DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-087/SLR-045

Baxter Healthcare Corporation
Anesthesia and Critical Care
95 Spring Street
Providence, NJ 07974

Attention: Priya Jambhekar
Director, Regulatory Affairs

Dear Ms. Jambhekar:

Please refer to your supplemental new drug applicationdated June 20, 2002, received June 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ethrane® (enflurane USP) Liquid for Inhalation.

This "Changes Being Effected" supplemental new drug application provides for changes to the ADVERSE REACTIONS section of the package insert.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lisa E. Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Cynthia G. McCormick, MD
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
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/

Cynthia McCormick

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