

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-587 / S-054

Trade Name: Primaxin I. V.

Generic Name: Imipenem and Cilastatin for injection

Sponsor: Merck & Company, Inc.

Approval Date: July 23, 2001

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

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APPROVAL LETTER

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CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION	NDA NUMBER
1	DAIDP (HFD-520)	50-587

3. NAME & ADDRESS OF APPLICANT	4. AF NUMBER
---	---------------------

Merck and Co Inc.
West Point, PA

5. SUPPLEMENT (S)
NUMBER (s) DATE SCS-
SCS-054 2/15/01 -

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Primaxin IV	Cilastin Sodium & Imipenem

8. SUPPLEMENT (s) PROVIDES FOR:
a change to the manufacturing process for Primaxin IV. The change would allow for the subdivision of the large blend into _____

9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF (s)
Antibiotic	Rx XX OTC	

13. DOSAGE FORM (s)	14. POTENCY (ies)
Parenteral, IV	250mg, 500mg vials

15. CHEMICAL NAME AND STRUCTURE

m.w. .
CAS Registry No. - -
_REVIEWED

16. RECORDS AND REPORTS
CURRENT
x Yes X No
REVIEWED
Yes X No

17. COMMENTS

This drug is the subject of a compendial monograph, USP XXIV, page 411-cilastin sodium and page 863-imipenem. See items 20-34 for detailed comments.

18. CONCLUSIONS AND RECOMMENDATIONS:

Recommend approval letter to issue for this supplement.

Cc: Orig: NDA 50-587
HFD-520/Div File HFD-520/MO/Moledina
HFD-520/Pharm/ HFD-520/CSO/Dillon-Parker
HFD-520/Shetty HFD-520/D. Katague:R/D initialed _

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REVIEWER

NAME: B. Vithal Shetty, Ph.D.

SIGNATURE

DATE COMPLETED

DISTRIBUTION

ORIGINAL JACKET

REVIEWER

7/10/2001

WITHHOLD 3 PAGE(S)

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

/s/

B.V. Shetty
7/11/01 01:45:29 PM
CHEMIST

David Katague
7/11/01 01:50:23 PM
CHEMIST