ANDA 216361

ANDA APPROVAL

Dr. Reddy's Laboratories, Inc.
U.S. Agent for Dr. Reddy's Laboratories SA
107, College Road East, 2nd Floor
Princeton, NJ 08540
Attention: Jaya Lakshmi Ayyagari
Head, Regulatory Affairs, NA

Dear Jaya Lakshmi Ayyagari:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 12, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC).

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 January 3, 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 for over-the-counter (OTC) use. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC) to be bioequivalent to the reference listed drug (RLD), Lumify Ophthalmic Solution, 0.025%, of Bausch & Lomb Incorporated (Bausch).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated September 9, 2021.

The RLD upon which you have based your ANDA, Bausch's Lumify Ophthalmic Solution, 0.025%, 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
8,293,742 (the '742 patent)	July 14, 2030

9,259,425 (the '425 patent)	July 14, 2030
11,596,600 (the '600 patent)	July 27, 2029
11,833,245 (the '245 patent)	July 27, 2029

Your ANDA contains paragraph IV certification 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 Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC), under this ANDA. You have notified the Agency that Dr. Reddy's Laboratories SA (Dr. Reddy's) 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 Dr. Reddy's for infringement of the '742 patent in the United States District Court for the District of New Jersey [Bausch & Lomb, Inc.; Bausch & Lomb Ireland Limited; and Eye Therapies, LLC v. Slayback Pharma LLC and Slayback Pharma India LLP, Civil Action No. 21-16766]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Dr. Reddy's was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC). Therefore, with this approval, Dr. Reddy's is eligible for 180 days of generic drug exclusivity for Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC). 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).

We note that Dr. Reddy's was granted a Competitive Generic Therapy (CGT) designation for Brimonidine Tartrate Ophthalmic Solution, 0.025% (OTC). However, as noted in the September 9, 2021, CGT Designation – Grant Letter, your drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act because there were unexpired patents or exclusivities listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for the RLD at the time of submission of your ANDA.

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 '425, '600, and '245 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.

Catherine Poole

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