in effect and/or were upheld on appeal.** Please be aware that whether or not these pediatric studies will be required will depend upon the resolution of the litigation. FDA will notify you as soon as possible as to whether these supplemental applications will be subject to the requirements of the Pediatric Rule as described below. In any event, we hope you will decide to conduct these pediatric studies to provide important information on the safe and effective use of these drug products in the relevant pediatric populations.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

Based on information submitted, we conclude the following:

For the treatment of nosocomial pneumonia,

- *We are deferring submission of pediatric studies for all pediatric patients until October 31, 2007.*

The pediatric exclusivity provisions of FDAMA as reauthorized by the Best Pharmaceuticals for Children Act are not affected by the court's ruling. Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity).

Please submit three copies of the introductory promotional materials that you propose to use for this new indication 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 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21CFR 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)

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
10/30/02 04:14:29 PM
NDA 20-634/s-025; NDA 20-635/S-022