



NDA 020688/S-032  
NDA 021545/S-022

## **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 applications (sNDAs) dated and received April 15, 2019 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 020688/S-032: Pataday Twice Daily Relief (olopatadine hydrochloride) ophthalmic solution, 0.1%
- NDA 021545/S-022: Pataday Once Daily Relief (olopatadine hydrochloride) ophthalmic solution, 0.2%

These "Prior Approval" supplemental new drug applications provide for the full prescription to over-the-counter switch of olopatadine hydrochloride 0.1% ophthalmic solution (NDA 020688) and olopatadine hydrochloride 0.2% ophthalmic solution (NDA 021545).

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

In the Pataday® Twice Daily Relief 5 mL (0.17 Fl oz) carton label for NDA 020688/S-032, revise the "Purpose" statement to "Antihistamine and redness reliever" in Drug Facts. Revising to the lower-case letter "r" for "redness" and "reliever" is consistent with 21 CFR 201.66(d)(1). Include the above revision when you submit your FPL, or in your next annual report, or in your next supplement, whichever is soonest.

**NDA 020688/S-032:**

<b>Submitted Draft Labeling</b>	<b>Date Submitted</b>
Pataday® Twice Daily Relief 5 mL (0.17 Fl oz) carton	1/22/2020
Pataday® Twice Daily Relief 5 mL (0.17 Fl oz) container	1/22/2020

**NDA 021545/S-022:**

<b>Submitted Draft Labeling</b>	<b>Date Submitted</b>
Pataday® ONCE DAILY RELIEF 0.5 mL (0.017 Fl Oz) carton	1/22/2020
Pataday® ONCE DAILY RELIEF 0.5 mL (0.017 Fl Oz) container	1/22/2020
Pataday® ONCE DAILY RELIEF 0.5 mL (0.017 Fl Oz) pouch	1/22/2020
Pataday® ONCE DAILY RELIEF 2.5 mL (0.085 Fl Oz) carton	1/22/2020
Pataday® ONCE DAILY RELIEF 2.5 mL (0.085 Fl Oz) container	1/22/2020
Pataday® ONCE DAILY RELIEF two 2.5 mL (0.085 Fl Oz each) carton	1/22/2020

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*.<sup>1</sup> For administrative purposes, designate these submissions “**Final Printed Labeling for approved NDA 020688/S-032**” and “**Final Printed Labeling for approved NDA 021545/S-022**.” Approval of these submissions by FDA is not required before the labeling are 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](http://FDA.gov).<sup>2</sup> 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.

<sup>1</sup> 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>.

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

## **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 LCDR Jung Lee, Senior Regulatory Project Manager, at (301) 796-3599.

Sincerely,

*{See appended electronic signature page}*

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

### ENCLOSURE(S):

- Carton and Container Labeling

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**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.**  
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/s/  
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KAREN M MAHONEY  
02/14/2020 01:30:44 PM