ANDA 205904

ANDA APPROVAL

Lupin Inc.
111 South Calvert Street
Harborplace Tower, 21st Floor
Baltimore, MD 21202
Attention: Debashis Mohanty
Associate Director, Regulatory Affairs

Dear Debashis Mohanty:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 1, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dronedarone Tablets USP, 400 mg.

Reference is also made to the complete response letter issued by this office on February 23, 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 Dronedarone Tablets USP, 400 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Multaq Tablets, 400 mg, of Sanofi-Aventis U.S. LLC (Sanofi-Aventis).

The RLD upon which you have based your ANDA, Sanofi-Aventis's Multaq Tablets, 400 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
8,410,167 (the '167 patent)	April 16, 2029
8,602,215 (the '215 patent)	June 30, 2031
9,107,900 (the '900 patent)	April 16, 2029

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 Dronedarone Tablets USP, 400 mg, under this ANDA. You have notified the Agency that Lupin Inc. (Lupin) 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 Lupin for infringement of the '167 patent in the United States District Court for the District of Delaware [Sanofi and Sanofi-Aventis U.S. LLC v. Lupin Atlantis Holdings S.A., Lupin Ltd. and Lupin Pharmaceuticals Inc., Civil Action No. 15-0415]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Lupin was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Dronedarone Tablets USP, 400 mg. Therefore, with this approval, Lupin may be eligible for 180 days of shared generic drug exclusivity for Dronedarone Tablets USP, 400 mg. The Agency notes that Lupin failed to obtain tentative approval of its ANDA within 30 months after the date on 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 Lupin's eligibility for 180-day generic drug exclusivity.

At least one first applicant remains eligible for 180-day generic drug exclusivity for Dronedarone Tablets USP, 400 mg, absent forfeiture under section 505(j)(5)(D) of the FD&C Act.[2] 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 by any first applicant, as 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

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[1] The Agency notes that the '215 and '900 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.

[2] See also draft guidance for industry on *180-Day Exclusivity: Questions and Answers*, Q. 42, at 26 (Jan. 2017).

Julie Kuriakose

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