

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 atrial fibrillation, atrial flutter or sinus tachycardia.

CENTER FOR DRUG EVALUATION AND RESEARCH

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

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-386/S001 and S002

APPROVAL LETTER

S-002 AP d/B
S-001 AP d/B 10/17/8
10/29/8

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,

RJ 8/15/88

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 *K. Bongiovanni 8-3-88*
- RWolters/8/1/88
- CResnick/8/1/88
- SChen/8/1/88
- CGraham/8/1/88
- NMorgens tern/8/2/88

APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-386/S001 and S002

APPROVABLE LETTER

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.