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RESEARCH**

APPLICATION NUMBER:

211243Orig1s000

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: November 9, 2018
Application Type and Number: NDA 211243
Product Name and Strength: Spravato (esketamine) nasal spray
(b) (4)
Total Product Strength: 28 mg/0.2 mL
Product Type: Combination Product
Rx or OTC: Rx
Applicant/Sponsor Name: Janssen Pharmaceuticals, Inc.
Panorama #: 2018-25666002
DMEPA Safety Evaluator: Loretta Holmes, BSN, PharmD
DMEPA Team Leader: Teresa McMillan, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Spravato, which was found conditionally acceptable under IND 114345 on March 19, 2018.^a 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 the proposed name would not misbrand the proposed product. DMEPA and the Division of Psychiatry Products (DPP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 28, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on November 7, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on November 9, 2018, they stated the name looks like Spiriva and could be administered as some sort of "puffs" which may make an error harder to catch. We evaluated the name Spiriva in our previous Spravato proprietary name review^a and we continue to find there are sufficient orthographic and phonetic differences between the name pair.

3 CONCLUSIONS

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 is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO THE APPLICANT

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

^a Whaley, E. Proprietary Name Review for Spravato (IND 114345). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 Mar 19. Panorama No. 2017-19809412.

If any of the proposed product characteristics as stated in your submission, received on September 4, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEAR THIS WAY ON ORIGINAL

4 REFERENCES

1. USAN Stems (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

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/

LORETTA HOLMES
11/09/2018

TERESA S MCMILLAN
11/09/2018