CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-384 / S-035

Trade Name: **Noroxin**

Generic Name: **Norfloxacin**

Sponsor: **Merck Research larboratories**

Approval Date: **December 6, 1996**

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APPLICATION NUMBER:

19-384 / S-035

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:

19-384 / S-035

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 6 1996

NDA 19-384/S-035

Henrietta Ukwu, M.D.
Director
Merck Research Laboratories
Sumneytown Pike
West Point Pa. 19486

Dear Dr. Ukwu:

Reference is made to your supplemental New Drug Application (NDA) dated June 18, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noroxin (norfloxacin) Tablets, 400 mg.

The supplemental application provides for alternate packaging in

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,

David B. Katague

David B. Katague, Ph.D.
Team Leader (Acting) DNDCIII
Office of Drug Evaluation IV
Division of Anti-Infective Drug Products (HFD-520)
Center for Drug Evaluation and Research

NDA 19-384/S-035

cc: HFD-130/JAllen
HFD-520/CSO/LeSane
HFD-520/PHARM/Buko
HFD-520/MO/Moledina
HFD-520/CHEM/Shetty
HFD-520/Katague R/D initialed_____

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APPLICATION NUMBER:

19-384 / S-035

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW

1. ORGANIZATION
DAIDP (HFD-520)

2. NDA NUMBER
19-384

3. NAME & ADDRESS OF APPLICANT
Merck Research Laboratories
Sumneytown Pike
West Point
PA. 19486

4. AF NUMBER

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
S-035 6/18/96

6. NAME OF DRUG
Noroxin

7. NONPROPRIETARY NAME
norfloxacin

8. SUPPLEMENT(s) PROVIDES FOR:
Alternate packaging in

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES
none

10. PHARMACOLOGICAL CATEGORY
Antibacterial

11. HOW DISPENSED
XXX
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablets

14. POTENCY(ies)
400 mg

15. CHEMICAL NAME AND STRUCTURE

m.w.
CAS Registry No. - -

16. RECORDS AND REPORTS
CURRENT
✓ Yes No
REVIEWED
✓ Yes No

17. COMMENTS
This drug is the subject of a compendial monograph, USP XXIII pg. 1104. See items 20-34 for detailed comments.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend approval letter to issue for this supplement.

cc: Orig: NDA -
HFD-520
HFD-520/Pharm
HFD-520/SPagay
HFC-130/JAllen
HFD-520/MO
HFD-520/CSO
HFD-520/SBRoy:R/D initialed 8/6/96

19.
NAME B.V. SHETTY
REVIEWER SIGNATURE BVShetty
DATE COMPLETED 8/5/96

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

20. Components and Composition

N/A

21. Facilities and Personnel

N/A

22. Synthesis

N/A

23. Raw Material Controls
a. New Drug Substance

N/A

b. Other Ingredients

N/A

24. Other Firm(s)

N/A

25. Manufacturing and Processing

N/A

26. Container/Closure

N/A

27. Packaging and Labeling

See attached comment

28. Laboratory Controls (In-process and Finished Dosage Form)

N/A

29. Stability

See attached comment.

30. Control Numbers

N/A

31. Samples and Results
a. Validation N/A
b. Market Package

32. Labeling

N/A

NOTE : If labelling is revised, approval letter should be copied to HFD-85, HFD-500, HFD-638 and HFD-735, with a copy of the final or draft label attached.

33. Establishment Inspection

N/A

34. Recalls

N/A

4 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry-1