



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-118/S-010

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

Attention: Leslie R. Koehler
Director, Global Regulatory Affairs

Dear Ms. Koehler:

Please refer to your supplemental new drug application dated November 7, 2005, received November 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Suprane (desflurane, USP) Liquid for Inhalation.

We acknowledge receipt of your submission dated November 30, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **HOW SUPPLIED: Safety and Handling** section of the package insert.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 30, 2005.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Bob Rappaport
5/8/2006 09:19:10 PM