

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-257

MICROBIOLOGY REVIEW

SEP 6 2000

**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/

8/7/00

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, 08/07/200

R/D initialed by: P. Cooney

/S/

9/6/2000