CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-537 / S-043

Trade Name: CIPRO

Generic Name: Ciprofloxacin

Sponsor: Bayer Corporation Pharmaceutical Division

Approval Date: December 13, 2002

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APPLICATION NUMBER:

19-537 / S-043

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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-043

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

Dear Mr. Verderame:

Please refer to your supplemental new drug application dated January 17, 2002, received January 18, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cipro® (ciprofloxacin hydrochloride) Tablets.

We acknowledge receipt of your submission dated May 24, 2002.

Your submission of August 14, 2002 constituted a complete response to our May 17, 2002 action letter.

This supplemental new drug application provides for the following:

- A new packaging configuration, Cipro 500 mg Tablets in bottles of 30
- An alternate primary bottle label with revised wording from the currently available commercial drug product
- Five-year expiration dating for the 30 count bottle

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and carton labels submitted August 14, 2002).

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jouhayna Saliba, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht
12/13/02 02:06:24 PM

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APPLICATION NUMBER:

19-537 / S-043

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 5/16/02	1. ORGANIZATION HFD-590	2. NDA NUMBER 19-537

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

4. TYPE OF SUPPLEMENT
PAS

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
SCP-043	1/17/02	1/18/02

6. NAME OF DRUG
Cipro Tablets

7. NONPROPRIETARY NAME
ciprofloxacin tablets

8. SUPPLEMENT PROVIDES FOR:
New packaging configuration (to supply Cipro 500-mg Tablets in bottles of 30).

9. AMENDMENTS/DATES
N/A

10. PHARMACOLOGICAL CATEGORY
Antibacterial

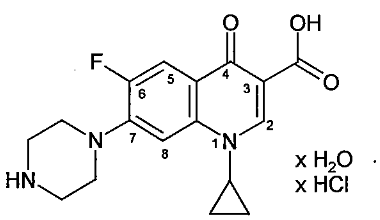
11. HOW DISPENSED
|X| ℞ | | OTC

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 a new packaging configuration of Cipro Tablets (500-mg tablets supplied in [redacted] ottles of 30) in response to the request of the Department of Defense (DOD). The same packaging components, as those approved for 100-count bottles, will be used but additional cotton will be added to fill the increased headspace. The applicant has proposed five (5) years of the expiration dating for Cipro Tablets, 30-count [redacted] bottles.

In support of this supplement, the applicant provided several reports on stability for Cipro Tablets packaged in approved packaging components of different counts. This includes five years of data for [redacted]. There are also several changes proposed for the container label. See Review Notes for details.

18. CONCLUSIONS AND RECOMMENDATIONS
This supplement is recommended for approval provided that an approval recommendation of the proposed label is made by a medical officer.

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
Dorota Matecka, Ph.D.	*[signed electronically in DFS]*	4/12/02

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

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

WITHHOLD 4 PAGE(S)

Chemistry Review

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/s/

Dorota Matecka
5/13/02 04:40:09 PM
CHEMIST

Norman Schmuff
5/15/02 06:48:01 AM
CHEMIST