CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-537 / S-044

Trade Name: **Cipro**

Generic Name: **Ciprofloxacin**

Sponsor: **Bayer Corporation**

Approval Date: **August 2, 2002**

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APPLICATION NUMBER:

19-537 / S-044

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-537/S-044

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

Dear Mr. Verderame:

Please refer to your supplemental new drug application dated April 9, 2002, received April 10, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cipro (ciprofloxacin hydrochloride) Tablets, 100 mg, 250 mg, 500 mg, and 750 mg.

This supplemental new drug application provides for the extension of the expiration dating from 3 years to 5 years for Cipro Tablets for the following dose/package configurations:

1. 50-count i[redacted] with child-resistant closure (250 mg);
2. 100-count in[redacted]e with child-resistant closure (250 mg);
3. 50-count in[redacted] with child-resistant closure (500 mg);
4. 100-count in[redacted]le with child-resistant closure (500 mg);
5. 50-count in[redacted] with child-resistant closure (750 mg);
6. Unit dose[redacted] all above doses).

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, call Jouhayna Saliba, Regulatory Project Manager, at (301) 827-2331.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Schmuff
8/2/02 02:50:35 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-537 / S-044

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 8/10/02	1. ORGANIZATION HFD-590	2. NDA NUMBER 19-537

3. NAME AND ADDRESS OF APPLICANT
Bayer Corporation Pharmaceutical Division
ATTN: Andrew S. Verderame
400 Morgan Lane
West Haven, CT 06516

4. TYPE OF SUPPLEMENT
PAS

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
SCE-044	4/9/02	4/10/02

6. NAME OF DRUG
Cipro Tablets

7. NONPROPRIETARY NAME
ciprofloxacin hydrochloride tablets

8. SUPPLEMENT PROVIDES FOR:
Extension of expiration date (from 3 to 5 years) for Cipro Tablets.

9. AMENDMENTS/DATES
N/A

10. PHARMACOLOGICAL CATEGORY
Antibacterial

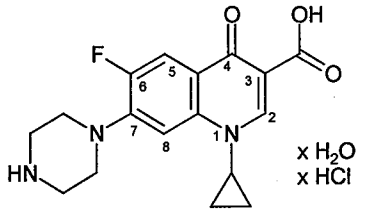
11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(s)
N/A

13. DOSAGE FORM(S)
tablets

14. POTENCY (CIES)
100 mg, 250 mg, 500 mg, 750 mg

15. CHEMICAL NAME AND STRUCTURE



3-quinoline carboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-, monohydrochloride, monohydrate

16. MEMORANDA
N/A

17. COMMENTS
This supplemental application provides for an extension of the expiration dating (from 3 to 5 years) for the following packaging configurations of Cipro Tablets:

1. 50-count in [redacted] th child-resistant closure (250 mg);
2. 100-count i [redacted] with child-resistant closure (250 mg);
3. 50-count in [redacted] with child-resistant closure (500 mg);
4. 100-count i [redacted] e with child-resistant closure (500 mg);
5. 50-count ir [redacted] with child-resistant closure (750 mg);
6. Unit dose I [redacted] ll above doses).

In support of this supplement, the applicant provided several reports on stability for Cipro Tablets of the above strengths packaged in approved packaging components of different counts. This includes five years of data for several batches of all strengths. See Review Notes for details.

18. CONCLUSIONS AND RECOMMENDATIONS
This supplement is recommended for approval.

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
Dorota Matecka	*[signed electronically in DFS]*	7/23/02

20. CONCURRENCE: HFD-590/NSchmuff *[signed electronically in DFS]*

DFS CC LIST		L			L			
L = Action Letter	R	L	Dorota Matecka	R	L	Med:		PharmTox
R = Review			NSchmuff			PM		Micro
						Biopharm		

4 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry-1a