



ND 213267 A

ANDA APPROVAL

Teva Pharmaceuticals US, Inc.
U.S. Agent for Natco Pharma Limited
Attention: John Derstine
Sr. Director, R, US Generics

Dear John Derstine:

This letter is in reference to your abbreviated new drug application (ND) received for review on December 11, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Thalidomide Capsules USP, 50 mg, 100 mg, 150 mg and 200 mg.

Reference is also made to our letter dated April 27, 2023, granting final approval to your Thalidomide Capsules USP, 150 mg and granting tentative approval to your Thalidomide Capsule USP, 50 mg, 100 mg, and 200 mg.

We have completed the review of this ND 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 ND is **approved**, effective on the date of this letter. We have determined your Thalidomide Capsules USP, 50 mg, 100 mg and 200 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Thalomid Capsules, 50 mg, 100 mg and 200 mg, of Bristol-Myers Squibb Company (Bristol) ND - 020785.

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 ND 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 February 6, 2020.

Your final proposed REMS, received on March 24, 2023, is approved, and will be posted on the FDA REMS website: <http://www.fda.gov/rdmt>. Other products may be added in the future if additional NDAs or ANDAs are approved.

The Thlidomid REMS consists of Elements to Assess Safety (ETASU) and an implementation system.

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

Your REMS, known as the Thlidomid REMS, is approved as a special REMS program from the list of the reference listed drug, using a different, comparable aspect of the ETASU. Pursuant to section 505-1(i)(3) of the FD&C Act, FDA is requiring that this REMS be comparable used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) of the FD&C Act that references the same listed drug.

Under section 505-1() (2)(C) of the FD&C Act, FDA cannot require the submission of REMS assessment if FDA determines an assessment is not 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 included for the Thlidomid REMS.

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

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information. The first 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission content in the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

ANDA 213267 REMS CORRESPONDENCE

(insert concise description of content in bold capital letters, . . .)

**UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT 1
METHODOLOGY)**

We remind you that you must include information to support proposed REMS modification for the addition, modification, or removal of any element of the REMS, as described in section 505-1(f)(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 safety 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 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 213267 REMS ASSESSMENT

or

**NEW SUPPLEMENT FOR ANDA 213267/S-000
CHANGES BEING EFFECTED IN 30 DAYS I
PROPOSED MINOR REMS MODIFICATION**

or

**NEW SUPPLEMENT FOR ANDA 213267/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION**

or

**I
NEW SUPPLEMENT FOR ANDA 213267/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING
CHANGES SUBMITTED IN SUPPLEMENT XXX**

Should you choose to submit 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 213267

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 Word format is preferred.

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 distribution and listing system (LIST). 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 Submissions in Electronic Format – Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling*.

For additional information on submitting REMS in SPL format, please mail REMSWebsite@fd.hhs.ov.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopoeia or official National Formulary (USP-NF) generally must comply with the compendial standards 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 drug continues to comply with compendial standards, application holders may work directly with USP-NF to review official USP monographs. More information on the USP-NF is available on USP's website at <https://www.uspnf.com/>.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidance, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and notification requirements, among others. **a**

For information on post-approval requirements and recommendations for ANDAs and list of resources for ANDA holders, refer you to <https://www.fda.gov/drugs/bbr/vit-d-nw-drug-application-and-requirements-and-resources-approval-and-s>.

Sincerely yours,

{See appended electronic signature page}

For K. S. Stewart, R. H., Pharm.D.
CA, Unit Director, Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosure: REMS Assessment Information

a

a

6 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page



Paul 3
Levi e 3

Initials: Paul Levi e
Date: 4/24/2026 06:05:17AM
GUID: 56 2 ddc00 554a87fad6698c2baa467 3