



NDA 208073/S-012

## APPROVAL LETTER

Bausch and Lomb Inc.  
Attention: Priyanka Shah, MS  
Senior Manager, Regulatory Affairs  
400 Somerset Corporate Blvd  
Bridgewater, NJ 08807

Dear Priyanka Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 4, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xiidra (lifitegrast) ophthalmic solution.

We acknowledge receipt of your amendment dated December 15, 2023, which constituted a complete response to our August 15, 2023, action letter.

This Prior Approval supplemental new drug application provides for the addition of (b) (4) as a drug substance manufacturer and quality control site with reference to DMF # (b) (4):

- (b) (4) for manufacture and all release and stability testing;
- (b) (4) to determine microbial limits and bacterial endotoxins on release;
- (b) (4) to perform X-ray powder diffraction for release and stability.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON LABELS**

Submit final printed carton labels that are identical to enclosed carton labels and carton labels submitted on September 28, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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*. For administrative purposes, designate this submission **“Product Correspondence – Final Printed Carton and Container Labels for approved NDA 208073/S-012.”** Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at [shazma.aftab@fda.hhs.gov](mailto:shazma.aftab@fda.hhs.gov) or (301) 796 - 3138.

Sincerely,

*{See appended electronic signature page}*

David Lewis, PhD  
Branch Chief, Branch II  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

- Carton Labeling:
  - Trade Carton
  - Sample Carton



David  
Lewis

Digitally signed by David Lewis

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