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**

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Application Number: NDA 50-679/S-002

APPROVAL LETTER
Dear Dr. McIlhenny:


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, 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  
HFD-520/SMO/J. Soreth  
HFD-520/SCSO/J. Bona  
HFD-725/BioStat/A. Chakravarty  
HFD-725/TLBioStat/D. Lin  
HFD-002/ORM (with labeling)  
HFD-104/D. Feigal (with labeling)  
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  
HFD-520/ActDivDir/G. Chikami  
P. Chikami  
5/4/97  

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

APPROVAL (AP)