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

August 07, 2000

A. 1. NDA/ANDA/IND#: NDA 21-257
2. TYPE OF SUPPLEMENT: NA
3. SUPPLEMENT PROVIDES FOR: NA
4. APPLICANT/SPONSOR: Alcon Universal, LTD.
   6201 South Freeway
   Fort Worth, Texas 76134-2099
5. MANUFACTURING SITE: Fort Worth, Texas
6. DRUG PRODUCT NAME:
   Proprietary: TRAVATAN™
   Nonproprietary: Travoprost Ophthalmic Solution, 0.0015% and
   0.004%
   Drug Priority Classification:

6. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
   STRENGTH/POTENCY: Ophthalmic solution 0.0015% and 0.004%.

8. METHOD(S) OF STERILIZATION: __________

9. PHARMACOLOGICAL CATEGORY: Ophthalmic Solution to reduce
   intraocular pressure.

B. 1. DOCUMENT/LETTER DATE: July 6, 2000
2. RECEIPT DATE: July 11, 2000
3. CONSULT DATE: July 12, 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 21-257, for 0.0015% and 0.004% Travoprost Ophthalmic Solution (TRAVATAN™). Volume 1 of 1 and volumes 1, 2 and 3 of 165 were submitted for review. The consult requests a microbiology review of this original NDA 21-262 submitted by Alcon Laboratories, Inc., Fort Worth, Texas.

D. **CONCLUSIONS:** The Microbiology section of this supplement is recommended for approval based on the information provided.

/\S/ 8/1/00

Vinnie Pawar, Ph.D.

cc:

Original NDA 21-199  
HFD 550/Div. File  
HFD 160/Consult  
HFD 550/Mike Puglisi  
HFD 160/Microbiologist/V.Pawar [HFD-805]

Drafted by: V. Pawar, 08/07/2006  
R/D initialed by: P. Cooney  