

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 22-220

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

5 JUNE 2008

NDA: 22-220 and amendments

Drug Product Name

Proprietary: TRIVARIS

Non-proprietary: triamcinolone acetonide injectable suspension, USP

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
8/15/2007	8/16/2007	N/A	8/20/2007
2/27/2008	2/28/2008	N/A	N/A
3/17/2008	3/18/2008	N/A	N/A
4/4/2008	4/7/2008	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Allergan, Inc.

Address: 2525 Dupont Drive, PO Box 19534, Irvine, CA

Representative: Elizabeth Bancroft

Telephone: 714-246-4391

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

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA [505(b)(2)]
2. **SUBMISSION PROVIDES FOR:** A sterile injectable drug product
3. **MANUFACTURING SITES:**
 Bulk and Finished Drug Product b(4)
 Allergan Inc
 Irvine, CA

 Finished Drug Product Only
 Allergan Pharmaceuticals Ireland
 Westport, County Mayo
 Ireland
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous gel suspension in a pre-filled syringe, for intra-vitreal injection, 80 mg/mL.
5. **METHOD(S) OF STERILIZATION:** b(4)
6. **PHARMACOLOGICAL CATEGORY:** Anti-Inflammatory
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF Microbiology b(4)
Review of DMF (dated 18 Jan 2008).
- C. **REMARKS:** This was an electronic submission in the eCTD format. An Initial Quality Assessment was performed by ONDQA (dated 27 Sept 2007).

filename: N022220R1.doc

10 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Bryan Riley
6/5/2008 11:34:40 AM
MICROBIOLOGIST

James McVey
6/5/2008 02:03:09 PM
MICROBIOLOGIST
I concur.