CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-587 / S-055

Trade Name: **Primaxin I. V.**

Generic Name: **Imipenem and Cilastatin for injection**

Sponsor: **Merck & Company, Inc.**

Approval Date: **August 29, 2001**

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APPLICATION NUMBER:

50-587 / S-055

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Reviews / Information Included in this NDA Review.	
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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-587/S-055
NDA 50-630/S-018

Merck & Co. Inc
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated April 27, 2001, received May 1, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRIMAXIN™ I.V. for injection (Imipenem and Cilastatin), NDA 50-587, and PRIMAXIN™ I.M. Injectable Suspension (Imipenem and Cilastatin), NDA 50-630. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for an alternate stability testing site at the [redacted] for the imipenem, as well as, an alternate [redacted] for imipenem.

We have completed the review of these supplemental applications, and they are approved.

We remind you that you must comply with the requirements for approved NDA's set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maureen Dillon-Parker, Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

David B. Katague, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products, (HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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APPLICATION NUMBER:

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CHEMISTRY REVIEW(S)

NDA 50-587/SCS-055

NDA SUPPLEMENT REVIEW

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

3. **NAME & ADDRESS OF APPLICANT**

Merck and Co Inc.
West Point,PA

4. **AF NUMBER**

5. **SUPPLEMENT(S)**

SCS-055 4/27/01_-_____

6. **NAME OF DRUG**	7. **NONPROPRIETARY NAME**
Primaxin IV	Cilastatin & Imipenem

8. **SUPPLEMENT(s) PROVIDES FOR:**
An alternate stability indicating ——— which will be used at an alternate testing site at ——— for imipenem

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)**	
I.V.		

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-cilastatin and page 863-imipenem. See items 29and35 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/Mulinde J
HFD-520/Pharm/Ellis HFD-520/CSO/Dillon-Parker

HFD-520/Shetty HFD-520/D. Katague:R/D initialed _

19 **REVIEWER**

NAME:B.Vithal Shetty,Ph.D.
SIGNATURE **DATE COMPLETED**
DISTRIBUTION ORIGINAL JACKET REVIEWER 7/10/2001

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20. Components and Composition: NA

21. Facilities and Personnel: NA

22. Synthesis:NA

23. Raw Material Controls: NA
    a. New Drug Substance
    b. Other Ingredients

24. Other Firms: NA

25. Manufacturing and Processing: NA

26. Container/Closure: NA

27. Packaging and Labeling: NA

28. Laboratory Controls (In-process and Finished Dosage Form): NA

29. Stability: ADEQUATE
The firm has submitted an alternative HPLC stability testing method which will be carried out at alternate testing site at the [redacted] for Primaxin IV injectable.
The [redacted]

30. Control Numbers: NA

31. Samples and Results: NA

32. Labeling: NA

33. Establishment: NA

34. Recall: NA

35. Environmental Assessment: ADEQUATE.
The firm requests a categorical exclusion from the requirements of an Environmental Assessment under 21CFR 25.31(a) because it will not increase the use of the drug. To the best of the firm's knowledge,no extraordinary circumstances exist to this action.