CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-537 / S-042

Trade Name: Cipro

Generic Name: (ciprofloxacin hydrochloride)

Sponsor: Bayer Corporation Pharmaceutical

Approval Date: December 4, 2001

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APPLICATION NUMBER:

19-537 / S-042

CONTENTS

Reviews / Information Included in this NDA Review.

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Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
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Administrative and Correspondence Document(s)	**X**

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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-042

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 June 19, 2001, received June 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CIPRO (ciprofloxacin hydrochloride) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a contract

configurations of CIPRO Tablets.

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) 827-2127.

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

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/s/

Norman Schmuff
12/4/01 12:55:24 PM

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APPLICATION NUMBER:

19-537 / S-042

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW # 1	DUE DATE 12/20/01	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 CBE-30 5. DOCUMENT(S) NUMBERS SUBMITTED RECEIVED SCM-042 6/19/01 6/20/01	
6. NAME OF DRUG CIPRO Tablets		7. NONPROPRIETARY NAME ciprofloxacin tablets	
8. SUPPLEMENT(S) PROVIDES FOR: New [redacted] Cipro Tablets.			9. AMENDMENTS AND OTHER 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, 250, 500 and 750 mg	
15. CHEMICAL NAME ciprofloxacin hydrochloride; 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 new [redacted] configurations of Cipro Tablets.

The applicant stated that there would be no changes in the [redacted] or the labeling of Cipro Tablets. The EER was submitted for this supplement and the facility was found acceptable on July 22, 2001 (EER copy attached in the end of this review). The information provided in the supplement was reviewed and found acceptable. See the Review Notes for further details.

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Dorota Matecka		11/23/01

20. CONCURRENCE: HFD-590/NSchmuff

DISTRIBUTION	X	Original Jacket	X	DMatecka	X	MO
	X	Division File	X	NSchmuff	X	CSO
			X	HFD-830/CChen		

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B4

Chemistry Review Ia

Comment:

The above commitment is in accordance with the recommendations in the Guidance for Industry entitled "Stability Testing of Drug Substances sand drug Products" (draft).

4. GMP status

The applicant stated that a successful GMP inspection was performed by the FDA in December 1999.

The EER was submitted for this supplement and the facility was found acceptable (based on profile) on July 22, 2001 (see attached copy of the EER).

18-NOV-2001 Page 1 of 1

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 19537/042** Priority: **1P** Org Code: **590**
Stamp: **20-JUN-2001** Regulatory Due: **20-DEC-2001** Action Goal: District Goal: **15-NOV-2001**
Applicant: **BAYER**
400 MORGAN LANE
WEST HAVEN, CT 065164175
Brand Name: **CIPRO**
Established Name:
Generic Name: **CIPROFLOXACIN HYDROCHLORIDE**
Dosage Form: **TAB (TABLET)**
Strength: **100 MG, 250 MG, 500 MG,**

FDA Contacts:

J. SALIBA	**(HFD-590)**	**301-827-2423**	**, Project Manager**
D. MATECKA	**(HFD-590)**	**301-827-2398**	**, Review Chemist**
N. SCHMUFF	**(HFD-590)**	**301-827-2425**	**, Team Leader**

Overall Recommendation:

ACCEPTABLE on 09-JUL-2001 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted] DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE** Responsibilities: [redacted]
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **09-JUL-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

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/s/

Dorota Matecka
12/3/01 04:54:27 PM
CHEMIST

Norman Schmuff
12/4/01 12:53:15 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-537 / S-042

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-537/S-042

CBE-30 SUPPLEMENT

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

Dear Mr. Verderame,

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Cipro® (ciprofloxacin hydrochloride) Tablets
NDA Number:	19-537
Supplement number:	S-042
Date of supplement:	June 19, 2001
Date of receipt:	June 20, 2001

This supplemental application was submitted as a "Supplement - Changes Being Effected in 30 days." The appropriateness of reporting the proposed change(s) as changes being effected in 30 days is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 20, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products, HFD-590
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Special Pathogen and Immunologic Drug Products
Attention: Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850

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

Sincerely yours,

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

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/s/

Ellen Frank
8/3/01 09:24:12 AM
NDA 19-537/S-042