DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202795

Akorn, Inc.
Attention: Sam Boddapati, Ph.D.
Senior Vice President, Regulatory Affairs
1925 West Field Court
Suite #300
Lake Forest, IL 60045

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 18, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Naphazoline Hydrochloride 0.025% and Pheniramine Maleate 0.3% Ophthalmic Solution, USP (OTC).

Reference is also made to your amendments dated March 1, March 16, March 31, May 3, and August 30, 3011; and February 23 (two submissions), March 2, March 8, March 22, June 12, June 27, and December 12, 2012.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted over-the counter (OTC) labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Naphazoline Hydrochloride 0.025% and Pheniramine Maleate 0.3% Ophthalmic Solution, USP to be bioequivalent to the reference listed drug (RLD), Visine-A Ophthalmic Solution, 0.025%/0.3%, of Johnson and Johnson Group Consumer Companies.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

01/24/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.