NDA 021897/S-055

SUPPLEMENT APPROVAL

Alkermes, Inc.
852 Winter Street
Waltham, MA 02451

Attention: Divyani Patel, PharmD
Senior Associate, Regulatory Affairs

Dear Dr. Patel:

Please refer to your supplemental new drug application (sNDA) dated and received April 2, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vivitrol (naltrexone for extended-release injectable suspension).

This prior approval supplemental new drug application provides for proposed modifications to the approved Vivitrol risk evaluation and mitigation strategy (REMS). This supplement is in response to our March 17, 2021, REMS Modification Notification letter / REMS Assessment Acknowledgment letter.

APPROVAL

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Vivitrol (naltrexone) was originally approved on March 22, 2010, and the most recent REMS modification was approved on June 7, 2019. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

In accordance with section 505-1 of the FDCA, we have determined that the following REMS modifications are necessary to minimize burden on the healthcare delivery system of complying with the REMS:

- Removal of the Medication Guide as an element of the REMS
- Removal of the communication plan

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Vivitrol (naltrexone) outweigh its risks. The Medication Guide will remain as part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

Additionally, we have determined that the communication plan is no longer necessary to ensure the benefits of VIVITROL (naltrexone) outweigh its risks because the communication plan has been completed. The most recent REMS assessment demonstrates that the communication plan has met its goals and has shown that healthcare provider respondents were aware of the risk of severe injection site reactions and the need to counsel patients regarding risks. Patient survey respondents were less able to identify all of the symptoms of severe injection site reactions, but were well aware that they should contact their healthcare provider about *any* reaction at the injection site that was concerning or got worse over time.

Therefore, because the Medication Guide (as part of the REMS) and communication plan are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Vivitrol (naltrexone).

As previously stated, the Medication Guide will remain as part of the approved labeling for Vivitrol (naltrexone).

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 LCDR Jessica Voqui, PharmD, MS, Safety Regulatory Project Manager, at 301-796-2915.

Sincerely,

{See appended electronic signature page}

LCDR Mark A. Liberatore, PharmD, RAC
Deputy Director for Safety
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARK A LIBERATORE
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