CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020634/S04 and 020635/S03

Trade Name: LEVAQUIN 250 MG TABLETS and LEVAQUIN INJECTION 25 MG/ML

Generic Name: LEVOFLOXACIN

Sponsor: THE R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE

Approval Date: 12/17/98

Indication(s): TREATMENT OF UNCOMPLICATED URINARY TRACT INFECTION (UTI)

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APPLICATION: 020634/S04 and 020635/S03

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Approvable Letter				X
Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)				X
Statistical Review(s)	X			
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)				X
Administrative Document(s)/ Correspondence	X			

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Application Number: 020634/S04 and 020635/S03

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-634/S-004
NDA 20-635/S-003

DEC 17 1998

The R. W. Johnson Pharmaceutical Research Institute
Attention: Wayne Napoliello
Manager, Regulatory Affairs
Route 202 , P. O. Box 300
Raritan, NJ 18869

Dear Mr. Napoliello:

Please refer to your supplemental new drug applications dated June 4, 1998, received June 4, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levaquin (levofloxacin) tablets 250 mg and Levaquin (levofloxacin) injection 25 mg/ml.

We acknowledge receipt of your submissions dated June 30, July 10 and 21, October 28, November 11, December 1 and 10, 1998.

These supplemental new drug applications provide for the use of Levaquin for the treatment of uncomplicated urinary tract infections (UTI).

We have completed the review of these supplemental 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 supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) for Levaquin tablets and the FPL for Levaquin intravenous injection must be identical to the submitted draft labeling (package insert submitted December 10, 1998). Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit 20 copies of the FPL for each product as soon as it is available, in no case more than 30 days after it is printed, to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-634/S-004" and "FPL for approved supplement 20-635/S-003." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

APPEARS THIS WAY
ON ORIGINAL

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Robin Anderson, Project Manager, at (301) 827-2127.

Sincerely,

/S/

APPEARS THIS WAY
ON ORIGINAL

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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