

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-214**

**MICROBIOLOGY REVIEW**

**REVIEW FOR HFD-550****OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805  
Microbiologist's Review #1 of NDA 21-214**

July 7, 2000

- A. 1. APPLICATION NUMBER:** 21-214
- APPLICANT:** CIBA Vision  
11460 Johns Creek Parkway  
Duluth GA 30097  
(tel) 678-415-4343  
(fax) 678-415-4198
- 2. PRODUCT NAME:** Rescula
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Unoprostone isopropyl (0.15%) topical ophthalmic solution.
- 4. METHODS OF STERILIZATION:**
- 5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Intraocular pressure-lowering docosanoid indicated for the treatment of elevated intraocular pressure in patients with open-angle glaucoma and ocular.
- 6. DRUG PRIORITY CLASSIFICATION:** P
- B. 1. DATE OF INITIAL SUBMISSION:** 2/14/00
- 2. DATE OF CONSULT:** 3/2/00
- 3. ASSIGNED FOR REVIEW:** 3/2/00
- 4. RELATED DOCUMENTS:** (none)
- C. REMARKS:** NME/Priority Review.

