ANDA 217679

ANDA APPROVAL

Lifestar Pharma LLC
U.S. Agent for Mankind Pharma Limited
Attention: Parimal Upadhyay
EVP-Strategic Planning and Operations

Dear Parimal Upadhyay:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 8, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ticagrelor Tablets, 60 mg and 90 mg.

Reference is also made to the complete response letter issued by this office on July 8, 2025, 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 Ticagrelor Tablets, 60 mg and 90 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Brilinta Tablets, 60 mg and 90 mg, of AstraZeneca Pharmaceuticals LP (AstraZeneca), NDA - 022433.

The RLD upon which you have based your ANDA, AstraZeneca's Brilinta Tablets, 60 mg and 90 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) 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
8,425,934 (the '934 patent)	October 17, 2030
10,300,065 (the '065 patent)	July 27, 2036

Your ANDA contains a paragraph IV certification to the '934 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), Brilinta Tablets, 60 mg and 90 mg, under this ANDA. You have notified the Agency that Mankind Pharma Limited (Mankind) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and

that no action for infringement was brought against Mankind within the statutory 45-day period.

With respect to the '065 patent, 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.

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 Kendra S. Stewart, R.Ph., Pharm.D.
CAPT, United States Public Health Service
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Catherine Poole

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