DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-737/S-018

Bausch & Lomb, Inc.
Attention: Fang Li, Ph.D., RAC
Associate Director, Brand
Global Regulatory Affairs, Pharmaceutical
7 Giralda Farms, Suite 1001
Madison, NJ 07940

Dear Dr. Li:

Please refer to your supplemental new drug application dated November 18, 2010, received November 19, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Retisert® (fluocinolone acetonide intravitreal implant) 0.59 mg and amended on November 30, 2010.

This supplemental new drug application provides for an extension of the expiration date to November 2011 for the remaining (b) (4) units of lot 5R0705001A and for the inclusion with these units of a letter which explains the extended expiration date. We completed our review of this supplemental new drug application. This supplement is approved.

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, call Althea Cuff, Regulatory Project Manager, at (301) 796-4061 or Raphael Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, MD
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Office of New Drugs
Center for Drug Evaluation and Research

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/s/

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WILEY A CHAMBERS
11/30/2010