CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209310Orig1s000

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 8, 2017
Application Type and Number:	NDA 209310
Product Name and Strength:	Sinuva (mometasone furoate) Sinus Implant 1350 mcg
Product Type:	Single-ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Intersect ENT
Panorama #:	2017-18004063
DMEPA Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Sinuva, which was found conditionally acceptable under IND 116042 on May 11, 2017.[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 Pulmonary, Allergy, and Rheumatology Products (DPARP) 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 October 30, 2017 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 Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on November 8, 2017. At that time we also requested additional information or concerns that could inform our review. DPARP did not state any additional concerns with the proposed proprietary name, Sinuva.

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 Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 29, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Owens, L. Proprietary Name Review for Sinuva (mometasone furoate) IND 116042 Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAY 11]. Panorama No. 2017-12759066

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.

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/s/

LISSA C OWENS
11/08/2017

SARAH K VEE
11/08/2017