DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-516/S-005

SUPPLEMENT APPROVAL

Bausch & Lomb, Inc.
Attention: Paul Nowacki
Director, Regulatory Affairs
50 Technology Drive
Irvine, CA 92618

Dear Mr. Nowacki:

Please refer to your Supplemental New Drug Application (sNDA) dated June 15, 2011, received June 16, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Istalol (timolol maleate ophthalmic solution) 0.5%.

We acknowledge receipt of your amendments dated October 31 and December 6, 2011.

This "Prior Approval" supplemental new drug application provides for conversion of the current label to Physician's Labeling Rule (PLR) format.

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 agreed-upon labeling text and with the revisions listed below and incorporated in the enclosed labeling.

1. Revise the Initial US Approval Date in the Highlights from (b) (4) to "1978."
2. Revise the second sentence in Section 5.10 Angle-Closure Glaucoma to read, "This may require constricting the pupil."
3. In Section 17 Patient Counseling Information, the word, "see," that is included in the two references to different sections/subsections [e.g. "(see CONTRAINDICATIONS, 4.1, 4.2)"], should not be in bold font.

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 to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 regarding this supplemental application, please call Ms. Leanna M. Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquires regarding this NDA, please contact Mr. Michael Puglisi, Regulatory Project Manager, at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of 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
06/17/2013