ANDA 215574

ANDA APPROVAL

Hetero USA, Inc.
U.S. Agent for Hetero Labs Limited Unit V
1035 Centennial Avenue
Piscataway, NJ 08854
Attention: Soma Raju Indukuri
Vice President, Regulatory Affairs

Dear Soma Raju Indukuri:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 29, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ospemifene Tablets, 60 mg.

Reference is also made to the tentative approval letter issued by this office on June 23, 2023, 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 Ospemifene Tablets, 60 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Osphena Tablets, 60 mg, of Duchesnay Inc. (Duchesnay).

The RLD upon which you have based your ANDA, Duchesnay's Osphena Tablets, 60 mg, 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
6,245,819 (the '819 patent)	July 21, 2025
8,236,861 (the '861 patent)	August 11, 2026
8,642,079 (the '079 patent)	July 9, 2028

Your ANDA contains paragraph IV certifications to the '819, '861, and '079 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 Ospemifene Tablets, 60 mg, under this ANDA. You have notified the Agency that Hetero Labs Limited Unit V (Hetero Labs) 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 Hetero Labs for infringement of the '079 patent in the United States District Court for the District of Delaware [Duchesnay Inc., Shionogi Inc., and QuatRX Pharmaceuticals Company v. Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA Inc., Civil Action No. 21-00538]. Litigation was also initiated within the statutory 45-day period against Hetero Labs for infringement of the '819 and '861 patents in the United States District Court for the District of Delaware [Duchesnay Inc., Shionogi Inc., and QuatRX Pharmaceuticals Company v. Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA Inc., Civil Action No. 21-01130]. You have also notified the Agency that these cases were dismissed.

With respect to 180-day generic drug exclusivity, we note that Hetero Labs was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Ospemifene Tablets, 60 mg. Therefore, with this approval, Hetero Labs is eligible for 180 days of generic drug exclusivity for Ospemifene Tablets, 60 mg. 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

Catherine Poole

Digitally signed by Catherine Poole
Date: 2/13/2024 08:51:35AM
GUID: 5407887a000a1c0c26055eafb8e3258a