Approval Package for:

APPLICATION NUMBER:

19-537 / S-044

Trade Name: Cipro

Generic Name: Ciprofloxacin

Sponsor: Bayer Corporation

Approval Date: August 2, 2002
## Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Approvable Letter</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td></td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td></td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td></td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td></td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
<td></td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td></td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:

19-537 / S-044

APPROVAL LETTER
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
   with child-resistant closure (250 mg);
2. 100-count
   with child-resistant closure (250 mg);
3. 50-count
   with child-resistant closure (500 mg);
4. 100-count
   with child-resistant closure (500 mg);
5. 50-count
   with child-resistant closure (750 mg);
6. Unit dose (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
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: SCE-044
   DATED: 4/9/02
   RECEIVED: 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 R
    OTC
    N/A

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 inner
   2. 100-count inner
   3. 50-count inner
   4. 100-count inner
   5. 50-count inner
   6. Unit dose

   th child-resistant closure (250 mg);
   with child-resistant closure (250 mg);
   with child-resistant closure (500 mg);
   with child-resistant closure (500 mg);
   with child-resistant closure (750 mg);
   all 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: Dorota Matecka
    SIGNATURE: [signed electronically in DFS]
    DATE OF DRAFT REVIEW: 7/23/02

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

    DFS CC LIST
    L Dorota Matecka
    Med: PharmTox
    L = Action Letter
    R L NShmuff PM
    R L PM
    R = Review
    BioPharm
4 Page(s) Withheld

✓ Trade Secret / Confidential

Draft Labeling

Deliberative Process