CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215985Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	January 11, 2022
Application Type and Number:	NDA 215985
Product Name and Strength:	Zoryve (roflumilast) cream, 0.3%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Arcutis Biotherapeutics, Inc. (Arcutis)
PNR ID #:	2021-1044724288
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Zoryve, which was found conditionally acceptable under IND 135681 on July 19, 2021.[a]

Thus, Arcutis submitted the name, Zoryve, under NDA 215985 for re-review on November 16, 2021. We note that there is a change in strength (b) (4) the 0.3% strength and a change in how the product will be supplied, (b) (4) (b) (4) to a 60 gram tube for NDA 215985. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zoryve would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Zoryve.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in strength (b) (4) only pursuing the 0.3% strength and a change in how the product will be supplied, (b) (4) to a 60 gram tube. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Zoryve.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 17, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Zoryve.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On January 11, 2022, we communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Zoryve, is acceptable.

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

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[a] Patel, M. Proprietary Name Review for Zoryve (IND 135681). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUL 19. PNR ID No. 2021-1044723843.

3.1 COMMENTS TO ARCUTIS BIOTHERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 16, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MADHURI R PATEL
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SEVAN H KOLEJIAN
01/11/2022 11:19:50 AM

MISHALE P MISTRY
01/11/2022 12:49:37 PM