DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-664/ S-014 and S-019

SUPPLEMENT APPROVAL

Bausch & Lomb Incorporated
Attention: Jeanine Gouveia
Regulatory Specialist
50 Technology Drive
Irvine, CA 92618

Dear Ms. Gouveia:

Please refer to your Supplemental New Drug Applications (sNDAs) S-014, dated May 10, 2010, received May 11, 2010 and S-019, dated November 8, 2012, received November 9, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Xibrom (bromfenac ophthalmic solution), 0.09%. We acknowledge receipt of your amendment dated June 6, 2013, to S-019.

These "Prior Approval" supplemental new drug applications provide for revisions to the package insert to comply with the Physicians Labeling Rule (PLR) format. We also note that S-014 is superseded by S-019, and it will be retained in our files.

APPROVAL & LABELING

We have completed our review of supplemental application NDA 21-664/S-019, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the labeling submitted on June 6, 2013.

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.

REPORTING REQUIREMENTS

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 Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S): 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
01/27/2014