



NDA 220341

NDA APPROVAL

Alcon Laboratories, Inc.
Attention: Ryo Iwata
Sr Manager, Global Regulatory Affairs
20511 Lake Forest Drive
Lake Forest, CA 92630

Dear Ryo Iwata:

Please refer to your new drug application (NDA) dated and received December 18, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Brytly (apraclonidine) ophthalmic solution, 0.125%.

This new drug application provides for the nonprescription use of Brytly (apraclonidine) ophthalmic solution, 0.125% to relieve redness of the eye due to minor eye irritations.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling, described in table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
0.5 mL immediate container label (sample) NDC: 0065-8596-06	June 12, 2026
0.5 mL carton label (sample) NDC: 0065-8596-06	July 13, 2026
2 mL immediate container label (trade) NDC: 0065-8596-05	December 18, 2025
2 mL carton label (trade) NDC: 0065-8596-05	July 13, 2026
5 mL immediate container label (trade) NDC: 0065-8596-04	December 18, 2025
5 mL carton label (trade) NDC: 0065-8596-04	July 13, 2026

The final printed labeling should be submitted electronically according to guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.¹ For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 220341.**” Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.² Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs & As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages birth to <5 years because there is evidence strongly suggesting that the drug product would be ineffective and/or unsafe in this pediatric group because the use of this product requires the assistance of a learned intermediary.

We note that you have fulfilled the pediatric study requirement for ages 5 to 17 years for this application.

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at [FDA.gov](https://www.fda.gov).³

If you have any questions, contact Elizabeth Thompson, Chief Project Management Staff, at 301-796-0824 or elizabeth.thompson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, M.D., Ph.D.
Acting Division Director
Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

³ <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARTHA K LENHART
10/16/2026 07:42:51 AM