



NDA 022510/S-010

**SUPPLEMENT APPROVAL**

Galena Biopharma, Inc.  
310 N. State St., Suite 208  
Lake Oswego, OR 97034

Attention: Hana Berger Moran, Ph.D.  
VP, Regulatory Affairs and Compliance

Dear Dr. Moran:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 21, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Abstral (fentanyl) Sublingual Tablets, 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg and 800 mcg.

We acknowledge receipt of your amendments dated June 21, and July 11, 2013, and your risk evaluation and mitigation strategy (REMS) assessment dated December 26, 2012.

This "Prior Approval" supplemental new drug application proposes updates to the package insert and medication guide to reflect the recent change in Sponsor.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), 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 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 that includes 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 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).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

### **RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for Abstral (fentanyl) was originally approved on January 7, 2011, and a REMS modification was approved on December 28, 2011, as part of the approval of the transmucosal immediate-release fentanyl (TIRF) REMS single-shared system. The REMS was last modified on June 5, 2012. The REMS consists of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of a revised Abstral Medication Guide to reflect the recent change in NDA Sponsorship.

Your proposed modified REMS, submitted on May 21, 2013, and appended to this letter, is approved.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

The timetable for submission of assessments of the REMS will remain the same as that approved on June 5, 2012.

There are no changes to the REMS assessment plan described in our December 28, 2011, letter.

In addition to the assessments submitted according to the timetable included in this approved REMS, you must submit a REMS assessment when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify any submission containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

**NDA 022510  
REMS ASSESSMENT**

**NEW SUPPLEMENT FOR NDA 022510  
PROPOSED REMS MODIFICATION  
REMS ASSESSMENT**

**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 Kimberly Compton, Senior Regulatory Project Manager, at (301) 796-1191.

Sincerely,

*{See appended electronic signature page}*

Judith A. Racoosin, M.D., M.P.H.  
Deputy Director for Safety  
Division of Anesthesia, Analgesia, and  
Addiction Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling  
REMS

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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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JUDITH A RACOOSIN  
07/26/2013