CENTER FOR DRUG EVALUATION AND RESEARCH

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	DUE DATE 25-Mar-2004	1. ORGANIZATION HFD-590	2. NDA NUMBER 19-537; 19-847; 19-857; and 20-780

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)

NUMBERS	DATED	RECEIVED
19-537/S-049	23-Sep-2003	25-Sep-2003
19-847/S-027	24-Sep-2003	29-Sep-2003
19-857/S-031	24-Sep-2003	29-Sep-2003
20-780/S-013	24-Sep-2003	29-Sep-2003

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

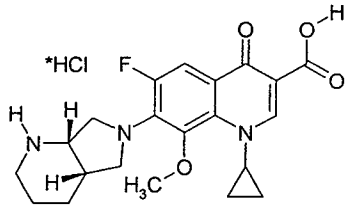
11. HOW DISPENSED
|X| Rx | | OTC

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



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	SIGNATURE	DATE OF DRAFT REVIEW
Dorota Matecka	*[signed electronically in DFS]*	24-Mar-2004

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

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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

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