

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203697Orig1s000

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**

Proprietary Name Review

Date: August 17, 2012

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

Team Leader: Todd Bridges, RPh
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) (Aspirin) Capsules, 325 mg

Application Type/Number: NDA 203697

Applicant: PLx Pharma Inc.

OSE RCM #: 2012-1210

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/s/

CHI-MING TU
08/17/2012

KELLIE A TAYLOR on behalf of TODD D BRIDGES
08/17/2012

KELLIE A TAYLOR
08/17/2012

CAROL A HOLQUIST
08/17/2012