

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**19-735 / S-022**

***Trade Name:* Floxin**

***Generic Name:* Ofloxacin**

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

***Approval Date:* September 3, 1992**

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**19-735 / S-022**

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**APPROVAL LETTER**

281

NDA 19-735/SCM-022

SEP 3 1992

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

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 200, 300, and 400 milligrams per tablet.

We also acknowledge receipt of your submission dated August 7, 1992.

The supplemental application provides for the addition of \_\_\_\_\_  
\_\_\_\_\_s an alternate microbiological testing facility.

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.

APPROVED

Sincerely yours,

WA 9/3/92

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/SCM-022  
HFD-520  
HFD-520/CSO/Fogarty  
HFD-520/Micro/Dionne  
HFD-520/MO/Szarfman  
HFD-520/CHEM/Shetty  
HFD-520/SUPVMICRO/R/D init AS 8/31/92  
HFD-520/SUPVCHEM/R/D init \_\_\_\_\_  
pdionne 8/27/92

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**CHEMISTRY REVIEW(S)**

AUG 3 | 1992

NDA Supplement  
Manufacturing Controls Review

1. Organization

DAIDP (HFD-520)

2. NDA #

19-735/SCM-022

3. Name and Address of Applicant

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

Isabel B. Drzewiecki  
Senior Director, Regulatory Affairs  
(908) 704-4547

4. AF No.

N/A

5. Supplement

SCM-022 (SCM) Received by CDER 7-14-92  
Received by Reviewer 7-30-92  
Letter Dated 07-13-92

6. Name of Drug

FLOXIN<sup>R</sup> Tablets

7. Nonproprietary Name

Ofloxacin tablets

8. Supplement Provides For

Addition of \_\_\_\_\_  
testing facility.

as an alternate microbiological

9. Amendments/Other Reports

Amendment dated August 7, 1992, providing full address of the facility and description of the type of microbiological testing performed.

10. Pharmacological Category

quinolone

11. How Dispensed

200 milligram, 300 milligram, and 400 milligram tablets

12. Related IND/NDA/DMF

None

13. Dosage Form

Tablets

14. Potencies

200 mg/tablet; 300 mg/tablet; 400 mg/tablet

15. Chemical Name and Structure

USAN, 1991 p. 430

16. Records and Reports

17. Comments

The original supplement did not contain the full address of \_\_\_\_\_ or tell exactly what type of testing was being performed. I called Isabel B. Drzewiecki on August 4, 1992 and requested that this information be submitted. An amendment dated August 7, 1992, gives the full address of the facility and states that \_\_\_\_\_ will perform microbiological testing for all excipients used in the manufacture of FLOXIN tablets, including water, that require a microbiological test for release. A check of the ingredients shows that this testing consist of microbial limits testing of the inactive ingredients: \_\_\_\_\_ and \_\_\_\_\_

The Division of Manufacturing & Product Quality (HFD-320) has found this site acceptable for microbiological testing as of August 26, 1992. A copy of the signed EER is attached.

The site is, therefore, satisfactory for microbiological testing and the supplement should be approved.

Conclusions and Recommendations

The supplement should be approved.

19. Reviewer

*Peter A. Dionne*

Peter A. Dionne  
Microbiologist/HFD-520  
Completed: 8-27-92

cc: NDA 19-735/SCM-022  
HFD-520  
HFD-520/CSO/Fogarty  
HFD-520/MO/Szarfman  
HFD-520/CHEM/Shetty  
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pdionne 8/27/92