ANDA 211287

**ANDA APPROVAL**

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Inc.
400 Campus Drive
Somerset, NJ 08873
Attention: Kalpana Vanam
Senior Vice President, Regulatory Affairs

Dear Kalpana Vanam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 11, 2018, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tiotropium Bromide Inhalation Powder, 18 mcg/capsule.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on August 16, 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 Tiotropium Bromide Inhalation Powder, 18 mcg/capsule to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Spiriva HandiHaler Inhalation Powder, 18 mcg/capsule, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer).

The RLD upon which you have based your ANDA, Boehringer's Spiriva HandiHaler Inhalation Powder, 18 mcg/capsule, 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 |
|---|---|
| 7,694,676 (the '676 patent) | September 12, 2027* |
| 8,022,082 (the '082 patent) | July 19, 2026* |

9,010,323 (the '323 patent) April 19, 2030

* with pediatric exclusivity added

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 Tiotropium Bromide Inhalation Powder, 18 mcg/capsule, 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 '676 patent in the United States District Court for the District of New Jersey [Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharma GmbH & Co. KG v. Lupin Atlantis Holdings SA and Lupin Limited, Civil Action No. 18-12663]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Lupin was a first ANDA applicant for Tiotropium Bromide Inhalation Powder, 18 mcg/capsule, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Lupin may be eligible for 180 days of generic drug exclusivity for Tiotropium Bromide Inhalation Powder, 18 mcg/capsule. 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 Lupin 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 Lupin'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 Lupin begins commercial marketing of Tiotropium Bromide Inhalation Powder, 18 mcg/capsule, or (b) at any time prior to the expiration of the '676, '082, and '323 patents if Lupin 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 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
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