CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-847 / S-022

Trade Name: **Cipro**

Generic Name: **Ciprofloxacin**

Sponsor: **Bayer Corporation**

Approval Date: **November 1, 1999**

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APPROVAL LETTER

NDA 19-847/S022

Bayer Corporation
Pharmaceutical Division
Attention: Andrew S. Verderame
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

NOV 1 1999

Dear Mr. Verderame:

Please refer to your supplemental new drug application dated July 6, 1999, received July 7, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CIPRO® (Ciprofloxacin) IV Solution.

This supplemental new drug application provides for the ———————————,

———

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Valerie Jensen, R.Ph., Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

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

cc:
Archival NDA 19-847
HFD-590/Div. Files
HFD-590/V. Jensen
HFD-590/N.Schmuff
HFD-590/D.Matecka
HFD-095/DDMS-IMT
HFD-830/C.Chen

Drafted by: /November 1, 1999

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-847 / S-022

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW Review #1

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

2. **NDA NUMBER** 19-847

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-022; 7/6/99

6. **NAME OF DRUG**
Cipro I.V.

7. **NONPROPRIETARY NAME**
Ciprofloxacin

8. **SUPPLEMENT(s) PROVIDES FOR:**

9. **AMENDMENTS AND OTHER DATES** n/a

10. **PHARMACOLOGICAL CATEGORY**
Antibacterial

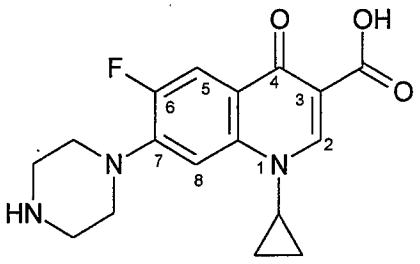
11. **HOW DISPENSED**
XXX
Rx OTC

12. **RELATED IND/NDA/DMF(s)**

13. **DOSAGE FORM(s)**
I.V. Solution

14. **POTENCY(ies)**
200, 400 and 1200 mg

15. **CHEMICAL NAME, STRUCTURE, MOLECULAR WEIGHT**
Ciprofloxacin, $C_{17}H_{18}N_3FO_3$, MW = 331.35
1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline carboxylic acid
CAS - 85721-33-1



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

17. COMMENTS

[ ]

This application was consulted with the Microbiology Staff of ONDC. The microbiology staff has completed its review of the submitted information and found it satisfactory (see attached review of Patricia F. Hughes, Ph.D. dated 8/26/99).

The EER was requested for this supplement and was found acceptable on October 14, 1999 (see attached copy of the EER).

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend an approval letter to issue for this supplement.

cc: Orig: NDA 19-847
HFD-590/Division File
HFD-590/CSO/VJensen
HFD-590/Chem/DMatecka

HFD-590/TL/NSchmuff:R/D initialed N Schmuff 10/19/99

19.	REVIEWER	
NAME	**SIGNATURE**	**DATE COMPLETED**
Dorota Matecka, Ph.D.	D. Matecka	10/19/99

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