



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 17-624/S-034

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

Attention: Ting Chen  
Associate Director, Global Regulatory Affairs

Dear Ms. Chen:

Please refer to your supplemental new drug application dated May 2, 2006, received May 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FORANE (isoflurane, USP) Liquid for Inhalation.

We acknowledge receipt of your submission dated August 8, 2006.

This "Changes Being Effected-30 days" supplemental new drug application provides for revisions to the **WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS** sections 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-118/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

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).

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

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

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Bob Rappaport  
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