ANDA 208175

ANDA APPROVAL

Dr. Reddy's Laboratories Inc.
U.S. Agent for Dr. Reddy's Laboratories SA
600 College Road East
Suite 4000
Princeton, NJ 08540
Attention: Jyothi Avirineni
Director - Regulatory Affairs

Dear Jyothi Avirineni:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 30, 2014, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Phentermine and Topiramate Extended-Release Capsules, 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg.

Reference is also made to the complete response letter issued by this office on December 16, 2022, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Phentermine and Topiramate Extended-Release Capsules, 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Qsymia ER Capsules 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg, of Vivus, LLC (Vivus), NDA 022580.

The RLD upon which you have based your ANDA, Vivus's Qsymia ER Capsules 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
8,580,298 (the '298 patent)	May 15, 2029

8,580,299 (the '299 patent)	June 14, 2029
8,895,057 (the '057 patent)	June 9, 2028
8,895,058 (the '058 patent)	June 9, 2028
9,011,905 (the '905 patent)	June 9, 2028
9,011,906 (the '906 patent)	June 9, 2028

With respect to: 1) the ‘298, ‘058 and ‘905 patents, 2) the ‘299 patent (excluding certain portions of the use code U-3399: for chronic weight management in adults with BMI >=30 kg/m^2, and patients age 12-17 with BMI >=30 kg/m^2 and in the 95th percentile or greater (standardized for age and sex), each having a weight-related comorbidity), and 3) the ‘057 and ‘906 patents (excluding certain portions of the use code U-3398: for chronic weight management in adults with BMI >=30 kg/m^2 or BMI>=27 kg/m^2 with a weight-related comorbidity, and patients age 12-17 with BMI >=25 kg/m^2 in the 95th percentile or greater (standardized for age and sex),your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Phentermine and Topiramate Extended-Release Capsules, 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15 mg/92 mg, under this ANDA. You have notified the Agency that Dr. Reddy's Laboratories SA (Dr. Reddy's) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Dr. Reddy's for infringement of the '298, '299, '057, and '058 patents in the United States District Court for the District of New Jersey [Vivus, LLC v. Dr. Reddy’s Laboratories, S.A., et.al., Civil Action No. 15-02693]. You have also notified the Agency that this case was dismissed.

With respect to: 1) the ‘299 patent (insofar as it pertains to certain portions of the use code U-3399: for chronic weight management in adults with BMI >=30 kg/m^2, and patients age 12-17 with BMI >=30 kg/m^2 and in the 95th percentile or greater (standardized for age and sex), each having a weight-related comorbidity) and 2) the ‘057 and ‘906 patents (insofar as it pertains to certain portions of the use code U-3398: for chronic weight management in adults with BMI >=30 kg/m^2 or BMI>=27 kg/m^2 with a weight-related comorbidity, and patients ages 12-17 with BMI >=25 kg/m^2 in the 95th percentile or greater (standardized for age and sex), your ANDA contains statements under section 505(j)(2)(A)(viii) of the FD&C Act that these are method-of-use patents that do not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the FD&C Act authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks [section 505-1(a) of the FD&C Act]. In accordance with section 505-1(i) of the FD&C Act, a drug that is the subject of an ANDA under section 505(j) of the FD&C Act is subject to certain elements of the REMS required for the applicable listed drug.

The details of the REMS requirements were outlined in our REMS notification letter dated March 25, 2015.

Your final proposed REMS, received on May 2, 2025, is approved, and will be posted on the FDA REMS website: http://www.fda.gov/rems. Other products may be added in the future if additional NDAs or ANDAs are approved.

The Phentermine and Topiramate Extended-Release Capsules REMS consists of a Medication Guide, Elements to Assure Safe Use (ETASU), and an Implementation System.

Your REMS must be fully operational before you introduce your drug into interstate commerce.

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.

FDA has determined that assessments are needed for the Phentermine and Topiramate Extended-Release Capsules REMS.

Additionally, the details for what should be included in your REMS assessments and the dates of the REMS assessments are listed in Appendix 1.

If the information provided in an assessment is insufficient to allow FDA to determine whether the REMS is meeting its goals or whether the REMS must be modified, FDA may require the submission of a new assessment plan that contains the metrics and/or methods necessary to make such a determination. Therefore, FDA strongly recommends obtaining FDA feedback on the details of your proposed assessment plan to ensure its success. To that end, we recommend that methodological approaches, other analysis plans and assessment approaches used to assess a REMS be submitted for FDA review as follows:

i. Submit your proposed audit plan and non-compliance plan for FDA review within 60 days of this letter.

ii. Submit your proposed protocol for the knowledge survey(s) for FDA review within 90 days of this letter.

Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

ANDA 208175 REQUEST FOR REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g.,
SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

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 also remind you that section 505-1(f)(8) of the FD&C Act prohibits holders of an approved covered application from using any element to assure safe use to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) of the FD&C Act could result in enforcement action.

Prominently identify any submission containing a REMS assessment 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 208175 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR ANDA 208175/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 208175/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR ANDA 208175/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 REVISION FOR ANDA 208175

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. 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.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

[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.

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.

Sincerely yours,

{See appended electronic signature page}

For Malik Imam, PharmD, MBA
CDR, United States Public Health Service
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

REMS – Appendix 1

Paul Levine

Digitally signed by Paul Levine
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