CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-735 / S-019

Trade Name: **Floxin**

Generic Name: **Ofloxacin**

Sponsor: **R.W. Johnson Pharmaceuticals**

Approval Date: **September 10, 1992**

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APPLICATION NUMBER:

19-735 / S-019

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APPROVAL LETTER

27.1 NDA 19-735/S-019

Ms. Isabel B. Drzewiecki
Senior Director, Regulatory Affairs
The R.W. Johnson Pharmaceutical
Research Institute
Route 202, P.O. Box 300
Raritan, New Jersey 08869-0602

SEP 10 1992

Dear Ms. Drzewiecki:

Reference is made to your supplemental New Drug Application (NDA) dated July 31, 1992, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Floxin (ofloxacin) Tablets.

The supplemental application provides for a new formulation of Floxin Tablets, [redacted]e.

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

This approval affects only those changes specifically submitted in this supplemental application. Other changes that may have been approved or are pending evaluation are not affected.

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

Sincerely yours,

MML 9/9/92

Murray M. Lumpkin, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: [redacted]
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Szarfman
HFD-520/Buko
HFD-521/Fogarty
HFD-520/Shetty BVS 9/5/92
init. by SUPVCHEM/8/27/92 WJ 9/8/92
th:9/1/92/n19735.s19
APPROVED

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APPLICATION NUMBER:

19-735 / S-019

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW SEP 8 1992

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DAIDP (HFD-520)	19-735

3. NAME & ADDRESS OF APPLICANT
R.W. Johnson
Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan, New Jersey 08869

4. AF NUMBER

5. SUPPLEMENT(s)

NUMBER(s)	DATE(s)
S-019	7/13/92

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Floxin	ofloxacin

8. SUPPLEMENT(s) PROVIDES FOR:

A new formulation for
Floxin Tablets.

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(s)
	XXX Rx OTC	

13. DOSAGE FORM(s)	14. POTENCY(ies)
Tablet	200, 300 and 400 mg

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS

CURRENT		
XXX	Yes	No
REVIEWED		
XXX	Yes	No

17. COMMENTS

The firm proposes a new formulation in this supplement. It differs from the approved formulation in that the [redacted] been increased to compensate quantitatively for the deletion.

The firm states that [redacted] which was used in the original NDA is not available.

A recent recall of 400 mg Floxin Tablets for failure to meet dissolution specification has been traced back to the use of another grade of [redacted]

The firm has submitted quantitative composition for the three new formulations of 200, 300 and 400 mg strengths, manufacturing processes and comparative data of tablets and granulations manufactured at [redacted]

The firm states that [redacted] is an additional facility for which approval was requested on July 13, 1992.

Stability data for all the three new formulations of tablets were generated at [redacted] The samples were tested initially and after three months storage at [redacted] RH, [redacted] and room light. They are all within specifications. The firm has also submitted comparative stability data of floxin [redacted]

A revised assay method has been described.

Under description, a copy of the revised package insert, which has [redacted] sodium, has been submitted.

18. **CONCLUSIONS AND RECOMMENDATIONS**
Approval letter should be issued by the Division Director; MO and Micro concurrences are needed.

cc: Orig: NDA 19-735/S-019
HFD-520
HFD-520/MO/Szarfman
HFD-520/Pharm/LBuko
HFD-520/CSO/PFogarty
HFD-520/CHEM/BVShetty/th/9/1/92
R/D initialed by SUPVCHEM/8/27/92____

19.	REVIEWER	
NAME	**SIGNATURE**	**DATE COMPLETED**
B. Vithal Shetty, Ph.D.	BVShetty 9/1/92	8/5/92

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