

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
203491Orig1s000

PROPRIETARY NAME REVIEW(S)

**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
Division of Medication Error Prevention and Analysis**

Proprietary Name Review

Date: August 9, 2012

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

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

Drug Name and Strength: (b) (4) (Nepafenac Ophthalmic Suspension), 0.3%

Application Type/Number: NDA 203491

Applicant: Alcon Research, Ltd

OSE RCM #: 2012-1599

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/s/

JUNG E LEE
08/09/2012

JAMIE C WILKINS PARKER
08/09/2012

**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**

Proprietary Name Review

Date: June 14, 2012

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

Acting Team Leader: Chi-Ming (Alice) Tu, PharmD
Division of Medication Error Prevention and Analysis

Deputy Director: Kellie Taylor, PharmD, MPH
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength: (b) (4) (Nepafenac Ophthalmic Suspension),
0.3%

Application Type/Number: NDA 203491

Applicant: Alcon Research, Ltd

OSE RCM #: 2012-626

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/s/

JUNG E LEE
06/14/2012

CHI-MING TU
06/14/2012

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
06/14/2012
Signing on behalf of Kellie Taylor

CAROL A HOLQUIST
06/14/2012