

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205029Orig1s000

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: April 2, 2013

Reviewer: Kimberly DeFronzo, RPh, MS, MBA
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

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

Drug Name and Strength(s): (b) (4) (Epinephrine Injection, USP) 1:1000 (1 mg/mL)

Application Type/Number: NDA 205029

Applicant/Sponsor: Belcher Pharmaceuticals, LLC

OSE RCM #: 2013-45

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/s/

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04/02/2013

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04/03/2013

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04/03/2013