



NDA 206289

**NDA APPROVAL**

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

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

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

### **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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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RENATA ALBRECHT  
07/18/2014