DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20851

NDA 21-214

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

Dear Ms. Skinner:

Please refer to your new drug application dated February 14, 2000, received February 15, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RESCULA (unoprostone isopropyl ophthalmic solution) 0.15%.

We acknowledge receipt of your pre-submissions dated December 21, 1999, and February 2, 2000. We also acknowledge receipt of your submissions dated February 15, 16, and 25, March 2, 6, 8 (two), 9, 23, and 31, April 7, 10, 13, 17, and 26, May 5, 11, and 24, June 12, 13 (two), 15, 16, 19, 21 (two), 23, 27, 28, and 29, and July 6, 7, 18 (two), 19, 21, 24, 25, 26 (two), and 27, 2000.

This new drug application provides for the use of RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text submitted July 27, 2000. Accordingly, this application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical in content to the labeling dated July 27, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format - NDAs" (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-214." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

/S/ 8-3-2000
Robert Delap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research