Dear Ms. Kaleck-Schlingsog:

Please refer to your supplemental new drug application dated December 30, 2005, received January 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultane® (sevoflurane).

This supplemental new drug application provides for changes to the DESCRIPTION, WARNINGS, and ADVERSE REACTIONS sections 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 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 20-478/S-016." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

   Food and Drug Administration
   Center for Drug Evaluation and Research
   Division of Drug Marketing, Advertising, and Communications
   5901-B Ammendale Road
   Beltsville, MD 20705-1266
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

Please submit one market package of the drug product when it is available.

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

/s/
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Bob Rappaport
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