DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-737

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

Dear Ms. Concepcion:

Please refer to your new drug application (NDA) dated October 7, 2004, received October 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RETISERT (fluocinolone acetonide intravitreal implant) 0.59mg.

We acknowledge receipt of your submissions dated May 28, and November 2, 11, 16, and 17, 2004, and January 14, and 31, February 3, 7, 9, 11, 23(two), 24, and 28, March 3, 7, 8, 14, 17, 28, and 31, and April 5, and 7, 2005.

This new drug application provides for the use of RETISERT (fluocinolone acetonide intravitreal implant) 0.59mg for the treatment of chronic non-infectious 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 agreed-upon labeling text.

The final printed labeling (FPL) must be consistent with the enclosed draft labeling (package insert submitted April 7, 2005, carton and container labeling submitted March 31, 2005). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated April 5, 2005. These commitments are listed below:

1. To ensure that there are no unique complications following cataract extractions, you will conduct two outcome analyses (one year apart) on patients from Clinical Studies BLP 415-001 and BLP 415-004 who have undergone cataract surgery.

   Analysis plan submission: by July 2005
   Initial analysis cataract outcomes report submission: by December 2005
   Final analysis cataract outcomes report submission: by December 2006

2. To monitor the potential for delamination of implants manufactured by the modified process, you will instruct all participating investigators in Clinical Studies BLP 415-001 and BLP 415-004 to report to B&L, on an ongoing basis, any observations of physical separation of implant components**,** regardless of cause. B&L will submit all reported instances to the Agency on a quarterly basis for the first three years post-approval.

   Physician instructions sent to investigators: by June 2005

3. To assess the effect of the implant on the corneal endothelium, you will complete a case-controlled study using a subset of approximately 100 patients from Clinical Studies BLP 415-001 and BLP 415-004 who have been implanted with Retisert for at least one year.

   Case control protocol submission: by August 2005
   Study Start: by January 2006
   Final Report Submission: by December 2006

Submit clinical protocols to your IND for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

In addition, submit three copies of the introductory promotional and educational materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

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, contact Raphael R. Rodriguez, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure:

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

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