CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209482Orig1s000

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:	January 10, 2017
Application Type and Number:	NDA 209482
Product Name and Strength:	Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) 100 mcg/62.5 mcg/25 mcg per inhalation
Product Type:	Multi-ingredient, drug-device combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	GlaxoSmithKline
Panorama #:	2016-11487111
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Trelegy Ellipta, which was found conditionally acceptable under IND 114873 on July 25, 2016.[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 January 9, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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, Trelegy Ellipta, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your November 21, 2016 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 Trelegy Ellipta (IND 114873). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 JUL 25. Panorama No. 2016-2732850.

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/

MADHURI R PATEL
01/10/2017

MISHALE P MISTRY
01/12/2017