DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-118/S-016

Baxter Healthcare Corporation
95 Spring Street
New Providence, NJ 07974

Attention: Andrea Gosda
Manager Global Regulatory Affairs

Dear Ms. Gosda:

Please refer to your supplemental new drug application dated January 30, 2009, received February 2, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Suprane (desflurane, USP).

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

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling text (FPL) submitted on January 30, 2009.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ayanna Augustus, Regulatory Project Manager, at (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Drugs
Office of New Drugs II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Rigoberto Roca
4/14/2009 09:14:21 AM
for Bob Rappaport, M.D.