CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 50-679/S-002

Trade Name: MAXIPIME FOR INJECTION

Generic Name:(cefepime Hydrochloride)

Sponsor: Bristol-Myers Squibb

Approval Date: May 16, 1997

INDICATION: Provides for the empiric use of Maxipime as monotherapy in febrile neutropenic patients.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 50-679/S-002

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				
Approvable Letter				
Final Printed Labeling				
Medical Review(s)	X			
Chemistry Review(s)				
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)	X			
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)				
Administrative Document(s)	X			
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 50-679/S-002

APPROVAL LETTER

D F

NDA 50-679/S-002

Bristol-Myers Squibb
Pharmaceutical Research Institute
Attention: Hugh McIlhenny, Ph.D.
Director, Worldwide Regulatory Affairs
5 Research Parkway
P.O. Box 5100
Wallingford, CT 06492-7660

MAY - 16 1997

Dear Dr. McIlhenny:

Please refer to your supplemental new drug application dated May 17, 1996, received May 17, 1996, submitted under section 507 of the Federal Food, Drug, and Cosmetic Act for Maxipime® (Cefepime Hydrochloride) for Injection.

We acknowledge receipt of your submissions dated July 31, 1996, October 22, 1996, December 12, 1996, January 30, 1997, February 6, 1997, February 20, 1997, February 25, 1997, and April 10, 1997, and May 15, 1997. The User Fee goal date for this application is May 16, 1997.

The supplemental application provides for the empiric use of Maxipime® as monotherapy in febrile neutropenic patients.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated May 15, 1997. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on May 15, 1997.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 50-679/S-002. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you

propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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, please contact Beth Duvall-Miller, Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K Chikami

Gary K.Chikami, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

cc:
Original NDA 50-679
HFD-520/Div. files
HFD-520/CSO/B. Duvall-Miller
HFD-520/MO/D. Ross 5/14/97
HFD-520/SMO/J. Soreth 5/15/97
HFD-520/SCSO/J. Bona
HFD-725/BioStat/A. Chakravarty 5/16/97
HFD-725/TLBioStat/D. Lin 5/16/97
HFD-002/ORM (with labeling)
HFD-104/D. Feigal (with labeling) 5/16/97
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFI-20/Press Office (with labeling)
HFD-021/ACS (with labeling)

Concurrence:
HFD-520/SCSO/J. Bona 5/16/97
HFD-520/ActDivDir/G. Chikami
5/16/97

Drafted by: bdm/May 8, 1997/M:\SUPPAP\N50679.002
Initialed by:
final: 5/15/97

APPROVAL (AP)