CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-587 / S-059

Trade Name: **Primaxin**

Generic Name: **Cilastatin sodium; imipenem**

Sponsor: **Merck and Co.**

Approval Date: **May 28, 2002**

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APPLICATION NUMBER:

50-587 / S-059

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APPLICATION NUMBER:

50-587 / S-059

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-587/S-059

Merck Research Laboratories
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
P. O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug application dated March 27, 2002, received March 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRIMAXIN™ IV for Injection (Imipenem and Cilastatin). We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for a change from :

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 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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/s/

David Katague
7/9/02 12:13:26 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-587 / S-059

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW 1. **ORGANIZATION.** 2. **NDA NUMBER**
1 DAIDP (HFD-520) 50-587
3. **NAME & ADDRESS OF APPLICANT** 4. **AF NUMBER**
Merck and Co
P. O. Box 4
Sumneytown Pike, BLA-20
West Point, PA. 19486

5. SUPPLEMENT(s)
NUMBER(s) DATE(s.
SCP-059 3/27/02

6. **NAME OF DRUG** 7. **NONPROPRIETARY NAME**
PRIMAXIN for Injection Imipenem-Cilastatin for Injection

8. **SUPPLEMENT(s) PROVIDES FOR:** A change from a

9. **AMENDMENTS AND OTHER(REPORTS, etc.) DATES**
None

10. **PHARMACOLOGICAL CATEGORY**
Antibiotic

11. **HOW DISPENSED** Rx XX OTC

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

13. **DOSAGE FORM(s)**
Powder

14. **POTENCY(ies)**
250mg,500mg

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,p.864 See items 26, 29 and 35 for detailed comments.

18. **CONCLUSIONS AND RECOMMENDATIONS:**
Recommend approval letter to issue for this supplement.

cc: Orig: NDA 50-587 HFD-520
HFD-520/Div File HFD-520/MO/Smith
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. 6/25/02
SIGNATURE **DATE COMPLETED**
DISTRIBUTION ORIGINAL JACKET REVIEWER DIVISION FILE

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 Firm(s) : NA

25. Manufacturing and Processing: ADEQUATE
    .

26. Container/Closure: ADEQUATE

27. Packaging and Labeling:NA

28. Laboratory Controls (In-process and Finished Dosage Form): NA
29. Stability :ADEQUATE
The firm has made a commitment to place one lot using t
stability.

30. Control Numbers: NA

31. Samples and Results: NA
    a. Validation

    b. Market Package

32. Labeling: :NA

33. Establishment : NA
34.Recalls:NA

35 Environmental Assessment: Adequate

The firm requests a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR 25.31 (a)

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/s/

B.V. Shetty
6/26/02 11:43:07 AM
CHEMIST

David Katague
6/26/02 12:12:17 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-587 / S-059

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-587/S-059

PRIOR APPROVAL SUPPLEMENT

Merck Research Laboratories
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
P.O. Box 4, BLA 20
West Point, PA 19486

Dear Ms. Snyder:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: PRIMAXIN™ IV for Injection (imipenem and cilastatin)

NDA Number: 50-587

Supplement Number: S-059

Date of Supplement: March 27, 2002

Date of Receipt: March 28, 2002

This supplement proposes the following change(s): a change from a _____ the _____.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 28, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be July 28, 2002 and the secondary user fee goal date will be September 28, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
HFD-520
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
HFD-520
Attention: Division Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850-3202

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

Sincerely,

{See appended electronic signature page}

Frances V. LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Frances LeSane
6/17/02 11:31:46 AM