CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-386/S011

Trade Name: Brevibloc 100 mg/ 10 ml vial

Generic Name: Esmolol Hydrochloride

Sponsor: Anaquest Inc.

Approval Date: November 24, 1993

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 Supplement 11

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Labeling	
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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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 19-386/S-011

Approval Letter(s)

281
goes W. 5011

NDA 19-386/S-011

Anaquest Inc.
Attention: Robert I. Outwater
110 Allen Road
P.O. Box 804
Liberty Corner, NJ 077938-0804

NOV 24 1993

Dear Mr. Outwater:

Please refer to your November 5, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Brevibloc (esmolol HCl) Injection.

The supplemental application provides for the substitution of a clear ——→ for the amber vial presently used for the 10 mL single dose vial of Brevibloc Injection (100 mg/vial).

We have completed the review of this supplemental application and it is 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,

RW 11/24/93

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:
Original NDA
HFC-130/JAllen
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-232 (with labeling)
HFD-730
HFD-110/DCunningham/11/18/93;11/23/93 DCunningham 11/23/93
clb/11/23/93/N19386.S11
R/D init: RWolters/11/22/93

Approval Date: December 31, 1986

APPROVAL

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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 19-386/S-011

Chemistry Review(s)

NOV 24 1993

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 19-386
3. Name and Address of Applicant (City & State) Anaquest Inc. 110 Allen Road P.O. Box 804 Liberty Corner, NJ 07938-0804		4. Supplement(s) Number(s) Date(s) S-011 11/5/93 (CS)
5. Drug Name Brevibloc	6. Nonproprietary Name Esmolol hydrochloride	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Substitution of a clear ———— for the amber vial presently utilized for the 10 mL single dose vial of Brevibloc (esmolol HCl) injection (100 mg esmolol HCl/vial).		
9. Pharmacological Category Anti-adrenergic (β-receptor)	10. How Dispensed ☒ Rx ☐ OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Intravenous injection	13. Potency(ies) 250mg/mL 10mL amp. 10 mg/mL 10mL vial	
14. Chemical Name and Structure		15. Records/Reports Current ☐ Yes ☐ No Reviewed ☐ Yes ☐ No

16. Comments:

There are no changes in the formulation, processing methods, the site of the manufacture.

The amber glass vial currently used was chosen to differentiate the product from 250 mg/mL 10 mL colorless vial ———— This differentiation is no longer necessary since only two dosage forms are manufactured: 10 mg/mL, 10 mL vial and 250 mg/mL ampule.

Apparently the 250 mg/mL strength will be packaged in ampules only.

cont'd

17. Conclusions and Recommendations:

AP. There was no change in formulation or manufacturing site, only the color of the vial.

18. REVIEWER		
Name Danute G. Cunningham	Signature Danute G. Cunningham	Date Completed November 18, 1993

Distribution:

☒ Original Jacket ☐ Reviewer ☐ Division File ☐ CSO ☐ District

19386S11.SUP

11-21-93

2 Page(s) Withheld

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

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling