CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210428Orig1s000

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:	October 10, 2017
Application Type and Number:	NDA 210428
Product Name and Strength:	(b) (4) (metoprolol succinate) extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sun Pharmaceutical Industries Ltd.
Panorama #:	2017-16330472
DMEPA Safety Evaluator:	Ashleigh Lowery, PharmD, BCCCP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

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/s/

ASHLEIGH V LOWERY
10/10/2017

CHI-MING TU
10/10/2017

DANIELLE M HARRIS
10/10/2017