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APPLICATION NUMBER:

203168Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	203168
Priority or Standard	Standard
Submit Date(s)	June 6, 2012
Received Date(s)	June 7, 2012
PDUFA Goal Date	April 7, 2013
Division / Office	OAP/DTOP
Reviewer Name(s)	William M. Boyd, M.D.
Review Completion Date	March 20, 2013
Established Name	bromfenac ophthalmic solution 0.07%
(Proposed) Trade Name	Prolensa
Therapeutic Class	nonsteroidal anti-inflammatory
Applicant	Bausch & Lomb, Inc.
Formulation(s)	bromfenac ophthalmic solution 0.07%
Dosing Regimen	one drop into the affected eye once daily
Indication(s)	treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery
Intended Population(s)	patients who have undergone cataract surgery

Template Version: March 6, 2009

Table of Contents

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