ANDA 201452/S-001

CHANGES BEING EFFECTED
APPROVAL

Natco Pharma Limited
c/o Watson Laboratories, Inc. (U.S. agent)
(subsidiary of Teva Pharmaceuticals USA, Inc.)
400 Interpace Parkway, Building A
Parsippany, NJ 07054

Attention: Srinivasa Rao Suryadevara
Executive Vice President-Operations

Dear Sir or Madam:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on June 10, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for lenalidomide capsules.

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

The sANDA, submitted as "Changes Being Effected in 30 Days," provides for minor modifications to the approved shared system risk evaluation and mitigation strategy (REMS) for lenalidomide products known as the Lenalidomide REMS Program as listed below.

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

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Your proposed modifications to the REMS consist of:

- Prescriber Enrollment Form: Removed reference to the Prescriber mobile app
- Patient-Physician Agreement Forms (PPAFs):
  - Updated disclosure language
  - New checkbox for patients to request Lenalidomide REMS materials
- Prescriber Guide: Removed reference to the Prescriber mobile app, added reference to Patient Companion App
- Pharmacy Training, Patient Guide, REMS Website: added reference to Patient Companion App

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

Your REMS, referenced in Drug Master File (DMF) [redacted] (b) (4) is approved and will be posted on the FDA REMS website: http://www.fda.gov/rems.

The modified REMS for **lenalidomide 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). A violation of this provision in 505-1(f) 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 201452 REMS ASSESSMENT
CROSS REFERENCE TO THE REMS DMF

NEW SUPPLEMENT FOR ANDA 201452 /S-000/
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION
CROSS REFERENCE TO THE REMS DMF

or

NEW SUPPLEMENT FOR ANDA 201452 /S-000/
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION
CROSS REFERENCE TO THE REMS DMF

or

NEW SUPPLEMENT FOR ANDA 201452/S-000/
PRIOR APPROVAL SUPPLEMENT

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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 201452**
> **CROSS REFERENCE TO THE REMS DMF**

The **lenalidomide** 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.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[2] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts.

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[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

[2] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

If you have any questions, call CAPT Stacy Barley, REMS Coordinator, at (301) 796-2137.

Sincerely,

{See appended electronic signature page}

Debra M. Catterson, RPh
Acting Deputy Director
Division of Clinical Safety and Surveillance
Office of Safety and Clinical Evaluation
Office of Generic Drugs
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/

DEBRA M CATTERSON
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