



NDA 019079/S-038

## SUPPLEMENT APPROVAL

Harrow Eye, LLC  
Attention: Glenda Potts, MPH  
Regulatory Affairs Manager  
102 Woodmont Blvd, Suite 610  
Nashville, TN 37205 -76134

Dear Glenda Potts:

Please refer to your supplemental new drug application (sNDA) dated and received July 12, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FLAREX (fluorometholone acetate ophthalmic suspension) 0.1%. This “Changes Being Effected” sNDA provides for revisions to the container labels and carton labeling.

### **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.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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 “**Final Printed Carton and Container Labeling for approved NDA 019079/S-038.**” Approval of this submission by FDA is not required before the labeling is used.

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

**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, please contact Michael Puglisi, Senior Regulatory Project Manager, at [michael.puglisi@fda.hhs.gov](mailto:michael.puglisi@fda.hhs.gov) or call (301) 796-0791.

Sincerely,

*{See appended electronic signature page}*

Charles J. Ganley, MD  
Director  
Office of Specialty Medicine  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE:

- 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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CHARLES J GANLEY  
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