



ANDA 213191

ANDA APPROVAL

Teva Pharmaceuticals, Inc.
400 Interpace Parkway, Building A
Parsippany, NJ 07054
Attention: Janet Vaughn
Vice President, Regulatory Affairs, Generics, North America

Dear Janet Vaughn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on June 29, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mesalamine Delayed-Release Tablets USP, 800 mg.¹

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 Delayed-Release Tablets USP, 800 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Asacol HD Tablets, 800 mg, of AbbVie Inc. (AbbVie).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated July 17, 2023.

We note that Teva Pharmaceuticals, Inc. (Teva) was granted a Competitive Generic Therapy (CGT) designation for Mesalamine Delayed-Release Tablets USP, 800 mg. With respect to 180-day CGT exclusivity, Teva may be the 'first approved applicant' for Mesalamine Delayed-Release Tablets USP, 800 mg as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act; however, we have not determined whether the criterion set forth in section 505(j)(5)(B)(v)(III)(bb)(CC) has been satisfied (i.e., whether this is a drug for which all drug versions have not forfeited eligibility for 180-day patent challenge exclusivity). Therefore, with this approval, Teva may be eligible for 180 days of CGT exclusivity for Mesalamine Delayed-Release Tablets USP, 800 mg, under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity would begin to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Teva, as specified in section 505(j)(5)(B)(v) of the FD&C Act. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C Act, this 180-day

CGT exclusivity would not block approval of other applications until Teva has commenced commercial marketing. Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. Please also submit notice of first commercial marketing via e-mail to the Patent and Exclusivity Team at CDER-OGDPET@fda.hhs.gov. This email should be sent the same day you commence commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 505(j)(5)(D)(iv) of the FD&C Act. Please be aware that, pursuant to this forfeiture rule, you will forfeit any eligibility for the 180-day CGT exclusivity period for Mesalamine Delayed-Release Tablets USP, 800 mg, if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

The Agency is not, however, making a formal determination at this time of Teva's eligibility for 180-day CGT exclusivity. We will do so only if another ANDA applicant for Mesalamine Delayed-Release Tablets USP, 800 mg becomes eligible for full approval during the timeframe when any CGT exclusivity would otherwise block such approval (i.e., within the first 180 days of commercial marketing by Teva, provided Teva markets the CGT within 75 days after the date on which the approval of this ANDA is made effective).

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

¹ We note that the reference listed drug (RLD) upon which you have based this ANDA, AbbVie's Asacol HD Tablets, 800 mg, is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that AbbVie's Asacol HD Tablets, 800 mg, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (88 FR 10525; February 21, 2023). This determination allows the Agency to approve ANDAs for the discontinued drug product.



Paul
Levine

Digitally signed by Paul Levine

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