CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203168Orig1s000

<u>OTHER REVIEW(S)</u>

****Pre-decisional Agency Information****

Memorandum

Date:	March 20, 2013
To:	Mike Puglisi, Regulatory Health Project Manager Division of Transplant and Ophthalmology Products (DTOP)
From:	Christine Corser, Pharm.D., Regulatory Review Officer Office of Prescription Drug Promotion (OPDP)
Subject:	OPDP Labeling Consult Review NDA #203168 PROLENSA™ (bromfenac ophthalmic solution) 0.07%

As requested in your consult dated July 23, 2012, the Office of Prescription Drug Promotion (OPDP) has reviewed the draft labeling for PROLENSA™ (bromfenac ophthalmic solution) 0.07%.

Our comments are based on the substantially complete version of the labeling titled, "nda 203168 draft PI 3_20_13.doc" which was received via email from Mike Puglisi on March 20, 2013.

OPDP has reviewed the PI and our comments are attached in the substantially complete clean version of the labeling.

If you have any questions about our comments on the PI, please contact Christine Corser at 6-2653 or at christine.corser@fda.hhs.gov.

Thank you for the opportunity to review this PI.

4 Pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS)

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

/s/

CHRISTINE G CORSER

03/20/2013

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Label, Labeling and Packaging Review

Date: February 8, 2013

Reviewer: Jung Lee, RPh
                               Division of Medication Error Prevention and Analysis

Team Leader: Jamie Wilkins Parker, PharmD
                               Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
                               Division of Medication Error Prevention and Analysis

Drug Name and Strength: Prolensa (Bromfenac Ophthalmic Solution), 0.07%

Application Type/Number: NDA 203168

Applicant: Bausch & Lomb, Inc

OSE RCM #:   2012-2059

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