ANDA 209986

ANDA APPROVAL

Mylan Pharmaceuticals Inc.
U.S. Agent for Mylan Laboratories Limited
3711 Collins Ferry Road
Morgantown, WV 26505
Attention: Beth Britton
Head, RA US Generics

Dear Beth Britton:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 14, 2016, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Cobicistat Tablets, 150 mg.

Reference is also made to the complete response letter issued by this office on August 14, 2019, 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 Cobicistat Tablets, 150 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Tybost Tablets, 150 mg, of Gilead Sciences, Inc. (Gilead).

The RLD upon which you have based your ANDA, Gilead's Tybost Tablets, 150 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
8,148,374 (the '374 patent)	March 3, 2030
10,039,718 (the '718 patent)	April 6, 2033

Your ANDA contains paragraph IV certifications to each of the patents[1], under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Cobicistat Tablets, 150 mg, under this ANDA. You have notified the Agency that Mylan Laboratories Limited (Mylan)

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 Mylan for infringement of the '374 patent in the United States District Court for the District of Delaware [Gilead Sciences, Inc. vs. Mylan Pharmaceuticals Inc., Civil Action No. 17-00187] and United States District Court for the Northern District of West Virginia [Gilead Sciences, Inc. vs. Mylan Pharmaceuticals Inc., Civil Action No. 17-00036]. You have also notified the Agency that these cases were dismissed.

The RLD upon which you have based your ANDA, Gilead's Tybost Tablets, 150 mg is also subject to a period of exclusivity. As noted in the Orange Book, the ODE-260 exclusivity is scheduled to expire on August 22, 2026. You have provided a copy of a letter, which notes that Gilead waives the unexpired ODE-260 exclusivity period with respect to ANDA 209986.

With respect to 180-day generic drug exclusivity, we note that Mylan was a first ANDA applicant for Cobicistat Tablets, 150 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Mylan may be eligible for 180 days of generic drug exclusivity for Cobicistat Tablets, 150 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The Agency notes that Mylan failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The Agency is not, however, making a formal determination at this time of Mylan's eligibility for 180-day generic drug exclusivity. We will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Mylan begins commercial marketing of Cobicistat Tablets, 150 mg, or (b) at any time prior to the expiration of the '374 patent if Mylan has not begun commercial marketing. 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

[1] The Agency notes that the '718 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

John Ibrahim

Digitally signed by John Ibrahim
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