



ANDA 219864

ANDA APPROVAL

Grace Consulting Services, Inc.
U.S. Agent for Annora Pharma Private Limited
Attention: Soma Raju
U.S. Agent - Regulatory Affairs

Dear Soma Raju:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on September 30, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mesalamine Extended-Release Capsules USP, 0.375 g.

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

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 Mesalamine Extended-Release Capsules USP, 0.375 g, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Apriso Extended-Release Capsules, 0.375 g, of Salix Pharmaceuticals, Inc. (Salix), NDA - 022301.

The RLD upon which you have based your ANDA, Salix's Apriso Extended-Release Capsules, 0.375 g, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
8,865,688 (the '688 patent)	May 1, 2030

Your ANDA contains a paragraph IV certification to the '688 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Mesalamine Extended-Release Capsules USP, 0.375 g, under this ANDA. You have notified the Agency that Annora Pharma Private Limited (Annora) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Annora within the statutory 45-day period.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

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/>.

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



Catherine
Poole

Digitally signed by Catherine Poole

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