# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# 203168Orig1s000

# <u>CHEMISTRY REVIEW(S)</u>

To: NDA 203168 File

Date: O5-April-2013

From: Rapti D. Madurawe, Ph.D., Branch Chief, Branch V/Division II, ONDQA

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Dr. Rao Kambhampati recommended CMC labeling revisions in Addendum1 to Review #1 dated 04-April-2013. The recommended labeling changes may be made post-approval and the NDA may be approved with the current labeling provided in Amendment 0012 dated 03-April-2013.

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/s/

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RAPTI D MADURAWE

04/05/2013

# NDA# 203168
## Addendum 1 to Quality Review #1
## For Division of Topical and Ophthalmology Products

1. NDA# **203168**

2. Amendment # and Date: 0011 dated 3/18/13

3. REVIEW DATE: 4-4-13

4. REVIEWER: Rao V. Kambhampati, Ph.D.

5. PREVIOUS DOCUMENTS:

| Previous Documents | Document Date |
|---|---|
| N203168 ORIG-1 0000 (0) Quality Review | 2/25/13 |

6. SUBMISSION(S) BEING REVIEWED:

| Submissions Reviewed | Global Submit Date |
|---|---|
| NDA 203-168 Amendment 0011 (11) | 3/18/13 |

7. NAME & ADDRESS OF APPLICANT:

| | |
|---|---|
| Name: | Bausch & Lomb Incorporated (formerly ISTA Pharmaceuticals, Inc.) |
| Address: | 50 Technology Drive Irvine, CA 92618 |
| Representative: | N/A |
| Telephone: | 949-727-0833 |

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Prolensa$^{TM}$
b) Non-Proprietary Name (USAN): Bromfenac ophthalmic solution, 0.07%
c) Code Name/# (ONDQA only): N/A
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: 5
- Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: NDA (CDA, 21 CFR 314.50), 505 (b)(1)

10. PHARMACOL CATEGORY: Nonsteroidal anti-inflammatory drug (NSAID) for ophthalmic use (Cyclooxygenase 1 and 2 inhibitor)

11. DOSAGE FORM:     Ophthalmic solution

12. STRENGTH/POTENCY:   0.07%

13. ROUTE OF ADMINISTRATION: Topical (ocular) instillation

14. Rx/OTC DISPENSED:     _X__Rx          ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
   _____SPOTS product – Form Completed

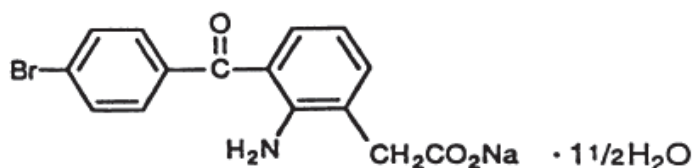   ___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
   Sodium [2-amino-3-(4-bromobenzoyl) phenyl] acetate sesquihydrate
   or
   Benzeneacetic acid, 2-amino-3-(4-bromobenzoyl)-, monosodium salt, sesquihydrate



   $C_{15}H_{11}$ BrNNaO$_3$ • 1½ H$_2$O
   383.17
   USAN Name: Bromfenac sodium

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