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
APPLICATION NUMBER:

19-537 / S-035

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NDA 19-537/S-035

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

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,

[Signature]
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/IMGoldberger
HFD-590/NSchmuff
HFD-590/DMatecka
HFD-830/CChen
District Office
APPLICATION NUMBER:

19-537 / S-035

CHEMISTRY REVIEW(S)
## CHEMIST'S REVIEW

1. **ORGANIZATION**
   DSPIDP (HFD-590)

2. **NDA NUMBER**
   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

12. **RELATED IND/ND/DMF(s)**
    Rx  OTC

13. **DOSAGE FORM(s)**
    Tablet

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

15. **CHEMICAL NAME, STRUCTURE, MOLECULAR WEIGHT**
    Ciprofloxacin Hydrochloride, \( C_{17}H_{18}N_2ClO_3 \), 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

![Chemical Structure](image)

16. **RECORDS AND REPORTS**
   CURRENT
   X Yes  No
   REVIEWED
   X Yes  No
17. COMMENTS

This Changes-Being-Effect supplement provides for an additional supplier of the to package Cipro Tablets.

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

19. REVIEWER

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<th>NAME</th>
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<td>Dorota Matecka, Ph.D.</td>
<td>D. Mateca</td>
<td>5/18/99</td>
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DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE
WITHHOLD 2 PAGE(S)
APPLICATION NUMBER:

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ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE
NDA 19-537/S-035

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