CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

203168Orig1s000

Trade Name: Prolensa Ophthalmic Solution 0.07%

Generic Name: Bromfenac Ophthalmic Solution

Sponsor: Bausch & Lomb, Inc.

Approval Date: 04/05/2013

Indications: Treatment of Postoperative Inflammation and Reduction of Ocular Pain in Patients Who Have Undergone Cataract Surgery.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 203168

NDA APPROVAL

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

Dear Mr. Nowacki:

Please refer to your New Drug Application (NDA) dated June 6, 2012, received June 7, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prolensa (bromfenac ophthalmic solution) 0.07%.

We acknowledge receipt of your amendments dated August 20 and 31, September 8, 12, and 20, October 9, November 16, and December 19 and 20, 2012, and March 12, 18, and April 3, 2013.

This new drug application provides for the use of Prolensa (bromfenac ophthalmic solution) 0.07% for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract 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.

CONTENT OF LABELING

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 text for the package insert. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE-CONTAINER LABELS

Submit final printed carton and immediate-container labels that are identical to the enclosed carton and immediate-container labels, 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 *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 203168**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

With the next scheduled printing, the cartons should be revised to include a more precise description of the active (i.e., bromfenac sodium sesquihydrate 0.0805%) consistent with the package insert.

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Michael Puglisi
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6162
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

PEDIATRIC ASSESSMENT

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.

Because your application does not include a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, this requirement is inapplicable.

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