CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208798Orig1s000

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:	May 11, 2016
Application Type and Number:	NDA 208798
Product Name and Strength:	ArmonAir RespiClick (Fluticasone Propionate) (b) (4) 55 mcg, 113 mcg, and 232 mcg
Product Type:	Drug-Device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Teva Pharmaceuticals Inc.
Panorama #:	2016-3178603
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, ArmonAir RespiClick, which was found conditionally acceptable under IND 108838 on February 9, 2016.[1]

(b) (4)

Under NDA 208798, the strengths proposed are 55 mcg, 113 mcg, and 232 mcg. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

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. We also evaluated previously identified names taking into account the change in the product's strengths. Our evaluation has not 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 May 3, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

The proposed product, ArmonAir RespiClick will be available in strength of 55 mcg, 113 mcg, and 232 mcg. Since these are not typical strengths that are not commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with ArmonAir RespiClick that were not identified previously in POCA, and found to have an overlap in strength with ArmonAir RespiClick.[2] We did not identify any names in our search.

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.

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.

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[1] Owens, L. Proprietary Name Review for ArmonAir RespiClick (IND 108838) 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 FEB 09. Panorama No. 2015-1592585.

[2] eDRLS search conducted on May 11, 2016

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 28, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

2. **Electronic Drug Registration and Listing System (eDRLS) Database**
   The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information

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/s/

LISSA C OWENS
05/11/2016

MISHALE P MISTRY
05/11/2016