ANDA 214640

ANDA APPROVAL

Xiromed, LLC
U.S. Agent for Xiromed Pharma Espana, S.L.
180 Park Avenue, Suite 101
Florham Park, NJ 07932
Attention: David A. Hernandez
Vice President, Regulatory Affairs

Dear David A. Hernandez:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 14, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 0.1 mg/0.02 mg and 75 mg.

Reference is also made to the complete response letter issued by this office on January 27, 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 Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 0.1 mg/0.02 mg and 75 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Balcoltra Tablets, of Avion Pharmaceuticals LLC (Avion).

Reference is also made to FDA's Competitive Generic Therapy (CGT) Designation – Grant letter dated April 19, 2021.

The RLD upon which you have based your ANDA, Avion's Balcoltra Tablets, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
7,838,042 (the '042 patent)	June 1, 2027

Your ANDA contains a paragraph IV certification to the '042 patent[1] under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 0.1 mg/0.02 mg and 75 mg, under this ANDA. You have notified the Agency that Xiromed Pharma Espana, S.L. (Xiromed) complied with the requirements of section 505(j)(2)(B) of the FD&C Act.

We note that Xiromed was granted a Competitive Generic Therapy (CGT) designation for Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets, 0.1 mg/0.02 mg and 75 mg. However, as noted in the April 19, 2021, 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 Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] The Agency notes that the '042 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.

Anh Pham

Digitally signed by Anh Pham
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