

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-262**

**MICROBIOLOGY REVIEW**

**REVIEW FOR HFD-550  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF/HFD-805  
MICROBIOLOGY REVIEW # 1 OF NDA**

OCT 24 2000

September 11, 2000

- A.**
1. **NDA/ANDA/IND/:** NDA 21-262
  2. **TYPE OF SUPPLEMENT:** NA
  3. **SUPPLEMENT PROVIDES FOR:** NA
  4. **APPLICANT/SPONSOR:** Allergan Inc.  
2525 Dupont Drive  
P.O. Box 19534  
Irvine, CA 92623-9534
  5. **MANUFACTURING SITE:** Waco, Texas 76712
  6. **DRUG PRODUCT NAME:**  
Proprietary: ALPHAGAN®  
Nonproprietary: Brimonidine-Purite™ Ophthalmic Solution 0.15%  
Drug Priority Classification:
  7. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Ophthalmic solution 0.15%
  8. **METHOD (S) OF STERILIZATION:**
  9. **PHARMACOLOGICAL CATEGORY:** Ophthalmic Solution to reduce intraocular pressure.
- B.**
1. **DOCUMENT/LETTER DATE:** June 29, 2000
  2. **RECEIPT DATE:** July 03, 2000
  3. **CONSULT DATE:** July 06, 2000
  4. **DATE OF AMENDMENT:** NA
  5. **ASSIGNED FOR REVIEW:** July 17, 2000
  6. **SUPPORTING/RELATED DOCUMENTS:** None

- C. **REMARKS:** The consult requests review of a New Drug Application, NDA 21-262, for 0.15% Brimonidine-Purite™ Ophthalmic Solution 0.15% (ALPHAGAN®). Volumes 1, and 25 - 33 were submitted for review. The consult requests a microbiology review of this original NDA 21-262 submitted by Allergan, Inc., Fort Worth, Texas.
- D. **CONCLUSIONS:** The Microbiology section of this supplement is recommended for approval based on the information provided.

/S/

Vinnie Pawar, Ph.D.

cc:

Original NDA 21-262  
HFD 550/Div. File  
HFD 160/Consult  
HFD 550/Gorski Lori  
HFD 160/Microbiologist/V.Pawar [HFD-805]

7S/

09/11/00

07/21/08

Drafted by: V. Pawar, 09/11/2000  
R/D initialed by: P. Cooney