CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-384 / S-034

Trade Name: **Noroxin**

Generic Name: **norfloxacin**

Sponsor: **Merck**

Approval Date: **July 18, 1996**

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APPLICATION NUMBER:

19-384 / S-034

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)	X

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19-384 / S-034

APPROVAL LETTER

DIVISION File

JUL 18 1996

NDA 19-384/S-034

Henrietta N. Ukwu, M.D.
Director, Regulatory Liaison
Merck Research Laboratories
P.O. Box 4 BLA-30A
West Point Pennsylvania 19486

Dear Dr. Ukwu:

Reference is made to your supplemental New Drug Application (NDA) dated April 12, 1996, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noroxin (norfloxacin), 400mg tablet.

The supplemental application provides for updating the ——————→ description and process.

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,

7/10/96

Suva B. Roy, Ph.D.
Team Leader, DNDC III
Division of Anti-infective Drug Products (HFD-520)
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc: Orig NDA 19-384/SCS-034
HFD-82
HFD-473
HFD-638
HFD-735
HFC-130/JAllen
HFD-520/DivDir/MFanning
HFD-520/MO/Moledina
HFD-520/PHARM/Buko
HFD-520/CSO/Fogarty
HFD-520/MICRO/Dionne
HFD-830/CHEM/Shetty BVS 7/10/96
HFD-830/SBRoy:R/D initialed_____
APPROVED

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APPLICATION NUMBER:

19-384 / S-034

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DAIDP (HFD-520)	19-384

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

4. AF NUBER

5. SUPPLEMENT(s)
NUMBER(s) DATE(s)
SCS-034 4/12/96

6. NAME OF DRUG
Noroxin

7. NONPROPRIETARY NAME
Norfloxacin

8. SUPPLEMENT(s) PROVIDES FOR:
Updating the ——— description and process

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATE
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)
400mg

15. CHEMICAL NAME AND STRUCTURE

m.w.
CAS Registry No.

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

17. COMMENTS
This drug is the subject of a compendial monograph, USP 23 pg.1104 See items 20-34 for detailed comments.

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

cc: Orig: NDA 19-384
HFD-520
HFD-520/Pharm/Buko
HFD-520/CSO/Fogarty
HFC-130/JAllen
HFD-520/MO/Bais
HFD-830/Shetty
HFD-830/SBRoy:R/D initialed 7/10/96

19.	REVIEWER	
NAME	SIGNATURE	DATE COMPLETED
BV Shetty	BVShetty 7/10/96	3/11/96

DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

20. Components and Composition

APPROVABLE

The firm has submitted formulation changes in the [redacted] tablets.

Satisfactory

21. Facilities and Personnel

N/A

22. Synthesis

N/A

23. Raw Material Controls

a. New Drug Substance

N/A

24. Other Firm(s)
N/A

25. Manufacturing and Processing

APPROVABLE

The firm has submitted the following information on changes in the [redacted] of Noroxin Tablets.

The differences listed below between the NDA and the current manufacturing descriptions are the subject of this supplement:

Preparation of [redacted]

[redacted]

9 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- 1a

30. **Control Numbers**

N/A

31. **Samples and Results**

N/A

a Validation

b. Market Package

32. **Labeling**

N/A

33. **Establishment Inspection**

N/A

34. **Recalls**

N/A

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APPLICATION NUMBER:

19-384 / S-034

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date APR 18 1996

NDA No. 19-384

Henrietta Ukwu, M.D.
Merck research Laboratories
Sumneytown Pike
West Point, PA 19486

Attention: Henrietta Ukwu, M.D.

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Noroxin Tablets

NDA Number: 19-384

Supplement Number: S-034

Date of Supplement: April 12, 1996

Date of Receipt: April 16, 1996

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control, Room 12B-30
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

for Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drug Evaluation and Research