

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 atrial fibrillation, atrial flutter or sinus tachycardia.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-386/S005

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Reviews / Information Included in this NDA Review.

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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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,

RJW 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-710

HFD-110/CSO

HFD-80/DBIR

HFD-100

HFD-232 (with labeling)

HFD-730

HFD-110/DCunningham/5/17/89

sh/5/18/89/1183h

R/D init:RWolters:5/17/89

APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-386/S005

APPROVABLE LETTER

DEC - 6 1988

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 an alternate manufacturer of drug substance esmolol hydrochloride.

We have completed the review of this supplemental application. Before the supplement may be approved, however, it will be necessary for a satisfactory establishment evaluation report of _____

Sincerely yours,



Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Orig NDA

HFD-110

HFD-110/CSO

HFD-80/DDIR

HFD-110/DCunningham/

sh/12/05/88/1091h

R/D init:RWolters:12/05/88

APPROVABLE

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-386/S005

CHEMISTRY REVIEW(S)

MAY 17 1989

CHEMIST'S REVIEW		1. Organization HFD - 110	2. NDA Number 19-386
3. Name and Address of Applicant (City & State) DuPont Critical Care, Inc. 1600 Waukegan Road Waukegan, IL 60085		4. AF Number	
6. Name of Drug Brevibloc	7. Nonproprietary Name Esmolol hydrochloride	5. Supplement(s) Number(s) : S-005	Date(s) Date(s) : 6/8/88
8. Supplement(s) Provides For: _____ as alternate manufacturer of drug substance esmolol hydrochloride.		9. Amendments and Other (Reports, etc.) Dates	
10. Pharmacological Category Anti-adrenergic (B-receptor)	11. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. Related IND/NDA/DMF(s) _____	
13. Dosage Form(s) Injection	14. Potency(ies) 100 mg/mL, 250 mg/mL 10 mg/mL		
15. Chemical Name and Structure		16. Records & Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
17. Comments EI of _____ requested on 6/29/88. Acceptable on 5/15/89.			
18. Conclusions and Recommendations AP			
19. REVIEWER			
Name Danute G. Cunningham	Signature <i>Danute G. Cunningham</i>	Date Completed May 17, 1989	
Distribution <input checked="" type="checkbox"/> Original Jacket	/ / Reviewer		/ / Div. File

Handwritten signature and date:
5/17/89

DEC - 5 1988

CHEMIST'S REVIEW		1. Organization HFD - 110	2. NDA Number 19-386
3. Name and Address of Applicant (City & State) DuPont Critical Care, Inc. 1600 Waukegan Road Waukegan, IL 60085		4. AF Number	5. Supplement(s) Number(s) Date(s)
6. Name of Drug Brevibloc	7. Nonproprietary Name Esmolol Hydrochloride	S-005	6/8/88
8. Supplement(s) Provides For: _____ as alternate manufacturer of drug substance esmolol hydrochloride.		9. Amendments and Other (Reports, etc.) Dates	
10. Pharmacological Category Anti-adrenergic (B receptor)	11. How Dispensed <input checked="" type="checkbox"/> /X/ <input type="checkbox"/> RX <input type="checkbox"/> / <input type="checkbox"/> OTC	12. Related IND/NDA/DMF(s) _____	
13. Dosage Form(s) Injection	14. Potency(ies) 100 mg/mL, 250 mg/mL (10 mg/mL -S-004)		
15. Chemical Name and Structure		16. Records & Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
17. Comments Currently approved manufacturers are _____ and _____ EI of _____ requested on 6/29/88. Continued on p. 2			
18. Conclusions and Recommendations Approvable pending satisfactory Establishment Evaluation report.			
19. REVIEWER			
Name Danute G. Cunningham	Signature <i>Danute G. Cunningham</i>	Date Completed December 2, 1988	
Distribution	<input checked="" type="checkbox"/> Original Jacket	<input type="checkbox"/> /Reviewer	<input type="checkbox"/> /Div. File

Wang 0156c

Handwritten initials and date:
12-5-88

10 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling