

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-816**

**MICROBIOLOGY REVIEW(S)**

JUN 5 1997

REVIEW FOR HFD-550

OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review #1 of NDA 20-816  
June 3, 1997

- A. 1. APPLICATION NUMBER: 20-816
- APPLICANT: Alcon Laboratories, Inc.  
P.O. Box 6600  
Fort Worth, Texas
2. PRODUCT NAME: AZOPT™ (brinzolamide, 1%)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Sterile, multi-dose, brinzolamide ophthalmic suspension 1% for topical (ocular) administration. The drug product will be supplied in DROP-TAINER® LDPE bottles.
4. METHOD OF STERILIZATION:
5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION: Carbonic anhydrase inhibitor indicated for treatment of intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
6. DRUG PRIORITY CLASSIFICATION: not provided
- B. 1. DATE OF INITIAL SUBMISSION: Jan. 26, 1997
2. RELATED DOCUMENTS:
3. DATE OF CONSULT: Feb. 3, 1997
4. ASSIGNED FOR REVIEW: Feb. 7, 1997
- C. REMARKS: The entire Part 7 (Microbiology) dossier was provided on CD-ROM using Word Perfect 5.1 format. Hard copies of volumes 1.1 (summary) and 1.50 (sterilization validation) also provided.

**D. CONCLUSIONS:**

The submission is recommended for approval for microbiology issues concerning sterility assurance. Specific comments are provided in "E. Review Notes".

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*6/3/97*

Neal Sweeney, Ph.D.

cc: NDA 20-816  
HFD-550/Division File  
HFD-550/Chemist/H. Patel  
HFD-550/CSO/L. Lobianco  
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, June 3, 1997  
R/D initialed by P. Cooney, June 3, 1997

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*For PH Cooney 6-5-97*

**APPEARS THIS WAY  
ON ORIGINAL**