

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**216018Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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## **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\*\*\***

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|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| <b>Date of This Review:</b>                                  | July 4, 2021                                                                                            |
| <b>Application Type and Number:</b>                          | NDA 216018                                                                                              |
| <b>Product Name and Strength:</b>                            | Aspruzyo Sprinkle (ranolazine) Extended release oral granule, 500 mg per sachet and 1,000 mg per sachet |
| <b>Product Type:</b>                                         | Single Ingredient Product                                                                               |
| <b>Rx or OTC:</b>                                            | Prescription (Rx)                                                                                       |
| <b>Applicant/Sponsor Name:</b>                               | Sun Pharmaceutical Industries Inc. (Sun)                                                                |
| <b>Panorama or PNR ID #:</b>                                 | 2021- 1044724001                                                                                        |
| <b>DMEPA Safety Evaluator:</b>                               | Mariette Aidoo, PharmD, MPH                                                                             |
| <b>DMEPA Team Leader:</b>                                    | Hina Mehta, PharmD                                                                                      |
| <b>DMEPA Associate Director of Nomenclature and Labeling</b> | Chi-Ming (Alice) Tu, PharmD, BCPS                                                                       |

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Aspruzyo Sprinkle, which was found conditionally acceptable under IND 135950 on February 26, 2021.<sup>a</sup> Thus, Sun submitted the name, Aspruzyo Sprinkle, under NDA 216018 for review on April 30, 2021. We note that all product characteristics remain the same.

## **2 METHODS AND DISCUSSION**

### **2.1 MISBRANDING ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined that Aspruzyo Sprinkle would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Aspruzyo Sprinkle.

### **2.2 SAFETY ASSESSMENT**

For re-assessment of the proposed proprietary name, we evaluated the proposed proprietary name considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The June 17, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Aspruzyo Sprinkle.

### **2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW**

We communicated our findings to the Division of Cardiology and Nephrology (DCN). At that time we also requested additional information or concerns that could inform our review. On July 4, 2021, the Division of Cardiology and Nephrology (DCN) stated no additional concerns with the proposed proprietary name, Aspruzyo Sprinkle.

## **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, Aspruzyo Sprinkle, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

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<sup>a</sup> Aidoo, M. Proprietary Name Review for Aspruzyo Sprinkle (IND 135950). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 26. Panorama No.: 2020-42549277.

### **3.1 COMMENTS TO SUN PHARMACEUTICAL INDUSTRIES INC.**

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

If any of the proposed product characteristics as stated in your submission, received on April 30, 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.

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/s/  
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