CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-537 / S-035

Trade Name: Cipro

Generic Name: (ciprofloxacin hydrochloride)

Sponsor: Bayer Corporation Pharmaceutical

Approval Date: June 9, 1999

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APPLICATION NUMBER:

19-537 / S-035

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	**X**

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APPROVAL LETTER

NDA 19-537/S-035

Andrew Verderame
Assistant Director, Regulatory Affairs
Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516-4175

JUN 9 1999

Dear Mr. Verderame:

Reference is made to your supplemental New Drug Application dated December 21, 1988 submitted pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act for Cipro (ciprofloxacin hydrochloride) Tablets.

This supplemental application provides for the use of ——— as an additional supplier of the ——— used to package Cipro Tablets.

We have completed the review of this supplemental application and it is approved, effective on the date of this letter.

We remind you that you must comply with requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA. If you have any questions, please contact Mary Dempsey, Project Manager, at 301-827-2127.

Sincerely yours,

Norman Schmuff, Ph.D.
Chemistry Team Leader, DNDC III
Division of Special Pathogens and
Immunologic Drug Products (HFD-590)
Office of Drug Evaluation IV
Center for Drug Evaluation and
Research

Distribution:
HFD-590/Orig. NDA
HFD-590/Division File
HFD-590/MGoldberger
HFD-590/NSchmuff
HFD-590/DMatecka
HFD-830/CChen
District Office

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CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

JUN 9 1999

CHEMIST'S REVIEW | **1. ORGANIZATION** | **2. NDA NUMBER**
Review #1 | DSPIDP (HFD-590) | 19-537

3. NAME & ADDRESS OF APPLICANT
Bayer Corporation
PharmaceuticalDivision
400 Morgan Lane
West Haven, CT 06516

4. AF NUMBER

5. SUPPLEMENT(s)
NUMBER(s)DATE(s)
S-035; 12/21/98

6. NAME OF DRUG
CIPRO Tablets

7. NONPROPRIETARY NAME
Ciprofloxacin hydrochloride

8. SUPPLEMENT(s) PROVIDES FOR:

Additional supplier of the ——— bottles to package Cipro Tablets.

9. AMENDMENTS AND OTHER DATES n/a

10. PHARMACOLOGICAL CATEGORY
Antibacterial

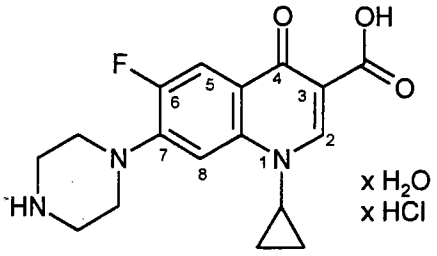
11. HOW DISPENSED
XXX
Rx OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(s)
Tablet

14. POTENCY(ies)
100, 250, 500 and 750 mg

15. CHEMICAL NAME, STRUCTURE, MOLECULAR WEIGHT
Ciprofloxacin Hydrochloride, $C_{17}H_{19}N_3ClFO_3$, MW = 385.8
3-quinoline carboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-, monohydrochloride, monohydrate
CAS - 86393-32-0



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

17. COMMENTS

This Changes-Being-Effected supplement provides for an additional supplier of the [redacted] to package Cipro Tablets.

[redacted]

The above information was reviewed found acceptable. See the Review Notes for further details.

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend an approval letter to issue for this supplement.

cc: Orig: NDA 19-537
HFD-590/Division File
HFD-590/CSO/MDempsey
HFD-590/Chem/DMatecka

HFD-590/TL/NSchmuff:R/D initialed MBS 6/9/99

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dorota Matecka, Ph.D.	D. Matecka	5/18/99

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WITHHOLD 2 PAGE(S)

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Chemistry Review 1a

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ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

7/1

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-537/S-035

JAN 12 1999

Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Attention: Andrew S. Verderame
Assistant Director, Regulatory Affairs

Dear Mr, Verderame:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Cipro® (ciprofloxacin hydrochloride) Tablets

NDA Number: 19-537

Supplement Number: S-035

Date of Supplement: December 21, 1998

Date of Receipt: December 23, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on February 21, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Ellen C. Frank

Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research