Dear Ms. Sullivan:

Please refer to your New Drug Application (NDA) dated July 30, 2013, received July 30, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Omidria (phenylephrine and ketorolac injection) 1% / 0.3%.

We acknowledge receipt of your amendments dated:

- August 9, 2013 (2)
- August 23, 2013
- September 26, 2013 (2)
- September 27, 2013
- October 4, 2013 (2)
- October 16, 2013
- October 18, 2013
- October 24, 2013
- November 6, 2013
- November 22, 2013
- November 26, 2013
- December 27, 2013
- January 8, 2014
- January 21, 2014
- March 14, 2014
- March 24, 2014
- March 27, 2014
- April 17, 2014
- April 24, 2014
- May 21, 2014

This new drug application provides for the use of Omidria (phenylephrine and ketorolac injection) 1% / 0.3% for maintaining pupil size by preventing intraoperative miosis and for reducing postoperative pain.

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 text.

**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](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

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, 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 205388.” 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.

**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. We are deferring submission of your pediatric assessment until September 30, 2017, because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act/FDCA is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act/FDCA. This required study is listed below.

<table>
<thead>
<tr>
<th>Reference ID</th>
<th>Study Description</th>
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<tbody>
<tr>
<td>2167-1</td>
<td>A single pediatric study in at least 60 patients (30 per arm) undergoing cataract surgery</td>
</tr>
<tr>
<td></td>
<td>Final Protocol Submission: 12/2013</td>
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<td></td>
<td>First Subject Visit: 06/2014</td>
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<tr>
<td></td>
<td>Last subject visit: Thirty months following first subject visit</td>
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<tr>
<td></td>
<td>Final Report Submission: Nine months following last subject visit</td>
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</tbody>
</table>
We acknowledge that you submitted the protocol(s) to your IND 78227 on December 18, 2013, with a cross-reference letter to this NDA.

Reports of this required pediatric postmarketing study must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS" in large font, bolded type at the beginning of the cover letter of the submission.

**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](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](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](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 Jacquelyn Smith, M.A., Senior Regulatory Project Manager, at 301-796-1600.

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

Enclosure(s):
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/

RENATA ALBRECHT
05/30/2014