NDA 022134/S-009

SUPPLEMENT APPROVAL

Allergan, Inc.
Attention: Linda Huynh, MSPH
Senior Manager, Global Regulatory Strategy, Ophthalmology
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Dear Ms. Huynh:

Please refer to your supplemental new drug application (sNDA) dated and received March 9, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lastacaft (alcaftadine ophthalmic solution).

This "Prior Approval" supplemental new drug application provides for the following changes:

1. Revises "NOW AVAILABLE without a prescription" to "ORIGINAL PRESCRIPTION STRENGTH"
2. Removes "Thank you for purchasing" from coupons
3. Introduces a new SKU for the 2x5 mL twin pack with a separate UPC/NDC

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 the 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
Lastacaft 5 mL Coupon	June 16, 2022
Lastacaft 2x5 mL Twin Pack Coupon	June 16, 2022
Lastacaft 1 mL Sample Carton	July 8, 2022
Lastacaft 5 mL Trade Carton – SKU 96977	July 8, 2022
Lastacaft 5 mL Trade Carton – SKU 98306	July 8, 2022
Lastacaft 2x5 mL Twin Pack Carton – SKU 97054	July 8, 2022
Lastacaft 2x5 mL Twin Pack Carton – SKU 98446	July 8, 2022

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-009**." 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.

REPORTING REQUIREMENTS

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

[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

If you have any questions, contact Michael Boblitz, PharmD, Regulatory Project Manager at Michael.Boblitz@fda.hhs.gov or (301) 837-7651.

Sincerely,

{See appended electronic signature page}

Karen Minerve Murry, MD, FACE
Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs II
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton Labeling

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/

KAREN M MURRY
08/29/2022 10:26:08 AM