



NDA 020478/S-023, S-024, S-027, S-028

SUPPLEMENT APPROVAL

AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064

Attention: Helen Bronder, MS, MBA
Manager, Regulatory Affairs, Global Regulatory Strategy

Dear Ms. Bronder:

Please refer to your supplemental new drug applications (sNDA) dated and received February 6, 2012 (S-023 and S-024), and June 26, 2014 (S-027 and S-028), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ultane (sevoflurane).

These Prior Approval sNDAs provide for changes to the **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS – DRUG INTERACTIONS** and **ADVERSE REACTIONS** sections of the package insert.

APPROVAL & LABELING

We have completed our review of these applications, as amended and are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effected” (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 *SPL Standard for Content of Labeling Technical Qs and As*.²

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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 labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

We note that your Prescribing Information (PI) is not required to be in Physician Labeling Rule (PLR) format, however, we recommend that you submit a prior approval supplement (PAS) with your proposed PLR-format labeling for FDA review within 6 months of receipt of this letter. PLR format represents a more useful and modern approach for communicating information on the safe and effective use of products and makes prescribing information more accessible for use with electronic prescribing tools and other electronic information resources

If you submit your draft labeling in PLR format, we recommend you:

- Review the labeling review resources on the *Prescription Drug Labeling Resources* website^[1] including:
 - Physician Labeling Rule on the content and format of the PI,
 - Regulations and related guidance documents,
 - A sample tool illustrating the format for Highlights of Prescribing Information (Highlights) and Contents,

^[1] <https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources>

- Selected Requirements for Prescribing Information (SRPI) – a checklist of important format items from labeling regulations and guidances,
- FDA’s established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading, and
- Additional resources for the PI, patient labeling, and carton/container labeling.
- Clearly mark on the cover letter “**Labeling/PLR Conversion**”
- Submit a clean version as well as a marked-up version of the PI (that identifies all your proposed changes to the last approved PI) in Microsoft Word format, and a clean version of the last approved PI in non-PLR format.
- Your supplement must include updated content of labeling 21 CFR 314.50(l)(1)(i) in structured product labeling (SPL) format as described at FDA.gov.^[2]

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, Senior Regulatory Health Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine,
and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling

^[2] <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RIGOBERTO A ROCA
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