CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209379Orig1s000

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:	January 16, 2019
Application Type and Number:	NDA 209379
Product Name and Strength:	(b) (4) (selenious acid) injection 60 mcg/mL
Total Product Strength:	600 mcg/10 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Luitpold Pharmaceuticals Inc.
Panorama #:	2018-27001302
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/

SHERLY ABRAHAM
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MISHALE P MISTRY
01/16/2019 11:34:01 AM