DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-897/S003

Alkermes, Inc.
88 Sidney Street
Cambridge, MA 02139

Attention: Paul Alessandro
Director, Regulatory Affairs

Dear Mr. Alessandro:

Please refer to your supplemental new drug application dated April 26, 2007, received April 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIVITROL (naltrexone for extended-release injectable suspension).

This "Changes Being Effected" supplemental new drug application provides for a revision to the **ADVERSE REACTIONS** section of the package insert.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on April 26, 2007.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Division Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Enter for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

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