

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**50-804 (formerly 21-675)**

**Microbiology Review(s)**

# **Product Quality Microbiology Review**

## **Review for HFD-550**

**24 October 2003**

**NDA:** 21-675

**Drug Product Name**

**Proprietary:** Zylet™

**Non-proprietary:** Loteprednol Etabonate and Tobramycin Ophthalmic  
Suspension 0.5%/0.3%

**Drug Product Classification:** Ophthalmic Suspension

**Review Number:** 1

**Subject of this Review**

**Submission Date:** 21 July 2003

**Receipt Date:** 22 July 2003

**Consult Date:** 03 September 2003

**Date Assigned for Review:** 24 September 2003

**Applicant/Sponsor**

**Name:** Bausch and Lomb

**Address:** 8500 Hidden River Parkway, Tampa, FL 33637

**Representative:** Julie Townsend

**Telephone:** (813)866-2299

**Name of Reviewer:** Paul Stinavage

**Conclusion:** The application is recommended for approval on the basis of  
sterility assurance.

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## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
  2. SUPPLEMENT PROVIDES FOR: N/A
  3. MANUFACTURING SITE: Bausch and Lomb, Tampa, FL
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Ophthalmic suspension, 0.5% loteprednol etabonate and 0.3% tobramycin
  5. METHOD(S) OF STERILIZATION:  
[ ]
  6. PHARMACOLOGICAL CATEGORY: Ophthalmic
- B. SUPPORTING/RELATED DOCUMENTS: DMF's 11105, 13713, 13774
- C. REMARKS: The product will be filled at the Bausch and Lomb facility in Tampa, FL. Container components will be sterilized by:

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\_\_\_\_\_ § 552(b)(4) Trade Secret / Confidential

\_\_\_\_\_ § 552(b)(5) Deliberative Process

\_\_\_\_\_ § 552(b)(5) Draft Labeling

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/s/

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Paul Stinavage  
11/7/03 01:15:00 PM  
MICROBIOLOGIST

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