

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-214**

**CORRESPONDENCE**

NDA 21-214

MAR 9 2000

CIBA Vision Corporation  
Attention: Jeannie-Marie Skinner  
Manager, Regulatory Submissions  
11460 Johns Creek Parkway  
Duluth, GA 30097

Dear Ms. Skinner:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: RESCULA (unoprostone isopropyl ophthalmic solution) 0.15%

Therapeutic Classification: Priority (P)

Date of Application: February 14, 2000

Date of Receipt: February 15, 2000

Our Reference Number: NDA 21-214

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 14, 2000, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be August 13, 2000.

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Anti-Inflammatory, Analgesic and  
Ophthalmic Drug Products, HFD-550  
Attention: Division Document Room  
5600 Fishers Lane  
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Anti-Inflammatory, Analgesic and  
Ophthalmic Drug Products, HFD-550  
Attention: Division Document Room  
9201 Corporate Blvd.  
Rockville, Maryland 20850-3202

If you have any questions, call Raphael R. Rodriguez, Project Manager, at (301) 827-2090.

Sincerely,

/s/

3-9-00

Leslie Vaccaro

Chief, Project Management Staff  
Division of Anti-Inflammatory, Analgesic and  
Ophthalmic Drug Products, HFD-550  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research