

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

218158Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME RECONSIDERATION REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	February 9, 2024
Application Type and Number:	NDA 218158
Product Name and Strength:	(b) (4) (clobetasol propionate) ophthalmic suspension, 0.05%
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Formosa Pharmaceutical Inc. (Formosa Pharma)
PNR ID #:	2024-1044725580
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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SOFANIT N GETAHUN
02/09/2024 10:02:52 AM

VALERIE S VAUGHAN
02/09/2024 10:14:01 AM

MISHALE P MISTRY
02/09/2024 11:39:03 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 8, 2024
Application Type and Number:	NDA 218158
Product Name and Strength:	(b) (4) (clobetasol propionate) ophthalmic suspension, 0.05%
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Formosa Pharmaceutical Inc. (Formosa Pharma)
PNR ID #:	2023-1044725409
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD

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01/08/2024 10:30:04 AM

VALERIE S VAUGHAN
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August 2, 2023

NDA should be on the cover page is NDA 218158

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	July 31, 2023
Application Type and Number:	NDA 215158, IND128133
Product Name and Strength:	(b) (4) (clobetasol propionate) ophthalmic suspension, 0.05%
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Formosa Pharmaceutical Inc. (Formosa Pharma)
PNR ID #:	2023-1044725130 and 2022-1044724595
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Acting Director:	Irene Z. Chan, PharmD, BCPS

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VALERIE S VAUGHAN
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IRENE Z CHAN
08/01/2023 09:39:11 AM