ANDA 204982/S-012

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Actavis Laboratories FL, Inc.
(an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA Inc.)
400 Interpace Parkway
Building A
Parsippany, NJ 07054

Attention: Bernard Domnic
Director, Regulatory Affairs

Dear Sir:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on February 28, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Phentermine and Topiramate Extended-Release Capsules.

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 proposed modifications to the approved Phentermine and Topiramate Extended-Release Capsules 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 modifications to the REMS consist of:

- Administrative updates to the REMS document.
- Changes to the Pharmacy Training including an updated indication and editorial changes to the "Counseling for All Patients" section to align with approved labeling.

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

Your REMS, received on February 28, 2025, is approved and will be posted on the FDA REMS website: http://www.fda.gov/rems.

The modified REMS for Phentermine and Topiramate Extended-Release Capsules SS REMS consists of a Medication Guide, 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 204982 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR ANDA 204982/S-000/
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204982/S-000/
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 204982/S-000/
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

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 204982

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

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 Submission in Electronic Format – Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling*[1].

For additional information on submitting REMS in SPL format, please email REMSWebsite@fda.hhs.gov.

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.

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If you have any questions, call James Barlow, REMS Coordinator, at (301) 402-8587.

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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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
05/29/2025 12:41:29 PM