NDA 022134/S-008

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Jeanne Quigg, MBA, RAC
Director, Global Regulatory Strategy, Eye Care
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Dear Ms. Quigg:

Please refer to your supplemental new drug application (sNDA) dated and received February 22, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lastacaft (alcaftadine ophthalmic solution), 0.25%.

This "Prior Approval" supplemental new drug application provides for the full prescription-to-over-the-counter (Rx-to-OTC) switch of Lastacaft (alcaftadine ophthalmic solution), 0.25%.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

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

Submitted Draft Labeling	**Date Submitted**
1 mL (0.03 fl. oz.) Sample bottle (primary packaging)	November 23, 2021
1 mL (0.03 fl. oz.) Sample carton includes Drug Facts Label (secondary packaging)	November 23, 2021
5 mL (0.17 fl. oz.) Trade bottle (primary packaging)	November 23, 2021

5 mL (0.17 fl. oz.) Trade carton includes Drug Facts Label (secondary packaging) – 2 SKUs (96977 and 98306)	December 8, 2021
2 x 5 mL (0.17 fl. oz. each bottle) Twin pack trade carton (secondary packaging) includes Drug Facts Label	November 23, 2021
5 mL (0.17 fl. oz.) coupon	November 23, 2021
2 x 5 mL (0.17 fl. oz. each bottle) Twin pack coupon	November 23, 2021
Safety seal bottle neckband	November 23, 2021
Carton tape seal	November 23, 2021

The FPL should be submitted electronically according to the 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 022134/S-008**." 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 the guidance for industry *SPL Standard for Content of Labeling Technical Qs and 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

[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

the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

If you have any questions, call Anna Thai, Regulatory Project Manager, at (301) 796-6533.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling
- Coupon Inserts
- Seals

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/

NUSHIN F TODD
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