CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-386/S005

Trade Name: Brevibloc

Generic Name: Esmolol hydrochloride in sodium chloride

Sponsor: Baxter Healthcare Corporation

Approval Date: May 26, 1989

Indications: Short-Term control of heart rate in patients with abnormally fast heart rhythms such as artrial fibrillation, atrial flutter or sinus tachycardia.

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19-386/S005

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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)	
Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

19-386/S005

APPROVAL LETTER

MAY 26 1989

NDA 19-386/S-005

DuPont Critical Care
Attention: John H. Waterman
1600 Waukegan Road
Waukegan, IL 60085

Dear Mr. Waterman:

Please refer to your June 8, 1988 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Brevibloc (esmolol hydrochloride) Injection.

The supplemental application provides for ———————— as alternate manufacturer of esmolol hydrochloride.

We have completed the review of this supplemental application and it is approved. Our letter of December 31, 1986 detailed the conditions relating to the approval of this application.

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

Sincerely yours,

RW 5/26/89

Robert J. Wolters, Ph.D.
Supervisory Chemist
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
~~Original NDA~~
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-232 (with labeling)
HFD-730
HFD-110/DCunningham/5/17/89 DCunningham
sh/5/18/89/1183h
R/D init:RWolters:5/17/89

APPROVAL

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APPROVABLE LETTER

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