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RESEARCH**

APPLICATION NUMBER:

219155Orig1s000

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:	September 20, 2024
Application Type and Number:	NDA 219155
Product Name, Dosage Form, and Strength:	Anzupgo (delgocitinib) cream, 2% (20 mg/g)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	LEO Pharma A/S (LEO Pharma)
PNR ID #:	2024-1044725903
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Anzupgo, which was found conditionally acceptable under IND 135351 on May 3, 2024.^a Thus, LEO Pharma submitted the proposed proprietary name, Anzupgo, under NDA 219155 for re-review on July 23, 2024.^b We note that there is a change in how the product will be supplied (addition of a 30 g tube) for NDA 219155. All other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Anzupgo, 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 addition of a 30 g tube presentation. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Anzupgo.

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 August 5, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Anzupgo.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On September 20, 2024, DMEPA 1 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, Anzupgo, is conditionally acceptable.

^a Bao, A. Proprietary Name Review for Anzupgo (IND 135351). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 May 03. PNR ID No. 2023-1044725482.

^b Cover Letter for NDA 219155 (Anzupgo). Ballerup (Denmark): LEO Pharma A/S; 2024 Jul 24. Available from: <\\Cdsesub1\evsprod\NDA219155\0001\m1\us\coverletter.pdf>

3.1 COMMENTS TO LEO PHARMA A/S

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

If any of the proposed product characteristics as stated in your submission, received on July 23, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at <https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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/

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