CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-007

CHEMISTRY REVIEW(S)

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)

6. NAME OF DRUG	7. NONPROPRIETARY NAME	
Floxin	ofloxacin	S-007 1/2/92

8. SUPPLEMENT(s) PROVIDES FOR:

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

[ ]

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

	Yes	No
CURRENT		
REVIEWED		

17. COMMENTS
The firm has made commitment to place the first three production batches on accelerated stability for at least three months and submit the data to the Center.

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

cc: Orig: NDA 19-735/S-007
HFD-520 HFD-520/MO/Szarfman
HFD-520/Pharm/LBuko HFD-520/CSO/PFogarty
HFD-520/CHEM/BVShetty/th/3/10/92
R/D initialed by SUPVCHEM/3/10/92____

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
B. Vithal Shetty, Ph.D.	B V Shetty 3/10/92	3/10/92

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