CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-275

CHEMISTRY REVIEW(S)
Division of Anti-inflammatory, Analgesic and Ophthalmic Drugs  
DAAODP  
Review of Chemistry, Manufacturing, and Controls  

**NDA #: 21-275**  

**REVIEW #: 3**  

**DATE REVIEWED:** March 15, 2001  

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**NAME & ADDRESS OF APPLICANT:**  

Allergan  
2525 Dupont Drive  
P. O. Box 19534  
Irvine, CA  92623-9534  

**DRUG PRODUCT NAME**  

- **Proprietary:** Lumigan  
- **Established:** Bimatoprost  
- **Code Name/#:** AGN 192024  
- **Chem Type/Ther Class:** Prostaglandin/IP  

**PHARMACOL. CATEGORY:** Prostamide  
**DOSEAGE FORM:** Solution  
**STRENGTHS:** 0.03%  
**ROUTE OF ADMINISTRATION:** Topical/ocular, one drop/day/eye  
**DISPENSED:** X Rx ___ OTC  

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:**
(1) Chemical Structure

![Chemical Structure Image]

(2) Molecular Weight
415.58

(3) Chemical Name
(Z)-7-[(1R, 2R, 3R, 5S)-3, 5-dihydroxy-2-[(1E, 3S)-3-hydroxy-5-phenyl-1-pentenyl]cyclopentyl]-N-ethyl-5-heptanamide

(4) USAN Name
Bimatoprost

(5) Chemical Abstract Number
CAS 155206-00-1

(6) Other Names
Prostamide; prostaglandin analog

SUPPORTING DOCUMENTS:

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* Allergan in NDA 21-275 has provided adequate data for the components of the packaging system. These data includes the source of the resins, coloring materials and extensive extractable studies.

** Also refer to evaluation of FDA's question #13 in chemistry review No. 2.
CONCLUSIONS & RECOMMENDATIONS:

From CMC standpoint, NDA 21-275 is approvable at this time.

The approvability of this NDA pending receipt of the satisfactory inspection results from the OC for all requested sites.

cc:
Orig. NDA: 21-275
HFD-550/Division File
HFD-550/Chemist/STso
HFDD-550/CSO/Puglisi
HFD-830/Cchen
HFD-550/Boyd
HFD-550/Zhou Chen
HFD-550/Linda Ng
HFD-550/Hkhorshidi
HFD-550/WChambers

3/15/01

/S/
Chemist, HFD-550/830
Hossein S. Khorshidi, Ph.D.

3/15/01

/S/
Chemistry Team Leader, HFD-550/830
Linda Ng, Ph.D.
Division of Anti-inflammatory, Analgesic and Ophthalmic Drugs
DAAODP
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-275

REVIEW # 2

DATE REVIEWED: February 26, 2001

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* Subject of this review

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** Also refer to evaluation of FDA's question #13 in this review.
CONCLUSIONS & RECOMMENDATIONS:

From CMC standpoint, this NDA application is approved pending receipt of the satisfactory inspection results for all proposed sites from the OC.

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Orig. NDA - 21-275
HFD-550/Division File
HFD-550/Chemist/STso
HFDD-550/CSO/Puglisi
HFD-830/Cchen
HFD-550/Boyd
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Chemist, HFD-550/830
Hossein S. Khorshidi, Ph.D.

Chemistry Team Leader, HFD-550/830
Linda Ng, Ph.D.
Division of Anti-inflammatory, Analgesic and Ophthalmic Drugs
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-275

REVIEW # 1  DATE REVIEWED: January 9, 2001

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NDA 21-275
Chemistry Review # 1

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RELATED DOCUMENTS:

REMARKS:

This drug is classified as 1P. It is a 0.03% solution of bimatoprost for lowering intraocular pressure in patients with glaucoma or ocular hypertension. Bimatoprost is a synthetic analog of prostaglandin. The drug product has not been marketed before.
CONCLUSIONS & RECOMMENDATIONS:
From a chemistry, manufacturing and controls perspective, the NDA is recommended for an approvable action. Firm should address all outstanding issues that were submitted as facsimiles and listed in the draft letter of this review. Other issues for the reviewer to follow up are a) the impurity specifications were sent to pharmacologist and medical officer for comment (memo dated 11/29/00), b) methods validation to FDA labs, and c) EES.

cc:
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HF -550/Chemist/STso
HFDD-550/CSO/Puglisi
HFD-830/Cchen
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HFD-550/HKhorshidi

/S/
Chemist, HFD-550/830
Su C. Tso, Ph.D.
7/10/01

/S/
Linda Ng, Ph.D.
Chemistry Team Leader, HFD-550/830
1/10/01