



ANDA 211094

ANDA APPROVAL

Teva Pharmaceuticals USA, Inc.
Attention: Elisabeth Gray
Director, Regulatory Affairs, US Generics

Dear Elisabeth Gray:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 26, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg.

Reference is also made to the tentative approval letter issued by this office on December 6, 2023, the complete response letter issued by this office on February 27, 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 Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Sprycel Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg, of Bristol-Myers Squibb Company (BMS) NDA - 021986.

The RLD upon which you have based your ANDA, BMS's Sprycel Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg, is subject to a period 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>
7,491,725 (the '725 patent)	September 28, 2026

Your ANDA contains a paragraph IV certification to the '725 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 Dasatinib Tablets, 20 mg, 50 mg, 70 mg, 80 mg, 100 mg and 140 mg, under this ANDA. You have notified the Agency that Teva Pharmaceuticals USA, Inc. (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day

period against Teva for infringement of the '725 patent in the United States District Court for the District of New Jersey [Bristol-Myers Squibb Company v. Teva Pharmaceuticals USA, Inc., Civil Action No. 20-03229]. You have also notified the Agency that this case was dismissed.

The RLD upon which you have based your ANDA, BMS's Sprycel Tablets 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg, is also subject to a period of exclusivity. As noted in the Orange Book, the ODE-225 exclusivity is scheduled to expire on June 21, 2026 (with pediatric exclusivity added). You have provided a copy of a letter from BMS that waives the unexpired ODE-225 exclusivity period associated with the RLD.

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



Paul
Levine

Digitally signed by Paul Levine

Date: 8/27/2025 02:09:04PM

GUID: 56323ddc003554a87fad6698c2baa467