CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-001

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

SUPPL NEW CORRES
S-001

THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

MAR 5 1991

Center for Drug Evaluation and Research
Office of Drug Review II, HFD #520
ATTN: DOCUMENT CONTROL ROOM #12B-30
5600 Fishers Lane
Rockville, Maryland 20857

NDA 19-735
FLOXIN® (ofloxacin) Tablets

Dear Gentlemen:

Reference is made to our approved New Drug Application 19-735 for FLOXIN (ofloxacin) Tablets. Reference is also made to our submission of January 21, 1991 which provided for several revisions to the Chemistry, Manufacturing, and Control section of our NDA.

[ ]

Should you have any questions and/or comments, please contact me directly at (1-908) 704-4547.

Very truly yours,

The R. W. Johnson
Pharmaceutical Research Institute

Stephanie Bar
for
Isabel B. Drzewiecki
Director
Regulatory Affairs

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
MAR 11 1991
HFD-520

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date JAN 28 1991

NDA No. 19-735

The R.W. Johnson
Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan, NJ 08869-0602

Attention: Isabel B. Drzewiecki

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Floxin Tablets

NDA Number: 19-735

Supplement Number: S-001

Date of Supplement: January 21, 1991

Date of Receipt: Jaucry 22, 1991

All communications concerning this NDA should be addressed as follows:

Center for Drugs and Biologics, HFN-815
Attention: Document Control Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drugs and Biologics

cc:
NDA File
HFN-815 File
CSO File

FORM FDA 3217d (7/84)

U.S. GOVERNMENT PRINTING OFFICE-1984-450-521/7435