DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022510/S-005

SUPPLEMENT APPROVAL

ProStrakan, Inc.
1430 US Highway 206, Suite 110
Bedminster, NJ 07921

Attention: Dalena DeGrezia, MBA
Director, US Regulatory Affairs

Dear Ms. DeGrezia:

Please refer to your Supplemental New Drug Application (sNDA) dated February 10, 2012, received February 13, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ABSTRAL (fentanyl) sublingual tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated February 10, 2012.

This supplemental new drug application proposes modifications to the approved REMS for ABSTRAL, which is part of the single shared system REMS, the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access Program.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

CONTENT OF LABELING

The label approved on December 28, 2011, as part of supplement S-003, is attached for your convenience.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for ABSTRAL was originally approved on January 7, 2011. The REMS was modified on December 28, 2011, as part of the approval of the TIRF REMS single-shared system. 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 modifications to the TIRF REMS consist of edits to the Patient-Prescriber Agreement Form, the addition of the Closed System Pharmacy Enrollment Form, the addition of the newly approved TIRF product, Subsys (fentanyl sublingual spray), and minor editorial changes. Additionally, the TIRF REMS Access Program “go-live” placeholder date has been updated with the actual "go-live" date of March 12, 2012.

Your proposed modified REMS, submitted on February 10, 2012, and appended to this letter, is approved.

The TIRF REMS Access program includes the following products:

NDA 020747	Actiq (fentanyl citrate) oral transmucosl lozenge and its authorized generic
NDA 021947	Fentora (fentanyl buccal tablets)
NDA 022266	Onsolis (fentanyl buccal soluble film)
NDA 022510	Abstral (fentanyl) sublingual tablets
NDA 022569	Lazanda (fentanyl) nasal spray
NDA 202788	Subsys (fentanyl) sublingual spray
ANDA 077312	Fentanyl Citrate Oral Transmucosal Lozenge
ANDA 078907	Fentanyl Citrate Oral Transmucosal Lozenge

Other products may be added in the future if additional NDAs or ANDAs are 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 is amended to correspond with the TIRF REMS Access Program timetable for submission of assessments approved on December 28, 2011. The first assessment is due June 28, 2012, and the second assessment is due December 28, 2012, and assessments are due annually thereafter.

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

We remind you that assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in this approved REMS, you must submit a REMS assessment and may propose a modification to the approved

REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of 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

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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

Enclosures:
Content of Labeling
REMS

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

/s/

JUDITH A RACOOSIN
06/05/2012