# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

*APPLICATION NUMBER:*

# 19-735 / S-018

*Trade Name:* **Floxin**

*Generic Name:* **Ofloxacin**

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

*Approval Date:* **December 8, 1992**

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*APPLICATION NUMBER:*

# 19-735 / S-018

## CONTENTS

## Reviews / Information Included in this NDA Review.

| | |
|---|---|
| Approval Letter | X |
| Approvable Letter | |
| Labeling | |
| Summary Review | |
| Officer/Employee List | |
| Office Director Memo | |
| Cross Discipline Team Leader Review | |
| Medical Review(s) | |
| Chemistry Review(s) | X |
| Environmental Assessment | |
| Pharmacology Review(s) | |
| Statistical Review(s) | |
| Microbiology Review(s) | |
| Clinical Pharmacology/Biopharmaceutics Review(s) | |
| Risk Assessment and Risk Mitigation Review(s) | |
| Proprietary Name Review(s) | |
| Administrative/Correspondence Document(s) | |

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*APPLICATION NUMBER:*

# 19-735 / S-018

# APPROVAL LETTER

**NDA 19-735/S-018**

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

DEC 8 1992

Dear Ms. Drzewiecki:

Reference is made to your supplemental New Drug Application (NDA) dated July 13, 1992, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Floxin (ofloxacin) Tablets.

We also acknowledge receipt of your amendment dated August 4, 1992.

The supplemental application provides for the addition of _____ as a manufacturer of Floxin Tablets.

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,

WD 12/2/92

Wilson H. De Camp, Ph.D.
Supervisory Chemist
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Orig: NDA 19-735/S-018
HFD-130/JAllen
HFD-520
HFD-520/Lumpkin (reading file)
HFD-520/Szarfman
HFD-520/Buko
HFD-521/Fogarty
HFD-520/Shetty
init. by SUPVCHEM/11/6/92
td:11/9/92n19735.s18
APPROVED

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*APPLICATION NUMBER:*

# 19-735 / S-018

# CHEMISTRY REVIEW(S)

NOV 25 1992

# NDA SUPPLEMENT REVIEW

| 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-018 | 7/13/92 |

| 6. NAME OF DRUG | 7. NONPROPRIETARY NAME |
|---|---|
| Floxin | ofloxacin |

8. SUPPLEMENT(s) PROVIDES FOR:

The addition of [redacted] PR as a manufacturer of 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 | | REVIEWED | |
|---|---|---|---|---|
| | Yes | No | Yes | No |
| | XXX | | XXX | |

17. COMMENTS

The firm states that [redacted]

The firm has used [redacted] (supplement filed on July 13, 1992) in which the [redacted] the amount of [redacted] has been increased to compensate for the [redacted] The firm states that the change has been necessitated due to [redacted] discontinuing the manufacture of the [redacted]

The firm has submitted three months stability data at [redacted] and room light for the 200mg, 300mg and 400mg [redacted] free tablets. In addition, comparative stability data with the formulation containing [redacted] have been submitted.

As per attached inspection report dated September 20, 1992, the [redacted] s acceptabl

The firm also states that the proposed action is not expected to alter the sections of the Environmental Assessment originally submitted with the filing of NDA 19-735.

18. **CONCLUSIONS AND RECOMMENDATIONS**
Approval letter should be issued from the Supervisory Chemist.

cc: Orig: NDA 19-735/S-018
HFD-520
HFD-520/MO/Szarfman
HFD-520/Pharm/LBuko
HFD-520/CSO/PFogarty
HFD-520/CHEM/BVShetty/th/11/9/92
R/D initialed by SUPVCHEM/11/6/92 11/4/92

| 19. | REVIEWER | |
|---|---|---|
| **NAME** | **SIGNATURE** | **DATE COMPLETED** |
| B. Vithal Shetty, Ph.D. | BVShetty 11/21/92 | 11/4/92 |

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