ANDA 206027

ANDA APPROVAL

Lupin Pharmaceuticals, Inc.
U.S. Agent for Lupin Limited
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 26, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Bromfenac Ophthalmic Solution, 0.07%.

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 April 21, 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 Bromfenac Ophthalmic Solution, 0.07% to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Prolensa Ophthalmic Solution, 0.07%, of Bausch & Lomb Incorporated (Bausch & Lomb).

The RLD upon which you have based your ANDA, Bausch & Lomb's Prolensa Ophthalmic Solution, 0.07%, 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
8,129,431 (the '431 patent)	September 11, 2025
8,669,290 (the '290 patent)	January 16, 2024

8,754,131 (the '131 patent)	January 16, 2024
8,871,813 (the '813 patent)	January 16, 2024
8,927,606 (the '606 patent)	January 16, 2024
9,144,609 (the '609 patent)	January 16, 2024
9,517,220 (the '220 patent)	November 11, 2033
9,561,277 (the '277 patent)	January 16, 2024
10,085,958 (the '958 patent)	November 19, 2032

Your ANDA contains paragraph IV certifications to each of the patents[0], 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 Bromfenac Ophthalmic Solution, 0.07%, under this ANDA. You have notified the Agency that Lupin Limited (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 '431, '290, '131, '813, '606, and '609 patents in the United States District Court for the District of New Jersey [Senju Pharmaceutical CO., Ltd, Bausch & Lomb Incorporated and Bausch & Lomb Pharma Holdings Corp v. Lupin Ltd and Lupin Pharmaceuticals inc., Civil Action No. 14-00667]. You have also notified the Agency that, on August 29, 2016, the court entered a Stipulated Consent Judgment and Injunction, closing the case.

With respect to 180-day generic drug exclusivity, we note that Lupin was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Bromfenac Ophthalmic Solution, 0.07%. Therefore, with this approval, Lupin is eligible for 180 days of generic drug exclusivity for Bromfenac Ophthalmic Solution, 0.07%. It is noted that this ANDA was not tentatively approved within the 30-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the Agency has determined that Lupin has not forfeited its eligibility for 180-day generic drug exclusivity.[2] This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. 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).

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

[1] The Agency notes that the '290, '131, '813, '606, '609, '220, '277, and '958 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] Lupin's ANDA 206027 was received on July 26, 2013. ANDA 206027 was never approved/tentatively approved on/by January 26, 2016. The Agency found that Lupin's failure to obtain tentative approval within 30 months was caused by a change in or review of the requirements for approval of the application imposed after the date on which the application was filed.

Paul
Levine

Digitally signed by Paul Levine
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