

**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**19-735 / S-004**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

Food and Drug Administration  
Rockville MD 20857

Date 4/24/91

NDA No. 19-735

js!

The R.W. Johnson  
Pharmaceutical Research Institute  
Route 202, P.O. Box 300  
Raritan, NJ 08864-3502

Attention: Isabel B. Drzewicki

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-004

Date of Supplement: April 8, 1991

Date of Receipt: April 15, 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



DEPARTMENT OF HEALTH & HUMAN SERVICES

1667

4/19/91

Memorandum

DATE: 6/19/91

TO : Division of Manufacturing & Product Quality (HFN-320)

FROM: Division of Anti-Infective Drug Products - HFN-520

Requester's Name DR. B. V. SHETTY Phone (301) 443-6714

ESTABLISHMENT EVALUATION REQUEST

Sterile Product \_\_\_\_\_ Non Sterile Product

Application and Supplement No. NDA 19-735/SEM-004

Brand Name (if any) FLOXIN (ofloxacin) Tablets

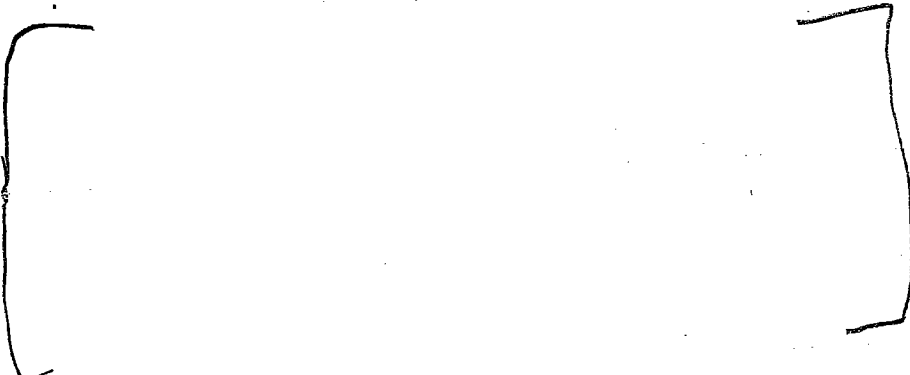
Establishment Name, Dosage Form and Strength Tablets: 200mg, 300mg, & 400mg

Profile Class Code: TCM

Priority Classification: \_\_\_\_\_ (See SMG BD-4820.3)
Applicant's Name: The R. W. Johnson Pharmaceutical Research Institute
Address: Rt 202, P.O. Box 300, Raritan, N.J. 08869-0602

Facilities to be Evaluated: (Name, full Address, DMF No., and responsibility)

For HFN-320 Use
Status & Date of Inspection:



Firm is Inactive
12/5/90
[Signature]

Other Information or Special Requests: \_\_\_\_\_

For HFN-320 Use Only:
Date Received June 25, 1991
CGMP Compliance Status of Facilities Evaluated: Firm inactive
CSO: [Signature] Date Completed 9/6/91

Distribution: Original and First Copy: HFN-320
Remaining Copies: Requesting Office Use

[Signature] 7/10/91



DEPARTMENT OF HEALTH & HUMAN SERVICES

6/19/91

Memorandum

DATE: 6/19/91

TO : Division of Manufacturing & Product Quality (HFN-320)
FROM: Division of Anti-Infective Drug Products (HFD) 520
Requester's Name: DR. B. V. SHETTY Phone: (301) 443-6714

ESTABLISHMENT EVALUATION REQUEST

Sterile Product Non Sterile Product

Application and Supplement No. NDA 19-735 / SCK-004
Brand Name (if any) Floxin (ofloxacin) Tablets
Establishment Name, Dosage Form and Strength Tablets: 200, 300 & 400 mg
Profile Class Code: TCM

Priority Classification: (See SMG BD-4820.3)
Applicant's Name: The R. W. Johnson Pharmaceutical Res. Institute
Address: Rt 202, P.O. Box 300, Raritan, N.J. 08869-0602

Facilities to be Evaluated: (Name, full Address, DMF No., and responsibility)



For HFN-320 Use
Status & Date of Inspection:
OK 9/26/90

Other Information or Special Requests:

For HFN-320 Use Only:
Date Received June 25, 1991
CGMP Compliance Status of Facilities Evaluated: Acceptable
CSO: [Signature] Date Completed 9/20/91

Distribution: Original and First Copy: HFN-320
Remaining Copies: Requesting Office Use

[Signature] 7/10/91



6/19/91

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

DATE: 6/19/91

TO : Division of Manufacturing & Product Quality (HFN-320)
FROM: Division of Anti-Infective Drug Products HFN-520
Requester's Name: DR. B.V. SHETTY Phone: (301) 443-6714

ESTABLISHMENT EVALUATION REQUEST

Sterile Product Non Sterile Product [checked]

Application and Supplement No. NDA 19-735/SCM-004

Brand Name (if any) FLOXIN (Ofloxacin) Tablets

Establishment Name, Dosage Form and Strength Tablets: 200, 300 and 400mg

Profile Class Code: TCM

Priority Classification:
Applicant's Name: The R.W. Johnson Pharmaceutical Research Institute (See SMG BD-4820.3)
Address: Rt 20, P.O. Box 300, Raritan, N.J. 08869-0602

Facilities to be Evaluated: (Name, full Address, DMF No., and responsibility)
For HFN-320 Use Status & Date of Inspection: AC-7/24/90

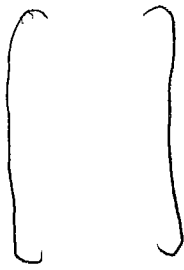
Other Information or Special Requests:

For HFN-320 Use Only:
Date Received June 25/1991
CGMP Compliance Status of Facilities Evaluated: Acceptable
CSO: [Signature] Date Completed 9/20/91
Distribution: Original and First Copy: HFN-320
Remaining Copies: Requesting Office Use

[Signature] 6/20/91

GOVERNMENT WIDE QUALITY ASSURANCE FACILITY PROFILE DATA

Facility ID:  
CFN:  
District:  
Facility Name:  
Last Profile Date:  
City:  
State/Country:  
Firm Out of Business:



Date Printed: 10-JUL-1991

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Prof Firm	Related Last Preaward Status/Date	GMP Status/Date	Insp Stat	Request Date	Comments
ZZ?					FIRM IS INACTIVE

F4 - Exit; Up/Down arrows - scroll through profiles;  
Press CTRL H to clear the screen and return to ID for another selection.  
Char Mode: Replace Page 1 Count: \*1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BALTIMORE DISTRICT OFFICE

MEMORANDUM

DATE: September 19, 1991

FROM: Director, Baltimore District, HFR-MA200

SUBJ: NDA 19-735/S-094

TO: Compliance Evaluation Staff, HFD-320

INFO: Medical Products Quality Assurance Staff, HFC-120  
Richard J. Davis, RFDD/HFR-MA1

PRODUCT: Floxin Tablets, 200, 300, and 400 mg

APPLICANT: R. W. Johnson Pharmaceutical Research Institute  
Raritan, NJ

ESTAB: [ ]

ESTAB TYPE: \_\_\_\_\_

DISTRICT RECOMMENDATION: Approve

DATE NDA AUDITED: None

COMMENTS: [ ]

Based on an acceptable compliance history, recent acceptable coverage as a drug repacker, and no pending compliance actions, we see no need for an inspection, and recommend approval of the referenced NDA.

*Thomas L. Hooker*  
THOMAS L. HOOKER

CC: HFR-MA1  
HFC-120  
HFR-MA200

ORJ 15

NDA NO. 19-735 REF. NO. SCM-004  
NDA SUPPL FOR Manufacturing

THE R.W. JOHNSON  
PHARMACEUTICAL RESEARCH INSTITUTE

ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

APR 8 1991

Food and Drug Administration  
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

**SUPPLEMENT**

**NDA 19-735**  
FLOXIN® (ofloxacin)  
Tablets

Dear Sir/Madam:

Reference is made to our approved New Drug Application 19-735 for FLOXIN (ofloxacin) Tablets. At this time, we submit herewith a supplement to provide for additional firms to serve as packagers of the drug product, FLOXIN Tablets. This change will allow bottle and/or blister packaging and labeling operations to be performed at the following three additional contract packaging facilities:

[ ]

Previously approved contract packaging facilities include: \_\_\_\_\_

\_\_\_\_\_ In support of this amendment, we have appended letters from each contract packager authorizing the FDA to cross refer to their respective DMF's and a revised Chemistry, Manufacturing, and Control Information page 03-00015 incorporating the above listed contract packaging facilities.

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



*I. B. Drzewiecki*  
Isabel B. Drzewiecki  
Director  
Regulatory Affairs

LA JOLLA

RARITAN

SPRING HOUSE

TORONTO

ZURICH