CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-004

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

nb.1

Date 4-24-91

NDA No. 19-735

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

Attention: Isabel R. 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-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

FORM FDA 3217d (7/84)

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

6/19/91

DEPARTMENT OF HEALTH & HUMAN SERVICES 1667

Memorandum

DATE: 6/19/91

TO : Division of Manufacturing & Product Quality (HFN-320) HFD-520

FROM: Division of Anti-Infective Drug Products HFN-

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/SCM-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
~~6/19/91~~ (Revoked)

Other Information or Special Requests: _____

For HFN-320 Use Only:

Date Received June 25, 1991

CGMP Compliance Status of Facilities Evaluated: Firm inactive

CSO: _____ Date Completed 9/6/91

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

7/16/91

FORM FDA 3274 (6-86)

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 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 / SCH-004

Brand Name (if any) Floxin (ofloxacin) Tablets

Establishment Name, Dosage Form and Strength Tablet: 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: MW Klemper Date Completed 9/20/91

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

7/10/91

FORM FDA 3274 (6-86)

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- 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/SCM-004

Brand Name (if any) FLOXIN (ofloxacin) Tablets

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

Profile Class Code: TCM

Priority Classification: 2 (See SMG BD-4820.3)

Applicant's Name: The R.W. Johnson Pharmaceutical Research Institute

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: M Thanga Date Completed 9/20/91

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

7/10/91

FORM FDA 3274 (6-86)

GOVERNMENT WIDE QUALITY ASSURANCE FACILITY PROFILE DATA

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

Date Printed: 10-JUL-1991

Prof	Related Firm	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-004

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

ORIG

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

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
APR 15 1991
HFD-520

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