Product Quality Microbiology Review

17 September 2007

NDA: 22-048

Drug Product Name
  Proprietary: Triesence
  Non-proprietary: triamcinolone acetonide injectable suspension.

Drug Product Priority Classification: Priority

Review Number: 1

Dates of Submission(s) Covered by this Review

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Applicant/Sponsor
Name: Alcon Hunenberg Switzerland

US Agent
Name: Alcon Research, Ltd.
Address: 6201 South Freeway
         Fort Worth, TX 76134-2099

Representative: Terry J. Dagnon
Telephone: 817-551-4325

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommended for approval.
Product Quality Microbiology Data Sheet

A.  1.  TYPE OF SUBMISSION: Original NDA.

2.  SUBMISSION PROVIDES FOR: A new drug product.

3.  MANUFACTURING SITE:
    Alcon Manufacturing, Ltd.
    6201 South Freeway
    Fort Worth, TX. 76134

4.  DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
    • Suspension for injection in ~ mL glass vial.
    • Intravitreal injection.
    • 40 mg/mL.

5.  METHOD(S) OF STERILIZATION: 

6.  PHARMACOLOGICAL CATEGORY: Ophthalmic.

B.  SUPPORTING/RELATED DOCUMENTS: None.

C.  REMARKS:
    The submission is provided in paper (6 white jacket microbiology copies of Module 3 and one green jacket of Module 2).
Executive Summary

I. Recommendations

A. Recommendation on Approvability – NDA 22-048 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 – The bulk drug suspension is filled into glass vials which are closed with rubber stoppers and aluminum seals prior to being placed into blister packages and sterilized.

B. Brief Description of Microbiology Deficiencies – There are no microbiology deficiencies identified.

C. Assessment of Risk Due to Microbiology Deficiencies – Not applicable.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block
   Bryan Riley, Ph.D.

C. CC Block
   N/A

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/s/

John Metcalfe
9/19/2007 12:34:32 PM
MICROBIOLOGIST

Bryan Riley
9/19/2007 12:50:17 PM
MICROBIOLOGIST

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