

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-275

MICROBIOLOGY REVIEW

REVIEW TO HFD 550
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #2 of NDA
February 6, 2001

- A. 1. NDA: 21-275-BI
2. APPLICANT/SPONSOR: Allergan
2525 Dupont Dr.
P.O. Box 19534
Irvine, CA 92623-9534
- Contact: Stephen Buxbaum
Director, Regulatory Affairs
(714) 246-4534
3. MANUFACTURING SITE: Allergan Inc.
8301 Mars Dr.
Waco, TX 76712
4. DRUG PRODUCT NAME
Proprietary: Lumigan™
Nonproprietary: Bimatoprost
Drug Priority Classification: Priority
5. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
- Ophthalmic solution
 - Topical
 - 0.03%
6. METHOD(S) OF STERILIZATION:
7. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:
Reduction of intraocular pressure

- B. 1. DOCUMENT/LETTER DATE: 1-25-01

2. RECEIPT DATE: 1-26-01
3. CONSULT DATE: 1-25-01
4. DATE OF AMMENDMENT: 1-25-01 (subject of this review)
5. ASSIGNED FOR REVIEW: 1-26-01
6. SUPPORTING/RELATED DOCUMENTS:
The Microbiology deficiencies found in NDA 21-275 were conveyed to the applicant in a fax dated January 16, 2001.

C. REMARKS: Microbiology data is found in volumes 49 and 50 of the original submission.

D. CONCLUSIONS: The submission is recommended for approval from the standpoint of microbial product quality.

Stephen E. Langille, Ph. D.

cc: Original NDA 21-275-BI
HFD-550/Division File
HFD-550/CSO/Vaccari/Puglisi
HFD 805/Consult File/Langille
Drafted by S. Langille c:reviews/21-275r2
Initialed by P. Cooney

**APPEARS THIS WAY
ON ORIGINAL**

REVIEW TO HFD 550
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #1 of NDA
December 28, 2000

- A. 1. NDA: 21-275
2. APPLICANT/SPONSOR: Allergan
2525 Dupont Dr.
P.O. Box 19534
Irvine, CA 92623-9534
- Contact: Stephen Buxbaum
Director, Regulatory Affairs
(714) 246-4534
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5. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
- Ophthalmic solution
 - Topical
 - 0.03%
6. METHOD(S) OF STERILIZATION:
7. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:
Reduction of intraocular pressure
- B. 1. DOCUMENT/LETTER DATE: 9-18-00
2. RECEIPT DATE: 9-19-00
3. CONSULT DATE: 9-20-00
4. DATE OF AMMENDMENT:
5. ASSIGNED FOR REVIEW: 9-28-00
6. SUPPORTING/RELATED DOCUMENTS:

- C. REMARKS: Microbiology data is found in volumes 49 and 50.
- D. CONCLUSIONS: The submission is approvable pending resolution of microbiological deficiencies. Specific comments regarding the [REDACTED] process are provided in "E. Review Notes" and "List of Microbiology Deficiencies and Comments".

Stephen E. Langille, Ph. D.

cc: Original NDA 21-275
HFD-550/Division File
HFD-550/CSO/Vaccari/Puglisi
HFD 805/Consult File/Langille
Drafted by S. Langille c:reviews/21-275r1
Initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

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