



NDA 020478/S-019 and S-020

**SUPPLEMENT APPROVAL**

Abbott Laboratories  
Dept PA77/Bldg AP30-LL  
200 Abbott Park Road  
Abbott Park, IL 60064-6147

Attention: Viraj B. Gandhi  
Manager, Regulatory Affairs -PPG

Dear Mr. Gandhi:

Please refer to your supplemental new drug applications dated June 30, 2010, received July 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ultane (sevoflurane) and Ultane NovaPlus (sevoflurane) volatile liquid for inhalation.

We acknowledge receipt of your amendments dated April 9, 2012.

These “Changes Being Effectuated” supplemental new drug applications provide for changes to the **WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS**, sections of the package insert.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(1)(1)(i)] in structured product labeling (SPL) format submitted on April 9, 2012.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at

<http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

### **REPORTING REQUIREMENTS**

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 A. Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia, and  
Addiction Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure  
Content of Labeling  
Ultane  
Ultane NovaPlus

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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BOB A RAPPAPORT  
08/16/2012