Approval Package for:

APPLICATION NUMBER:

206289Orig1s000

Trade Name: Atropine Sulfate Ophthalmic Solution, USP, 1%

Generic Name: Atropine Sulfate Ophthalmic Solution, USP, 1%

Sponsor: Akorn, Inc.

Approval Date: July 18, 2014

Indications: For cycloplegia, mydriasis, and penalization of the healthy eye in the treatment of amblyopia.
## CENTRAL FOR DRUG EVALUATION AND RESEARCH

### 206289Orig1s000

### CONTENTS

### Reviews / Information Included in this NDA Review.

<table>
<thead>
<tr>
<th>Review Type</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td></td>
</tr>
<tr>
<td>Other Action Letters</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>X</td>
</tr>
<tr>
<td>REMS</td>
<td></td>
</tr>
<tr>
<td>Summary Review</td>
<td>X</td>
</tr>
<tr>
<td>Officer/Employee List</td>
<td>X</td>
</tr>
<tr>
<td>Office Director Memo</td>
<td></td>
</tr>
<tr>
<td>Cross Discipline Team Leader Review</td>
<td>X</td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Assessment</td>
<td></td>
</tr>
<tr>
<td>Pharmacology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Microbiology / Virology Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Clinical Pharmacology/Biopharmaceutics Review(s)</td>
<td>X</td>
</tr>
<tr>
<td>Other Reviews</td>
<td>X</td>
</tr>
<tr>
<td>Risk Assessment and Risk Mitigation Review(s)</td>
<td></td>
</tr>
<tr>
<td>Proprietary Name Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative/Correspondence Document(s)</td>
<td>X</td>
</tr>
</tbody>
</table>
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206289Orig1s000

APPROVAL LETTER
Dear Dr. Boddapati:

Please refer to your New Drug Application (NDA) dated October 22, 2013, originally received October 23, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atropine Sulfate Ophthalmic Solution, USP, 1%. We also refer to our correspondence dated November 6, 2013, stating that as the User Fee for this application was received by the Office of Financial Management on October 30, 2013, we would consider this date as the receipt date for this application.

We acknowledge receipt of your amendments dated:

- October 29, 2013
- November 4, 2013
- November 11, 2013
- December 3, 2013
- December 12, 2013
- January 10, 2014
- February 14, 2014
- March 21, 2014
- April 9, 2014
- April 24, 2014
- April 30, 2014
- May 18, 2014
- May 22, 2014
- July 16, 2014

This new drug application provides for the use of Atropine Sulfate Ophthalmic Solution, USP, 1% for cycloplegia, mydriasis, and penalization of the healthy eye in the treatment of amblyopia.

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 agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling as follows:

1. A continuous line has been added between the FULL PRESCRIBING INFORMATION: CONTENTS* and the FULL PRESCRIBING INFORMATION sections of the package insert.

2. The words Cycloplegia, Mydriasis and Penalization have been capitalized in the INDICATIONS AND USAGE sections of the HIGHLIGHTS OF PRESCRIBING INFORMATION and FULL PRESCRIBING INFORMATION: CONTENTS*)
3. The introductory statement and the HIGHLIGHTS OF PRESCRIBING INFORMATION has been bolded

4. The statement See 17 for PATIENT COUNSELING INFORMATION has been bolded in the HIGHLIGHTS OF PRESCRIBING INFORMATION

CONTENT OF LABELING

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

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, which are identical to the carton and immediate container labels submitted on July 16, 2014, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008). Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “Final Printed Carton and Container Labels for approved NDA 206289.” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry Contents of a Complete Submission for the Evaluation of Proprietary Names, available at
REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. Your application contained the required assessment. This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Christina Marshall, Regulatory Project Manager, at (301) 796-3099.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Transplant and Ophthalmology
Products
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

Enclosures: Content of Labeling
Carton and Container Labeling
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RENEA ALBRECHT
07/18/2014