

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

50-630 / S-019

Trade Name: Primaxin

Generic Name: Cilastatin sodium; imipenem

Sponsor: Merck and Co

Approval Date: May 28, 2002

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APPLICATION NUMBER:

50-630 / S-019

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Reviews / Information Included in this NDA Review.

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Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
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APPROVAL LETTER



NDA 50-587/S-056
NDA 50-630/S-019

Merck and 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 December 5, 2002, received December 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRIMAXIN™ IV for Injection (Imipenem and Cilastatin) and PRIMAXIN™ IM Injectable Suspension (Imipenem and Cilastatin). 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 the use of the Merck facility in Wilson, North Carolina as an _____ site for cilastatin sodium.

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 NDAs set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ms. 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
5/28/02 10:55:06 AM

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APPLICATION NUMBER:

50-630 / S-019

CHEMISTRY REVIEW(S)

NDA SUPPLEMENT REVIEW

CHEMIST'S REVIEW	1. ORGANIZATION	NDA NUMBER
1	DAIDP (HFD-520)	50-630
3. NAME & ADDRESS OF APPLICANT	4. AF NUMBER	
Merck and Co. Inc. Sumneytown Pike BLA-20, P.O. Box 4 West Point, PA 19486		
5. SUPPLEMENT (s)		
		NUMBER (s) DATE (s)
		SCM-019 12/5/01
6. NAME OF DRUG	7. NONPROPRIETARY NAME	
PRIMAXIN IM Injectable Suspension	Imipenem and Cilastatin	
8. SUPPLEMENT (s) PROVIDES FOR: Use of the Merck facility in Wilson, North Carolina as an site for cilastatin sodium.		
9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES		
		12/5/01
10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF (s)
Antibiotic	Rx XX OTC	50-557/S-056
13. DOSAGE FORM (s)	14. POTENCY (ies)	
Powder	250mg, 500mg	
15. CHEMICAL NAME AND STRUCTURE		
m.w.		16. RECORDS AND REPORTS
CAS Registry No.	- -	CURRENT
<u>REVIEWED</u>		<u>x</u> Yes X No
		REVIEWED
		Yes X No
17. COMMENTS		
This drug is the subject of a compendial monograph, USP XXIV, p.864. See item 29, 33 and 35 for detailed comments..		
18. CONCLUSIONS AND RECOMMENDATIONS:		
Recommend approval letter to issue for this supplement.		
cc: Orig: NDA 50-630-; 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.		5/7/02
SIGNATURE		DATE COMPLETED
DISTRIBUTION ORIGINAL JACKET REVIEWER		DIVISION FILE

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 50630/019 Priority: 3S Org Code: 520
Stamp: 06-DEC-2001 Regulatory Due: 06-JUN-2002 Action Goal: District Goal: 02-MAY-2002
Applicant: MERCK Brand Name: PRIMAXIN
SUMNEYTOWN PIKE BLA20 Established Name:
WEST POINT, PA 19486 Generic Name: CILASTATIN SODIUM; IMIPENEM
Dosage Form: 356 ()
Strength: 250MG AND 500MG

FDA Contacts: M. DILLON PARKER (HFD-520) 301-827-2125 , Project Manager
R. SHETTY (HFD-520) 301-827-2187 , Review Chemist
D. KATAGUE (HFD-520) 301-827-2184 , Team Leader

Overall Recommendation:**ACCEPTABLE on 06-FEB-2002 by J. D AMBROGIO (HFD-324) 301-827-0062**

Establishment: 1036761 DMF No:
MERCK AND CO INC AADA No: 050587
4633 MERCK RD
WILSON, NC 27893

Profile: CTL OAI Status: NONE Responsibilities: DRUG SUBSTANCE STABILITY
Last Milestone: OC RECOMMENDATION TESTER
Milestone Date 06-FEB-2002
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

**This is a representation of an electronic record that was signed electronically and
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/s/

B.V. Shetty
5/15/02 06:47:29 AM
CHEMIST

David Katague
5/15/02 09:58:11 AM
CHEMIST