CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-386/S010

Trade Name:	Brevibloc 100mg/10mL and 2.5g/10ml ampule Injection
Generic Name:	Esmolol Hydrochloride
Sponsor:	Anaquest Inc.
Approval Date:	July 1, 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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Reviews / Information Included in this NDA Review.	
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Labeling	X
Medical Review(s)	X
Chemistry Review(s)	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-386/S-010

Anaquest Inc.
Attention: Ms. Brenda Marczi
110 Allen Road
Liberty Corner, NJ 07938-0804

JUL 1 1993

Dear Ms. Marczi:

We acknowledge the receipt on June 2, 1993 of your June 1, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Brevibloc (esmolol HCl) 100 mg/10 ml vial and 2.5 g/10 ml ampule Injection.

The supplemental application provides for final printed labeling revised as follows:

1. Under the **PRECAUTIONS/Pregnancy Category C** subsection the first sentence of the second paragraph has been revised to read as follows:

> Although there are no adequate and well controlled studies in pregnant women, use of esmolol in the last trimester of pregnancy or during labor or delivery has been reported to cause fetal bradycardia, which continued after termination of drug infusion. Brevibloc should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

2. The name and address of the sponsor has been changed to:

> Anaquest Inc.
> 110 Allen Road
> PO Box 804
> Liberty Corner, NJ 07938-0804
>
> A subsidiary of BOC Health Care Inc
> BOC Health Care

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.

Should you have any questions, please contact:

Ms. Zelda McDonald
Consumer Safety Officer
Telephone: (301) 443-4730

Sincerely yours,

RL 7/1/93

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-232 (with labeling)
HFD-110/ZMcDonald/6/15/93;6/16/93 zm 6/30/93
sb/6/15/93;6/30/93
R/D: RWolters/6/21/93
CResnick/6/21/93
SChen/6/21/93
NMorgenstern/6/30/93

Approval Date: December 31, 1986

APPROVAL

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