NDA 206276/S-005

SUPPLEMENT APPROVAL

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

Dear Mr. Nanevie:

Please refer to your supplemental new drug application (sNDA) dated and received September 13, 2019 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pataday Once Daily Relief (olopatadine hydrochloride ophthalmic solution, 0.7%).

This "Prior Approval" supplemental new drug application provides for the full prescription to over-the-counter switch of olopatadine hydrochloride 0.7% ophthalmic solution.

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 submitted labeling and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Draft Labeling	Date Submitted
Pataday® Once Daily Relief (Extra Strength) 2.5 mL (0.085 Fl oz) 0.7% carton	July 9, 2020
Pataday® Once Daily Relief (Extra Strength) 2.5 mL (0.085 Fl oz) 0.7% immediate container	June 25, 2020
Pataday® Once Daily Relief (Extra Strength) Two X 2.5 mL (0.085 Fl oz) 0.7% carton - Twin Pack	July 9, 2020
Pataday® Once Daily Relief (Extra Strength) Sample 0.5 mL (0.017 Fl oz) 0.7% carton	July 9, 2020

Pataday® Once Daily Relief (Extra Strength) Sample 0.5 mL (0.017 Fl oz) 0.7% immediate container	June 25, 2020
Pataday® Once Daily Relief (Extra Strength) Sample 0.5 mL (0.017 Fl oz) 0.7% pouch	June 25, 2020

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 206276/S-005**." 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 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.

[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).

POSTMARKETING COMMITMENT

As part of an Enhanced Pharmacovigilance Commitment, for a period of 3 years, submit as 15-day alert reports, all initial and follow-up postmarketing adverse event reports of nonprescription overuse and nonprescription misuse from all postmarketing sources, including consumer reports, solicited reports, foreign reports, and clinical study reports. As part of the periodic safety reports, provide a summary analysis of nonprescription overuse and nonprescription misuse adverse events, from postmarketing reports and those published in the medical literature, as well as a cumulative summary of these events.

If you have any questions, call LCDR Jung Lee, Safety Regulatory Project Manager, at (301) 796-3599.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Carton and Container 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
07/13/2020 08:19:30 PM