CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-386/S001 and S002

Trade Name: Brevibloc Injection

Generic Name: Esmolol Hydrochloride

Sponsor: Dupont Critical Care, Inc.

Approval Date: August 15, 1988

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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APPLICATION NUMBER:

19-386/S001 and S002

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter	
Labeling	X
Medical Review(s)	**X**
Chemistry Review(s)	**X**
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	**X**

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APPLICATION NUMBER:

19-386/S001 and S002

APPROVAL LETTER

S-002 AP 8/3
S-001 AP 8/3 10/17/8 10/9/8

AUG 15 1988

NDA 19-386/S-004
S-006

DuPont Critical Care, Inc.
Attention: Mr. John H. Waterman
1600 Waukegan Rd.
Waukegan, IL 60085

Dear Mr. Waterman:

Please refer to your September 17, 1987 and July 12, 1988 supplemental new drug applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Brevibloc (esmolol HCl) Injection.

We also acknowledge receipt of your amendments to your September 17 supplemental application dated November 19, 1987, March 10 and June 17, 30, 1988. The latter contained final printed labeling.

Your September 17 supplemental application provides for a new dosage form of Brevibloc (esmolol HCl) consisting of a 10 mL single use vial containing esmolol HCl 10 mg/mL (total of 100 mg) suitable for direct intravenous injection.

Your July 12 supplemental application provides for final printed labeling revised to strengthen the Overdosage and Dosage and Administration sections of the package insert for Brevibloc.

We have completed the review of these supplemental applications and they are 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.

Sincerely yours,

R Z 8/10/88

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
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/KBongiovanni/7/11/88;8/1/88
clb/7/11/88;8/3/88/0850C
R/D: DCunningham/8/1/88
RWolters/8/1/88
CResnick/8/1/88
SChen/8/1/88
CGraham/8/1/88
NMorgenstern/8/2/88

K. Bongiovanni 8-3-88

APPROVAL

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APPROVABLE LETTER

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