DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-386/S-024

Baxter Healthcare Corporation, Anesthesia & Critical Care
Attention: Lidia D. Mostovy
Associate Director, Regulatory Affairs
95 Spring Street
New Providence, NJ 07974

Dear Ms. Mostovy :

Please refer to your supplemental new drug application dated April 25, 2003, received April 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Brevibloc Concentrate (esmolol hydrochloride) 250 mg/mL in 10 mL ampuls.

We also acknowledge receipt of your submission dated July 28, 2003.

This supplemental new drug application provides for reformulation of Brevibloc Concentrate with a reduced overage of the active ingredient (reduced from 10% to 2%).

We have completed the review of this supplemental application as amended, 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.

If you have any questions, call Ms. Melissa Robb, Regulatory Health Project Manager, at (301) 594-5313.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar
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