APPLICATION NUMBER:

19-537 / S-049
20-780 / S-013
19-847 / S-027
19-857 / S-031

CHEMISTRY REVIEW(S)
### SUPPLEMENTAL NDA CHEMIST'S REVIEW

<table>
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<tr>
<th>SUPPLEMENTAL NDA CHEMIST'S REVIEW</th>
<th>DUE DATE</th>
<th>1. ORGANIZATION</th>
<th>2. NDA NUMBER</th>
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<td>25-Mar-2004</td>
<td>HFD-590</td>
<td>19-537; 19-847; 19-857; and 20-780</td>
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### 3. NAME AND ADDRESS OF APPLICANT

Bayer Pharmaceuticals Corporation  
ATTN: Andrew S. Verderame  
400 Morgan Lane  
West Haven, CT 06516

### 4. TYPE OF SUPPLEMENT

PAS

### 5. DOCUMENT(S)

<table>
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<tr>
<th>NUMBERS</th>
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<td>24-Sep-2003</td>
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### 6. NAME OF DRUG

Cipro Tablets (NDA 19-537); Cipro I.V. (NDA 19-847)  
Cipro I.V. (NDA 19-857); Cipro Oral Suspension (NDA 20-780)

**7. NONPROPRIETARY NAME**

ciprofloxacin hydrochloride (NDA 19-537) and ciprofloxacin (NDAs 19-847, 19-857, and 20-780)

### 8. SUPPLEMENT PROVIDES FOR:

The update of Pediatric Use and Animal Pharmacology sections of labeling.

### 9. AMENDMENTS/DATES

BC, 24-Mar-2004

### 10. PHARMACOLOGICAL CATEGORY

Antibacterial

### 11. HOW DISPENSED

[X] Rx  |  || OTC  |  N/A

### 12. RELATED IND/NDA/DMF(s)

N/A

### 13. DOSAGE FORM(S)

- Tablets (NDA 19-537); I.V. solution (vials, NDA 19-847); I.V. solution (NDA 19-857; 0.2% solution in 5% Dextrose; flexibags); oral suspension (NDA 20-780)

**14. POTENCY (CIES)**

- 100, 250, 500 and 750 mg (NDA 19-537)
- 200, 400 and 1200 mg (NDA 19-847)
- 200 mg and 400 mg (NDA 19-857)
- 5% and 10% (NDA 20-780)

### 15. CHEMICAL NAME AND STRUCTURE

<Chemical Structure Image>

Monohydrochloride salt of 1-cyclopropyl-7-[(S,S)-2,8-diazabicyclo[4.3.0]non-8-yl]-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinoline carboxylic acid (ciprofloxacin)

### 16. MEMORANDA

N/A

### 17. COMMENTS

These are efficacy supplements that provide for updates to the Pediatric Use and Animal Pharmacology sections of labeling. They do not provide for any chemistry changes. The environmental assessment issue was addressed in the amendment dated 24-Mar-2004. The applicant stated that these pediatric supplements are not expected to increase the use of the active moiety and to the applicant’s knowledge, no extraordinary circumstances exist as per 21 CFR 25.15 (d). The applicant is requesting exemption of an environmental assessment (categorical exclusion) for these submissions as per 21 CFR 25.31(a), which is acceptable.

### 18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval.

### 19. REVIEWER

**NAME**

| Dorota Matecka |

**SIGNATURE**

[signed electronically in DFS]

**DATE OF DRAFT REVIEW**

24-Mar-2004

### 20. CONCURRENCE:

| HFD-590/NSchmuff |

| [signed electronically in DFS] |

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/s/
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Dorota Matecka
3/24/04 07:52:45 PM
CHEMIST

________________________
Norman Schmuff
3/24/04 08:13:43 PM
CHEMIST