

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-386/S012

Trade Name: Brevibloc 100 mg/ 10 ml vial

Generic Name: Esmolol Hydrochloride

Sponsor: Ohmeda Inc.

Approval Date: January 13, 1994

Indications: Short-Term control of heart rate in patients with abnormally fast heart rhythms such as atrial fibrillation, atrial flutter or sinus tachycardia.

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APPLICATION NUMBER:
19-386 Supplement 12

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Reviews / Information Included in this NDA Review.

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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 19-386/S-012

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-386/S-012

JAN 13 1994

Ohmeda Inc.
Attention: Mr. Robert I. Outwater
110 Allentown Road
P.O. Box 804
Liberty Corner, NJ 07938-0804

Dear Mr. Outwater:

We acknowledge receipt on December 13, 1993 of your December 10, 1993 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 reinstating the originally approved amber vial, in addition to the clear _____ so that this product may be exported to other countries where the clear _____ is not approved. (Supplement 11 provided for the clear _____ as a "substitute" for the amber vial when it should have been and "alternative" to the amber 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,

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/ZMcDonald/1/12/94;1/12/94 *3m 1/13/94*

sb/1/12/94;1/13/94

R/D: DCunningham/1/13/94

RWolters/1/13/94

Approval Date: December 31, 1986

APPROVAL