



ANDA 216620

**ANDA APPROVAL**

Grace Consulting Services Inc.  
U.S. Agent for Annora Pharma Private Limited  
121 New England Ave  
Piscataway, NJ 08854  
Attention: Soma Raju  
Us Agent-Regulatory Affairs

Dear Soma Raju:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on April 22, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Eltrombopag for Oral Suspension, 12.5 mg and 25 mg.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the tentative approval letter issued by this office on July 14, 2023, 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 Eltrombopag for Oral Suspension, 12.5 mg and 25 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Promacta for Oral Suspension, 12.5 mg and 25 mg, of Novartis Pharmaceuticals Corporation (Novartis).

The RLD upon which you have based your ANDA, Novartis's Promacta for Oral Suspension, 12.5 mg and 25 mg, is subject to periods of patent protection. The following patent and expiration date (with pediatric exclusivity added) 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>
7,547,719 (the '719 patent)	January 13, 2026

Your ANDA contains a paragraph IV certification to the '719 patent (excluding those portions pertaining to the use code U-2452: combination with immunosuppressive therapy for first-line treatment of adult patients 2 years and older with severe aplastic anemia) 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 Eltrombopag for Oral Suspension, 12.5 mg and 25 mg, 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.

With respect to the '719 patent (insofar as it pertains to those portions of the use code U-2452: combination with immunosuppressive therapy for first-line treatment of adult patients 2 years and older with severe aplastic anemia), your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Annora was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Eltrombopag for Oral Suspension, 12.5 mg and 25 mg. Therefore, with this approval, Annora is eligible for 180 days of generic drug exclusivity for Eltrombopag for Oral Suspension, 12.5 mg and 25 mg. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

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 Edward M. Sherwood  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Paul  
Levine

Digitally signed by Paul Levine

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