ANDA 215081

ANDA APPROVAL

Micro Labs USA Inc.
U.S. Agent for Micro Labs Ltd
220 Davidson Avenue, Suite 402
Somerset, NJ 08873
Attention: Umesh Jayakumar
Associate Vice President

Dear Umesh Jayakumar:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 13, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Lifitegrast Ophthalmic Solution, 5%.

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 tentative approval letter issued by this office on November 10, 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 Lifitegrast Ophthalmic Solution, 5% to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xiidra Ophthalmic Solution, 5%, of Novartis Pharmaceuticals Corporation (Novartis).

The RLD upon which you have based your ANDA, Novartis's Xiidra Ophthalmic Solution, 5%, 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
7,314,938 (the '938 patent)	March 10, 2025
7,745,460 (the '460 patent)	November 5, 2024
7,790,743 (the '743 patent)	November 5, 2024

7,928,122 (the '122 patent)	November 5, 2024
8,084,047 (the '047 patent)	May 17, 2026
8,168,655 (the '655 patent)	May 9, 2029
8,367,701 (the '701 patent)	April 15, 2029
8,592,450 (the '450 patent)	May 17, 2026
8,927,574 (the '574 patent)	November 12, 2030
9,085,553 (the '553 patent)	July 25, 2033
9,216,174 (the '174 patent)	November 5, 2024
9,353,088 (the '088 patent)	October 21, 2030
9,447,077 (the '077 patent)	April 15, 2029
9,890,141 (the '141 patent)	October 21, 2030
10,124,000 (the '000 patent)	November 5, 2024
11,058,677 (the '677 patent)	December 18, 2033

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 Lifitegrast Ophthalmic Solution, 5%, under this ANDA. You have notified the Agency that Micro Labs Ltd (Micro) 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 Micro for infringement of the '938, '460, '743, '122, '047, '655, '701, '450, '174, '077, and '000 patents in the United States District Court for the District of Delaware [Novartis Pharmaceuticals Corporation v. Micro Labs Limited and Micro Labs USA Inc., Civil Action No. 21-00969]. You have also notified the Agency that this case was dismissed.

With respect to 180-day generic drug exclusivity, we note that Micro was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification for Lifitegrast Ophthalmic Solution, 5%. Therefore, with this approval, Micro is eligible for 180 days of shared generic drug exclusivity for Lifitegrast Ophthalmic Solution, 5%. 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 '677 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.

Catherine Poole

Digitally signed by Catherine Poole
Date: 8/04/2023 10:08:55AM
GUID: 5407887a000a1c0c26055eafb8e3258a