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RESEARCH**

APPLICATION NUMBER:

207071Orig1s000

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)

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Date of This Review:	December 12, 2014
Requesting Office or Division:	Division of Dermatology and Dental Products (DDDP)
Application Type and Number:	NDA 207071
Product Name and Strength:	Finacea (b) (4) (Azelaic Acid) Foam, 15%
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bayer Healthcare
Submission Date:	October 24, 2014
Panorama #:	2014-40644
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, RPh
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

The proposed proprietary name, Finacea Foam, was found acceptable under IND 077516¹. We note that the product characteristics are the same for NDA 207071 currently under review as in the IND. DMEPA searched the USAN stem list² to determine if the name contains any USAN stems since the last USAN update. The December 12, 2014 stems search did not find any USAN stems in the proposed proprietary name. Therefore, this memorandum is to communicate that DMEPA maintains the proposed proprietary name, Finacea Foam, is acceptable from both a promotional and safety perspective under the NDA 207071.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

2 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 24, 2014 submission are altered, the name must be resubmitted for review.

¹ Mena-Grillasca, CM. Proprietary Name Review for Finacea Foam (IND 077516). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 February 07. 22 OSE RCM No.: 2013-9242.

² USAN Stems List contains all the recognized USAN stems.
<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>

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/s/

CARLOS M MENA-GRILLASCA
12/12/2014

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