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
RECEIPT DATE: 1-26-01
CONSULT DATE: 1-25-01
DATE OF AMMENDMENT: 1-25-01 (subject of this review)
ASSIGNED FOR REVIEW: 1-26-01

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
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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   • 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 AMENDMENT:
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 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