CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209377Orig1s000

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)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	January 16, 2019
Application Type and Number:	NDA 209377
Product Name and Strength:	(b) (4) (zinc sulfate) injection 3 mg/mL and 5 mg/mL
Total Product Strength:	30 mg/10 mL and 25 mg/5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Luitpold Pharmaceuticals Inc.
Panorama #:	2018-26612322
DMEPA Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, Pharm.D.
DMEPA Associate Director:	Mishale Mistry, Pharm.D., MPH

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/s/

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MISHALE P MISTRY
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