DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021897/S-005 & S-010

Alkermes, Inc.
852 Winter Street
Waltham, MA 02451-1420

Attention: Renee Howard
Director, Regulatory Affairs

Dear Ms. Howard:

Please refer to your supplemental new drug applications dated January 11, 2008, received January 14, 2008 (S-005), and dated June 4, 2009, received June 5, 2009 (S-010), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIVITROL (naltrexone for extended-release injectable suspension).

We acknowledge receipt of your submissions dated March 3, 2008, December 8, 2009, and January 29 and February 9, 2010.

These Changes Being Effected supplemental new drug applications provide for the addition of language to the package insert regarding the risk of serious injection site reactions, a Medication Guide, and a Risk Evaluation and Mitigation Strategy (REMS).

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 for the Package Insert and Medication Guide, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on February 9, 2010. We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your February 9, 2010, submission containing final printed carton labels.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the FDCA authorizes FDA to require the submission of a Risk Evaluation and Mitigation Strategy (REMS) if FDA becomes aware of new safety information and makes a

determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)).

Since VIVITROL (naltrexone for extended-release injectable suspension) was approved on April 13, 2006, we have become aware of serious injection site reactions associated with VIVITROL (naltrexone for extended-release injectable suspension) that are likely caused by incorrect administration of the drug. This information came from your reports as well as our search of FDA's Adverse Event Reporting System (AERS) Database. We considered this information to be "new safety information" as defined in section 505-1(b) of the FDCA.

Your proposed REMS, submitted on January 29, 2010, and appended to this letter, is approved. The REMS consists of the Medication Guide included with this letter and the timetable for submission of assessments of the REMS.

The REMS assessment plan should include, but is not limited to, an evaluation of patients' understanding of the serious risks of VIVITROL (naltrexone for extended-release injectable suspension).

The requirements for assessments of an approved REMS under section 505-1(g)(3) include, in 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. 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 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.

We remind you that in addition to the assessments submitted according to the timetable included in the 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.

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

NDA 021897 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 021897
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT FOR (NEW INDICATION FOR USE)
FOR NDA 021897
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

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

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to 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 following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Lisa Basham, Senior Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, MD, MHS
Deputy Director for Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure
- Package Insert
- Medication Guide
- Carton Labeling (split into two pages)
- REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21897	SUPPL-10	ALKERMES INC	VIVITROL (NALTREXONE LONG ACTING INJECTI
NDA-21897	SUPPL-5	ALKERMES INC	VIVITROL (NALTREXONE LONG ACTING INJECTI

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

/s/

LARISSA LAPTEVA
03/22/2010