DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-478/S-007

Abbott Laboratories
D-398, Bldg. 45
200 Abbott Park Road
Abbott Park, IL 60064-6133

Attention: Surendera Tyagi, PhD
Associate Director, Regulatory Affairs; Hospital Products Division

Dear Dr. Tyagi:

Please refer to your supplemental new drug application dated August 18, 2000, received August 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultane (sevoflurane).

We acknowledge receipt of your submissions dated March 28, 2001, and October 28, 2002. Your submission of October 28, 2002, constituted a complete response to our October 9, 2002, action letter.

This supplemental new drug application provides for changes to the container labels and to the DESCRIPTION section of the package insert. The information regarding the presence of water is revised.

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

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}

Bob Rappaport, MD
Acting 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/

Bob Rappaport

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