NDA 020688/S-033
NDA 021545/S-023

SUPPLEMENT APPROVAL

Alcon Research, LLC
Attention: Vincent Nanevie, MS, MBA, RAC
Director, Global Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Dear Mr. Nanevie:

Please refer to your supplemental new drug applications (sNDAs) dated and received April 3, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following applications:

NDA 020688/S-033: Pataday Twice Daily Relief (olopatadine hydrochloride) ophthalmic solution, 0.1%

NDA 021545/S-023: Pataday Once Daily Relief (olopatadine hydrochloride) ophthalmic solution, 0.2%

These "Prior Approval" supplemental new drug applications provide for the following:

NDA 020688/S-033:

- Revises the "Purpose" statement, "Antihistamine and redness reliever", in the Drug Facts Label to the lower-case letter "r" in the words "redness" and "reliever"

- Replaces the banner on the top of the Principal Display Panel from "NOW AVAILABLE without a prescription" to "Original Prescription Strength" for the 5 mL carton

NDA 021545/S-023:

- Replaces the banner on the top of the Principal Display Panel from "NOW AVAILABLE without a prescription" to "Original Prescription Strength" for the 2.5 mL carton and 2 x 2.5 mL twin pack carton

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 must be in the "Drug Facts" format (21 CFR 201.66), where applicable and be identical to the following:

NDA 020688/S-033:

Submitted Labeling	**Date Submitted**
5 mL carton	June 19, 2020

Submit the container label for this 5 mL fill size for a complete labeling record.

NDA 021545/S-023:

Submitted Labeling	**Date Submitted**
2.5 mL carton	April 3, 2020
2 x 2.5 mL Twin Pack carton	April 3, 2020

Submit the container label for this 2.5 mL fill size for a complete labeling record.

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 020688/S-033**" and "**Final Printed Labeling for approved NDA 021545/S-023.**" Approval of these submissions by FDA is not required before the labeling is used.

[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.

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

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

REPORTING REQUIREMENTS

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

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

Sincerely,

{See appended electronic signature page}

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

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

ENCLOSURES:

- 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 MAHONEY
09/30/2020 05:00:44 PM