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APPLICATION NUMBER:

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PHARMACOLOGY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA REVIEW AND EVALUATION

Application number:	203168
Supporting document/s:	000
Applicant's letter date:	6/5/2012
CDER stamp date:	6/7/2012
Product:	Prolensa™: bromfenac ophthalmic solution, 0.07%
Indication:	Treatment of inflammation and pain associated with cataract extraction
Applicant:	ISTA Pharmaceuticals, Inc
Review Division:	CDER/OAP/Division of Transplant and Ophthalmology Products
Reviewer:	Robeena Aziz, MPH, PhD
Supervisor/Team Leader:	Lori Kotch, PhD, DABT
Division Director:	Renata Albrecht, MD
Project Manager:	Michael Puglisi

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1 Executive Summary

1.1 Introduction

The sponsor (ISTA Pharmaceuticals, Inc) is submitting this NDA application for bromfenac ophthalmic solution, 0.07% (also referred to bromfenac sodium, or bromfenac in this review). Bromfenac ophthalmic solution 0.07% is a topical, nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of inflammation and pain associated with cataract extraction. Patients will apply one drop to affected eye(s) once daily beginning one day prior to cataract surgery, on the day of surgery, and through 14 days post surgery.

The indication is the same as the currently marketed product, Bromday™ (bromfenac ophthalmic solution) 0.09%, administered once daily (sNDA 021664 for Bromday™ FDA approval on 10/2010) and Xibrom™ administered twice daily (NDA 21644 FDA approval 3/2005). The bromfenac ophthalmic solution 0.07% formulation in the current submission differs from the currently marketed bromfenac 0.09% product in the amounts of bromfenac sodium and its target pH. (b) (4) The same manufacturer, Regis Technologies, will continue to supply the bromfenac sodium solution.

The oral formulation of bromfenac (Duract capsules) was developed by Wyeth-Ayerst and was approved for marketing under NDA 20 535 in 1997. However, due to clinical findings of hepatotoxicity after marketing, Duract was withdrawn from the market in June 1998.

Bromfenac sodium was licensed to Senju Pharmaceutical Co., Ltd, Osaka, Japan for development as an ophthalmic solution in Japan (Bronuck®; bromfenac sodium ophthalmic solution, 0.1% dosed BID). The Japanese formulation is identical to the US product, with the concentration of the active shown as the salt form (0.1% bromfenac sodium) rather than the free acid (0.09% bromfenac), respectively. Bronuck was approved in Japan in July 2000, and is indicated for the treatment of blepharitis, conjunctivitis, scleritis (including episcleritis) and post-operative inflammation.

Senju conducted non-clinical and clinical studies for bromfenac ophthalmic solution and obtained approval for marketing in Japan in 2000. Senju recently sublicensed bromfenac for ophthalmic use in the United States to ISTA Pharmaceuticals, Inc. The non-clinical studies submitted in this NDA were conducted by Wyeth-Ayerst and Senju Pharmaceuticals. The nonclinical studies to support this NDA application are referenced to the approved products mentioned above.

This indication in the current submission is supported by two clinical trials (Studies Nos. S00124-ER and S00124-WR) to evaluate the efficacy and safety of bromfenac ophthalmic solution 0.07% vs. placebo for the treatment of ocular inflammation and pain associated with cataract surgery.

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