ANDA 202090/S-010

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Hikma Pharmaceuticals USA Inc.
1809 Wilson Road
Columbus, OH 43228

Attention: James Connell
Associate Director, Regulatory Affairs

Dear Sir:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on April 17, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Sodium Oxybate Oral Solution.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as a "Prior Approval Supplement," provides for modifications to the approved Sodium Oxybate Shared System (SS) Risk Evaluation and Mitigation Strategy (REMS).

We have completed the review of this sANDA, as amended, and it is **approved**.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Your proposed modification to the REMS consists of editorial changes to the presentation of the demographic information on the Patient Enrollment Form and the Prescripton Form; and changes to the Patient Quick Start Guide to replace product specific Instructions for Use (IFU) with text that refers to the IFU in the labeling of the product.

Your REMS, referenced in Drug Master File (DMF) 036796, is approved and will be posted on the FDA REMS website: http://www.fda.gov/rems.

The modified Sodium Oxybate SS REMS consists of elements to assure safe use and an implementation system.

Other products may be added in the future if additional NDAs or ANDAs are approved.

Under section 505-1(g)(2)(C) of the FD&C Act, FDA can require the submission of a REMS assessment if FDA determines an assessment is needed to evaluate whether the REMS should be modified to ensure the benefits of the drug outweigh the risks or to minimize the burden on the healthcare delivery system of complying with the REMS.

We remind you that you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FD&C Act.

We remind you that section 505-1(f)(8) of the FD&C Act 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) of the FD&C Act. A violation of this provision in 505-1(f) of the FD&C Act could result in enforcement action.

Prominently identify any submission containing the 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 as appropriate:

ANDA 202090 REMS ASSESSMENT
CROSS REFERENCE TO THE REMS DMF

or

NEW SUPPLEMENT FOR ANDA 202090/S-000/
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION
CROSS REFERENCE TO THE REMS DMF

or

NEW SUPPLEMENT FOR ANDA 202090/S-000/
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION
CROSS REFERENCE TO THE REMS DMF

or

NEW SUPPLEMENT FOR ANDA 202090/S-000/
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES
SUBMITTED IN SUPPLEMENT XXX
CROSS REFERENCE TO THE REMS DMF

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR ANDA 202090
CROSS REFERENCE TO THE REMS DMF

The Sodium Oxybate REMS uses a Type V DMF for shared system REMS submissions. Please refer to the draft guidance for industry *Use of a Drug Master File for Shared System REMS Submissions*,[1] for instructions on how to submit and reference the shared system REMS DMF.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

As soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in Structured Product Labeling (SPL) format using the FDA automated drug registration and listing system (eLIST). Do not submit the SPL to your application nor to your REMS DMF (if applicable). Content of the REMS document must be identical to the approved REMS document. The SPL will be publicly available.

Information on submitting REMS in SPL format may be found in the guidance for industry *Providing Regulatory Submissions in Electronic Format – Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.*

REQUIREMENTS AND RECOMMENDATIONS POST-APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post-approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

[1] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

If you have any questions, call Charles Kerns, REMS Coordinator, at (301) 796-6271.

Sincerely,

{See appended electronic signature page}

Debra M. Catterson, RPh
Deputy Director
Division of Clinical Safety and Surveillance
Office of Safety and Clinical Evaluation
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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Silver Spring, MD 20903
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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/

DEBRA M CATTERSON
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