NDA 050810/S-019

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 May 17, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AZASITE (azithromycin ophthalmic solution) 1%. This "Changes Being Effected" sNDA provides for the addition of a 2.5 mL physician sample presentation.

APPROVAL & LABELING

We have completed our review of this application, as amended. This supplement is approved.

CARTON AND CONTAINER LABELING

We acknowledge your November 1, 2021, submission containing final printed carton and container labeling.

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 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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