DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200738

NDA APPROVAL

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

Dear Dr. Li:

Please refer to your New Drug Application (NDA) dated December 22, 2009, received December 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotemax (loteprednol etabonate ophthalmic ointment) 0.5%.

We acknowledge receipt of your amendments dated October 14, 2010, and January 21, and April 11, 2011. The January 21, 2011, submission constituted a complete response to our October 20, 2010, action letter.

This new drug application provides for the use of Lotemax (loteprednol etabonate ophthalmic ointment) 0.5% for the treatment of post-operative inflammation and pain following ocular surgery. We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical in content to the enclosed labeling (text for the package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf The SPL will be accessible via publicly available labeling repositories.

Please submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on October 14, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format –

Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 200738**." Approval of this submission by FDA is not required before the labeling is used. Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

If sending via USPS, please send to:

Fariba Izadi, PharmD
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22 Room: 6115
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Fariba Izadi, PharmD
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22 Room:6115
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are waiving the pediatric study requirement for this application because there is evidence strongly suggesting that the drug product would be unsafe in pediatric age groups. Safety and effectiveness in pediatric patients have not been established and it should not be used in children following ocular surgery because its use may interfere with amblyopic treatment by hindering the child's ability to see out of the postoperative eye.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more

information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Fariba Izadi, Pharm.D., Regulatory Health Project Manager, at (301) 796-0563.

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(S):
Content of Labeling
Carton and Container Labeling

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

/s/

WILEY A CHAMBERS
04/15/2011