DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-737/S-010

Bausch & Lomb, Inc.
Attn: Yelen Concepcion
Manager, Regulatory Affairs
8500 Hidden River Parkway
Tampa, FL 33637

Dear Ms. Concepcion:

Please refer to your supplemental new drug application dated October 4, 2007, received October 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Retisert (fluocinolone acetonide intravitreal implant) 0.59 mg.

We acknowledge receipt of your submissions dated October 25, and 31, December 26, 2007, and January 11, June 27, July 31, and August 1, 2008.

This supplemental new drug application provides for changes to the **CLINICAL STUDIES, WARNINGS AND PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package to reflect the 3-year data from pivotal clinical studies in chronic noninfectious uveitis affecting the posterior segment of the eye.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling in structured product labeling (SPL) format submitted on August 1, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert submitted August 1, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-737/S-010."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

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

Enclosure Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers

8/5/2008 11:44:31 AM