CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-384 / S-032

Trade Name: **Noroxin**

Generic Name: **norfloxacin**

Sponsor: **Merck**

Approval Date: **June 18, 1996**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-384 / S-032

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-384 / S-032

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DIV.

Food and Drug Administration
Rockville MD 20857

NDA 19-384/S-032

JUN 18 1996

Henrietta Ukwu, M.D.
Director
Regulatory Liaison
Merck & Co. Inc.
P.O. Box BLA-30A
West Point PA 19486

Dear Dr. Ukwu:

Reference is made to your supplemental New Drug Application (NDA) dated February 22, 1996 submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Noroxin (norfloxacin) 400mg.

The supplemental application provides for the alternate use of

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,

Suva B. Roy

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/S-032
HFD-82
HFD-473
HFD-520
HFD-735
HFD-730
HFD-104
HFD-638
HFC-130/JAllen
HFD-520/DivDir/MFanning
HFD-520/MO/Moledina
HFD-520/CSO/Fogarty
HFD-520/PHARM/Buko
HFD-830/CHEM/Shetty
HFD-830/SBRoy: R/D initialed_____

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-384 / S-032

CHEMISTRY REVIEW(S)

DW.

NDA SUPPLEMENT REVIEW

JUN 13 1996

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

3. NAME & ADDRESS OF APPLICANT:
Merck Research laboratories
Summeytown Pike
West Point PA 19486

4. AF NUMBER

5. SUPPLEMENT(S) NUMBER(s) DATE(s):
S-032 2/22/96

6. NAME OF DRUG: Noroxin

7. NONPROPRIETARY NAME: Norfloxacin

8. SUPPLEMENT(s) PROVIDES FOR:
The alternate use of [redacted]

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):
400mg

15. CHEMICAL NAME AND STRUCTURE

m.w.
CAS

16. RECORDS AND REPORTS

CURRENT: X

REVIEWED: X

YES NO

17. COMMENTS
This drug is the subject of a compendial monograph, USP XXIII, pg. 1103 See itmes 20-34 for detailed comments.

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

cc:Orig NDA
HFD-520/MO/Moledina
HFD-520/CSO/Fogarty
HFC-130/JAllen
HFD/520/Pharm/Buko
HFD-830/CHEM/Shetty
HFD-830/SBR:R/D initialed 6/13/96

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
B.V. Shetty	BV Shetty 6/5/96	4/10/96

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

24. Other Firm (S)
N/A

25. Manufacturing and Processing
N/A

26. Container/Closure

[redacted]

27. Packaging and Labeling
N/A

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

29. Stability

APPROVABLE

The firm states that they have incorporated one early production lot of Tablets Norfloxacin packaged with

[redacted]

They meet the specifications. A protocol for placing three additional production batches of final drug product has been submitted.

30. Control Numbers
N/A

31. Samples and Results
N/A

32. Labeling

33. Establishment Inspection
N/A

34. Recalls
N/A

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-384 / S-032

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DIV.

Food and Drug Administration
Rockville MD 20857

Date MAR -7 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-032

Date of Supplement: February 22, 1996

Date of Receipt: February 27, 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

FORM FDA 3217d (12/91)

70/