DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-735/S-051

R.W. Johnson Pharmaceutical Research Institute
Attention: Ms. Robyn S. Keown
Regulatory Affairs
920 Route 202 South
P. O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Keown:

Please refer to your supplemental new drug applications dated October 10, 2003, received October 14, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FLOXIN® (ofloxacin) Tablets.

We acknowledge receipt of your submission dated March 1, 2004.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to comply with the Final Rule entitled "**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use"** (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003.

This "Changes Being Effected" supplemental new drug application provides for the following additions to the package insert:

Location	**Text**
At the beginning of the label, under "**PRODUCT NAME"**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of FLOXIN and other antibacterial drugs, FLOXIN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
INDICATIONS AND USAGE	To reduce the development of drug-resistant bacteria and maintain the effectiveness of FLOXIN and other antibacterial drugs, FLOXIN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
PRECAUTIONS section, under "General" subsection	Prescribing FLOXIN in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria."

PRECAUTIONS section, under "Information for Patients"	Patients should be counseled that antibacterial drugs including FLOXIN should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When FLOXIN is prescribed to treat a bacterial infection, patient should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not competing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacterial will develop resistance and will not be treatable by FLOXIN or other antibacterial drugs in the future.

We completed our review of this application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted October 10, 2003. Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 19-735/S-051**." Approval of this submission by FDA is not required before the labeling is used.

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 Robin Anderson, R.N., M.B.A., Labeling Reviewer 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

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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