ANDA 218851

ANDA APPROVAL

Mylan Pharmaceuticals Inc.
Attention: Joshua Craig
Director, Regulatory Affairs

Dear Joshua Craig:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on November 7, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial.

Reference is also made to the complete response letter issued by this office on January 22, 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 Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Aponvie Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), of Heron Therapeutics, Inc. (Heron Therapeutics) NDA - 216457.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated September 15, 2023.

The RLD upon which you have based your ANDA, Heron Therapeutics's Aponvie Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/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
9,561,229 (the '229 patent)	September 18, 2035
9,808,465 (the '465 patent)	September 18, 2035
9,974,742 (the '742 patent)	September 18, 2035

9,974,793 (the '793 patent)	September 18, 2035
9,974,794 (the '794 patent)	September 18, 2035
10,500,208 (the '208 patent)	September 18, 2035
10,624,850 (the '850 patent)	September 18, 2035
10,953,018 (the '018 patent)	September 18, 2035
11,173,118 (the '118 patent)	September 18, 2035
11,744,800 (the '800 patent)	September 18, 2035
11,878,074 (the '074 patent)	September 18, 2035
12,115,254 (the '254 patent)	September 18, 2035
12,115,255 (the '255 patent)	September 18, 2035
12,290,520 (the '520 patent)	September 18, 2035

Your ANDA contains paragraph IV certifications to each of the patents, 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 Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial, under this ANDA. You have notified the Agency that Mylan Pharmaceuticals Inc. (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 '229, '465, '742, '793, '794, '208, '850, '018, '118 and '800 patents in the United States District Court for the District of Delaware [Heron Therapeutics, Inc. v. Mylan Pharmaceuticals Inc., Civil Action No. 23-01015 (consolidated)]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial. Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial. 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).

We note that Mylan was granted a Competitive Generic Therapy (CGT) designation for Aprepitant Injectable Emulsion, 32 mg/4.4 mL (7.2 mg/mL), Single-Dose Vial. However, as noted in the September 15, 2023, CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for the RLD at the time of submission of 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

Paul
Levine

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