# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 208085Orig1s000

# PROPRIETARY NAME REVIEW(S)

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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|---|---|
| **Date of This Review:** | February 22, 2018 |
| **Application Type and Number:** | NDA 208085 |
| **Product Name and Strength:** | (b) (4) (hydrocodone bitartrate and guaifenesin) Tablets, 5 mg/400 mg |
| **Product Type:** | Multi-Ingredient Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | ECI Pharmaceutical LLC |
| **Panorama #:** | 2017-19313322 |
| **DMEPA Safety Evaluator:** | Lissa C. Owens, PharmD |
| **DMEPA Team Leader:** | Sarah K. Vee, PharmD |
| **DMEPA Associate Director:** | Mishale Mistry, PharmD, MPH |
| **DMEPA Division Director:** | Todd Bridges, RPh |

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/s/

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LISSA C OWENS
02/22/2018

SARAH K VEE
02/22/2018

MISHALE P MISTRY
02/22/2018

TODD D BRIDGES
02/22/2018

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|---|---|
| **Date of This Review:** | July 29, 2016 |
| **Application Type and Number:** | NDA 208085 |
| **Product Name and Strength:** | (b) (4) (hydrocodone bitartrate/guaifenesin) Tablets 5 mg/400 mg |
| **Product Type:** | Multi-Ingredient Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | ECI Pharmaceuticals, LLC |
| **Panorama #:** | 2016- 7928232 |
| **DMEPA Primary Reviewer:** | Matthew Barlow, RN, BSN |
| **DMEPA Team Leader:** | Mishale Mistry, PharmD, MPH |
| **DMEPA Associate Director (acting):** | Danielle Harris, PharmD, BCPS |
| **DMEPA Director:** | Todd Bridges, RPh |

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/s/

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MATTHEW J BARLOW
08/01/2016

MISHALE P MISTRY
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