NDA 21-897 VIVITROL® (naltrexone for extended-release injectable suspension)

Opioid Antagonist

Alkermes, Inc.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goal of this REMS is to inform patients about the serious risks associated with the use of VIVITROL, including injection site reactions.

A. Medication Guide

Alkermes will ensure that a currently approved Medication Guide will be dispensed with each VIVITROL prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Alkermes will submit REMS Assessments to the FDA at 18 months, 3 years, and 7 years following the initial REMS approval of March 22, 2010. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment will conclude no earlier than 60 days before the submission date for that assessment.

Alkermes will submit each assessment so that it will be received by the FDA on or before the due date.

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/s/

RIGOBERTO A ROCA
10/12/2010