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RESEARCH**

*APPLICATION NUMBER:*  
**22-369**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

5 DECEMBER 2008

**NDA:** 22-369

**Drug Product Name**

**Proprietary:** Not yet finalized

**Non-proprietary:** bimatoprost solution 0.03%

**Drug Product Priority Classification:** Prostaglandin 404-2130

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Consult Request	Assigned to Reviewer
June 26, 2008	June 27, 2008	July 16, 2008	July 8, 2008

**Submission History (for amendments only) – N/A**

**Applicant/Sponsor**

**Name:** Allergan, Inc.

**Address:** 2525 Dupont Drive, Irvine, CA 92623

**Representative:** Elizabeth Bancroft, Senior Director, RA

**Telephone:** 714-246-4391, fax: 714-246-4272

**Name of Reviewer:** Vinayak B. Pawar, Ph.D.

**Conclusion:** The application is recommended for approval from microbiology product quality standpoint.

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
  2. **SUBMISSION PROVIDES FOR:** Topical application of a previously approved ophthalmic drug.
  3. **MANUFACTURING SITE:** Allergan Inc. Waco, Texas 76712
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 0.03% bimatoprost solution for topical application.
  5. **METHOD(S) OF STERILIZATION:** \_\_\_\_\_ **b(4)**
  6. **PHARMACOLOGICAL CATEGORY:** A prostaglandin.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The consult requests review of an original NDA 22-369 for topical application of 0.03% bimatoprost solution. This drug has been originally approved as an ophthalmic presentation. This application was submitted as an eCTD submission. Although this application was initially fileable, additional information was requested by the reviewer in a letter dated October 6, 2008 (filed in DFS through the Project Manager, Michael Puglisi). This information was addressed by the sponsor in an amendment dated October 11, 2008. The IQA was filed by Linda NG on September 4, 2008.

**filename:** C:\my documents\review\NDA\N022369R1

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**Executive Summary****I. Recommendations**

- A. Recommendation on Approvability** – The application is recommended for approval based on microbiology product quality review.
- 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** - There are no changes in the previously approved manufacturing process for 0.03% bimatoprost solution except that the newly designated product would be used for external application. An external applicator kit is provided.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** - None

**III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Vinayak B. Pawar, Ph.D.
- B. Endorsement Block** \_\_\_\_\_  
Stephen Langille, Ph.D.
- C. CC Block**  
N/A

8 Page(s) Withheld

X Trade Secret / Confidential (b4)

       Draft Labeling (b4)

       Draft Labeling (b5)

       Deliberative Process (b5)

Withheld Track Number: Microbiology- 1

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/s/

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Vinayak Pawar  
12/8/2008 10:43:43 AM  
MICROBIOLOGIST

Recommended for approval from microbiology product quality standpoint.

Stephen Langille  
12/8/2008 11:02:16 AM  
MICROBIOLOGIST