ANDA 212572

ANDA APPROVAL

Mylan Pharmaceuticals Inc.
U.S. Agent for Mylan Laboratories Limited
Attention: Kristen McElwayne
Senior Director, Regulatory Affairs

Dear Kristen McElwayne:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 27, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial.

Reference is also made to any amendments submitted prior to the issuance of this letter.

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 Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Injectafer Injection, 750 mg/15 mL (50 mg/mL), of American Regent, Inc. (American Regent) NDA 203565.

The RLD upon which you have based your ANDA, American Regent's Injectafer Injection, 750 mg/15 mL (50 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
7,612,109 (the '109 patent)	February 5, 2027
7,754,702 (the '702 patent)	February 15, 2028
8,895,612 (the '612 patent)	January 8, 2027
11,364,260 (the '260 patent)	January 8, 2027

11,433,091 (the '091 patent)	January 8, 2027
11,478,502 (the '502 patent)	January 8, 2027

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 Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial, 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 '109, '702 and '612 patents in the United States District Court for the District of New Jersey [Vifor (International) AG and American Regent, Inc. v. Mylan Laboratories Ltd. and Sandoz Inc., Civil Action No. 19-13955] and the United States District Court for the Northern District of West Virginia at Clarksburg [Vifor (International) AG and American Regent, Inc. v. Mylan Laboratories Ltd., Civil Action No. 19-00126]. You have also notified the Agency that these cases were dismissed.

With respect to 180-day generic drug exclusivity, we note that Mylan was a first ANDA applicant for Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial, 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 Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial. 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 Ferric Carboxymaltose Injection, 750 mg/15 mL (50 mg/mL) Single-Dose Vial, or (b) at any time prior to the expiration of the '109 and '702 patents 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 at 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.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Paul
Levine

Digitally signed by Paul Levine
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