

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210566Orig1s000

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:	May 4, 2018
Application Type and Number:	NDA 210566
Product Name and Strength:	(b) (4) (halobetasol propionate) foam, 0.05%
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Therapeutics, Inc.
Panorama #:	2018- 20850203
DMEPA Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, PharmD

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/s/

SHERLY ABRAHAM
05/04/2018

MISHALE P MISTRY on behalf of SARAH K VEE
05/04/2018

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 22, 2018
Application Type and Number:	NDA 210566
Product Name and Strength:	(b) (4) (halobetasol propionate) foam, 0.05%
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Therapeutics, Inc.
Panorama #:	2017- 19081749
DMEPA Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH
DMEPA Division Director:	Todd Bridges, RPh

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/s/

SHERLY ABRAHAM
01/22/2018

SARAH K VEE
01/22/2018

MISHALE P MISTRY
01/24/2018

TODD D BRIDGES
01/24/2018