DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-419/S-026

Baxter Healthcare Corporation Anesthesia and Critical Care
Attention: Ms. Valerie Shinault
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Ms. Shinault:

Please refer to your supplemental new drug application dated October 9, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Inderal (propranolol hydrochloride) Injection 1 mg/mL.

We acknowledge receipt of your submissions dated April 17, 2003, October 6, 2004, April 7, 2005 and April 10, 2006.

Your submission of April 10, 2006 constituted a complete response to our April 10, 2003 action letter.

This supplemental new drug application provides for the separation of the prescribing information for propranolol hydrochloride Injection and Tablets which is currently presented in a common package insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 10, 2006.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, please call Ms. Melissa Robb, Regulatory Project Manager, at (301) 796-1138.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director

Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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