

NDA 206289/S-011

SUPPLEMENT APPROVAL

Akorn Operating Company LLC
Attention: John Franolic, PhD
Vice President, Regulatory Affairs
1925 West Field Court, Suite 300
Lake Forest, IL 60045

Dear Dr. Franolic:

Please refer to your supplemental new drug application (sNDA) dated and received September 20, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atropine Sulfate Ophthalmic Solution USP, 1%. This Prior Approval sNDA provides for revisions to the container labels and carton labeling for the 2 mL, 5 mL, and 15 mL fill sizes.

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 206289/S-011.**” Approval of this submission by FDA is not required before the labeling is used.

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 regarding this supplement, call Derek Alberding, Clinical Analyst, at (240) 402-0963.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

WILEY A CHAMBERS
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