

**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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## CONTENTS

### Reviews / Information Included in this NDA Review.

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

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**APPROVAL LETTER**

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.

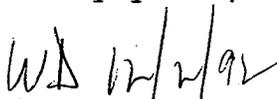
The supplemental application provides for the addition of \_\_\_\_\_  
\_\_\_\_\_ as a manufacturer of Floxin  
Tablets.

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,



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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**CHEMISTRY REVIEW(S)**

NDA SUPPLEMENT REVIEW

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

6. NAME OF DRUG Floxin	7. NONPROPRIETARY NAME ofloxacin	S-018 7/13/92
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8. SUPPLEMENT(s) PROVIDES FOR:  The addition of _____ PR as a manufacturer of Floxin Tablets.	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
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10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED XXX Rx OTC	12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM(s) Tablet	14. POTENCY(ies) 200, 300 and 400 mg	

15. CHEMICAL NAME AND STRUCTURE	16. RECORDS AND REPORTS CURRENT XXX Yes No REVIEWED XXX Yes No
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17. COMMENTS

The firm states that \_\_\_\_\_

\_\_\_\_\_

The firm has used \_\_\_\_\_ (supplement filed on July 13, 1992) in which the \_\_\_\_\_

\_\_\_\_\_ the amount of \_\_\_\_\_ has been increased to compensate for the \_\_\_\_\_. The firm states that the change has been necessitated due to \_\_\_\_\_ discontinuing the manufacture of the \_\_\_\_\_

\_\_\_\_\_

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

As per attached inspection report dated September 20, 1992, the \_\_\_\_\_ 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

*WJ/rj/92*

**19.**

**REVIEWER**

**NAME**

**SIGNATURE**

**DATE COMPLETED**

B. Vithal Shetty, Ph.D.

*BVShetty 11/21/92*

11/4/92

**DISTRIBUTION**

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**REVIEWER**

**DIVISION FILE**