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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APPROVAL LETTER
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 Jouhaya 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
APPLICATION NUMBER:

19-537 / S-042

CHEMISTRY REVIEW(S)
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<th>SUPPLEMENTAL NDA CHEMIST’S REVIEW #1</th>
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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 Cipro Tablets.

9. AMENDMENTS AND OTHER DATES
   N/A

10. PHARMACOLOGICAL CATEGORY
    Antibacterial

11. HOW DISPENSED
    [X] 8 [ ] 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:
    configurations of Cipro Tablets.
    The applicant stated that there would be no changes in 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
    Dorota Matecka

20. CONCURRENCE: HFD-590/NSchmuff
    DISTRIBUTION X Original Jacket X DMatecka X MO
    X Division File X NSchmuff X CSO
    X HFD-830/CChen
Comment:

The above commitment is in accordance with the recommendations in the Guidance for Industry entitled “Stability Testing of Drug Substances and 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).
FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 19537/042
Applicant: BAYER
400 MORGAN LANE
WEST HAVEN, CT 065164175

Priority: IP
Action Goal: CIPRO
Brand Name: CIRO
Established Name: CIROFLOXACIN HYDROCHLORIDE
Generic Name: CIROFLOXACIN 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: [ ]
DMF No: 
AADA No: 

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

Responsibilities: [ ]
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this page is the manifestation of the electronic signature.

/s/

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

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

19-537 / S-042

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE
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,

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 Jouhaya 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