APPLICATION NUMBER:
21-132

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review

2 JULY 2009

NDA: 22-427 and amendments

Drug Product Name
Proprietary: ACUVAIL 0.45% Preservative-Free
Non-proprietary: ketorolac tromethamine ophthalmic solution

Review Number: 1

<table>
<thead>
<tr>
<th>Dates of Submission(s) Covered by this Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>21 Nov 2008</td>
</tr>
<tr>
<td>30 Apr 2009</td>
</tr>
<tr>
<td>17 Jun 2009</td>
</tr>
</tbody>
</table>

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Allergan
Address: 2525 Dupont Drive, Irvine, CA 92612
Representative: Elizabeth Bancroft
Telephone: 714-246-4391

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval
Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original NDA [505(b)(1)]

2. **SUBMISSION PROVIDES FOR:** A sterile drug product

3. **MANUFACTURING SITE:** Allergan, Inc.
   8301 Mars Drive
   Waco, TX

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile ophthalmic solution in unit dose (LDPE) vials, 0.4 mL/vial, 0.45%

5. **METHOD(S) OF STERILIZATION:** (b) (4)

6. **PHARMACOLOGICAL CATEGORY:** Non-Steroidal Anti-Inflammatory

B. **SUPPORTING/RELATED DOCUMENTS:** N/A

C. **REMARKS:** This was an eCTD submission. An information request was sent to the applicant (5 November 2008) requesting validation data for the filling equipment and an endotoxin specification for the drug product. The equipment sterilization validation information and endotoxin specification were provided in amendment 0003 (dated 21 November 2008). Two endotoxin testing facilities were added in amendment 0007 (dated 30 April 2009). An additional endotoxin testing facility was added in amendment 0008 (dated 17 June 2009).

filename: N022427R1.doc
Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval from the standpoint of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – (b)(4)

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature

Bryan S. Riley, Ph.D.
Senior Review Microbiologist OPS/NDMS

B. Endorsement Block

James L. McVey
Team Leader OPS/NDMS

C. CC Block

N/A

6 Pages Withheld as b(4) Trade Secret/Confidential
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bryan Riley  
7/8/2009 07:58:38 AM  
MICROBIOLOGIST

James McVey  
7/8/2009 01:30:54 PM  
MICROBIOLOGIST  
I concur.