CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-735 / S-023

Trade Name: **Floxin**

Generic Name: **Ofloxacin**

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

Approval Date: **September 3, 1992**

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19-735 / S-023

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APPROVAL LETTER

NDA 19-735/SCM-023

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

SEP 3 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 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 [redacted] as 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,

WHD 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-023
HFD-520
HFD-520/CSO/Fogarty
HFD-520/Micro/Dionne
HFD-520/MO/Szarfman
HFD-520/CHEM/Shetty
HFD-520/SUPVMICRO/R/D init 8/31/92
HFD-520/SUPVCHEM/R/D init_____
pdionne 8/27/92

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CHEMISTRY REVIEW(S)

AUG 3 1 1992

NDA Supplement
Manufacturing Controls Review

1. Organization

DAIDP (HFD-520)

2. NDA #

19-735/SCM-023

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-023 (SCM) Received by CDER 7-14-92
Received by Reviewer 7-30-92
Letter Dated 07-13-92

6. Name of Drug

FLOXIN^{R} Tablets

7. Nonproprietary Name

Ofloxacin tablets

8. Supplement Provides For

Addition of [redacted] co as an alternate microbiological testing facility.

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 [redacted] s, Inc. 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 [redacted] 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; [redacted]

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
Microbiologist/HFD-520
Completed: 8-27-92

cc: NDA 19-735/SCM-022
HFD-520
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