

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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19-384 / S-034

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APPROVAL LETTER

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 7/10/98*

HFD-830/SBRoy:R/D initialed _____

APPROVED

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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 Merck and Co Sumneytown Pike West Point, PA 19486		4. AF NUMBER
		5. SUPPLEMENT(s) NUMBER (s) DATE (s) SCS-034 4/12/96

6. NAME OF DRUG Noroxin	7. NONPROPRIETARY NAME Norfloxacin
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8. SUPPLEMENT(s) PROVIDES FOR: Updating the _____ description and process	9. AMENDMENTS AND OTHER (REPORTS, etc.) DATE None
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10. PHARMACOLOGICAL CATEGORY Antibacterial	11. HOW DISPENSED XXX	12. RELATED IND/NDA/DMF (s)
--	---------------------------------	--

13. DOSAGE FORM(s) Tablets	14. POTENCY (ies) 400mg
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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

R/S 7/10/96

19.	REVIEWER
NAME BV Shetty	SIGNATURE <i>BV Shetty</i>
	DATE COMPLETED 3/11/96

DISTRIBUTION	ORIGINAL JACKET	REVIEWER	DIVISION FILE
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20. Components and Composition

APPROVABLE

The firm has submitted formulation changes in the _____
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

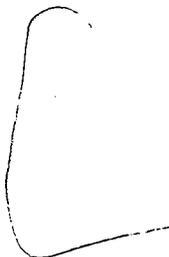
25. Manufacturing and Processing

APPROVABLE

The firm has submitted the following information on changes in
the _____ of Noroxin Tablets.

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

Preparation of _____



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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ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



Food and Drug Administration
Rockville MD 20857

Date APR 18 1996

NDA No. 19-384

Henrietta Ukwu, M.D.
Merck research Laboratories
Sunnytown 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,

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