ANDA 215572

ANDA APPROVAL

Amneal Pharmaceuticals LLC
50 Horseblock Road
Brookhaven, NY 11719
Attention: Janie M. Gwinn
Senior Director, Regulatory Affairs

Dear Janie M. Gwinn:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 31, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Spironolactone Oral Suspension, 25 mg/5 mL.

Reference is also made to the tentative approval letter issued by this office on July 11, 2022, 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 Spironolactone Oral Suspension, 25 mg/5 mL, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Carospir Oral Suspension, 25 mg/5 mL, of CMP Development LLC (CMP).

The RLD upon which you have based your ANDA, CMP's Carospir Oral Suspension, 25 mg/5 mL, is subject to periods of patent protection. The following patents and expiration dates 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
9,757,394 (the '394 patent)	October 28, 2036
10,493,083 (the '083 patent)	October 28, 2036
10,624,906 (the '906 patent)	October 28, 2036
10,660,907 (the '907 patent)	October 28, 2036
10,888,570 (the '570 patent)	October 28, 2036

11,389,461 (the '461 patent)	October 28, 2036
11,395,828 (the '828 patent)	October 28, 2036
11,491,166 (the '166 patent)	October 28, 2036

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 Spironolactone Oral Suspension, 25 mg/5 mL, under this ANDA. You have notified the Agency that Amneal Pharmaceuticals LLC (Amneal) 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 Amneal for infringement of the '394, '083, '906 and '907 patents in the United States District Court for the District of Delaware [CMP Development, LLC v. Amneal Pharmaceuticals LLC, Civil Action No. 21-00549]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Amneal was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Spironolactone Oral Suspension, 25 mg/5 mL. Therefore, with this approval, Amneal is eligible for 180 days of generic drug exclusivity for Spironolactone Oral Suspension, 25 mg/5 mL. 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

[1] The Agency notes that the '570, '461, '828, and '166 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Anh Pham

Digitally signed by Anh Pham
Date: 9/05/2023 08:42:54AM
GUID: 54e4c56f00060bb2c61b878bc7a7bf95