DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-478/S-013

Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6157

Attention: Steven F. Hoff, R.Ph, Ph.D.
Associate Director, Global Pharmaceutical Regulatory Affairs

Dear Dr. Hoff:

Please refer to your supplemental new drug application dated December 20, 2004, received December 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultane (sevoflurane).

We acknowledge receipt of your submissions dated May 12, 2005 and June 15, 2005.

This supplemental application proposes revisions to the DESCRIPTION, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections of the package insert. The information regarding sevoflurane degradation products and pathways and the language related to replacement of desiccated CO_2 absorbent canisters is added.

We have completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter with the revision listed below.

As agreed to by you, the second sentence of the last paragraph of the DESCRIPTION section will be revised as follows:

> Concentrations of formaldehyde observed with desiccated soda lime in this experimental anesthesia respiratory circuit were consistent with levels that could potentially result in respiratory irritation.

The final printed labeling (FPL) must be identical to the labeling submitted on June 15, 2005.

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 NDA 20-478/S-013**." 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, HFD-410
FDA
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 Alison Meyer, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division 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 this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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