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APPLICATION NUMBER:

206255Orig1s000

PROPRIETARY NAME REVIEW(S)

Proprietary Name Memorandum

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: March 19, 2014
Requesting Office or Division: Division of Dermatology and Dental Products (DDDP)
Application Type and Number: NDA 206255
Product Name and Strength: Soolantra (Ivermectin) Cream, 1%
Product Type: Single ingredient product
Rx or OTC: Rx
Applicant/Sponsor Name: Galderma Research and Development
Submission Date: 03/12/2014
Panorama #: 2014-17060
DMEPA Primary Reviewer: Carlos M Mena-Grillasca, RPh
DMEPA Associate Director: Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary name, Soolantra, was found acceptable in OSE review # 2013-863, dated September 12, 2013 under IND 076064. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Soolantra, is acceptable from both a promotional and safety perspective under the NDA 206255.

If you have further questions or need clarifications, please contact Teena Thomas, OSE project manager, at 301-796-0549.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Soolantra, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your March 12, 2014 submission are altered, the name must be resubmitted for review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CARLOS M MENA-GRILLASCA
03/19/2014

LUBNA A MERCHANT
03/20/2014