

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207070Orig1s000

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: August 10, 2015
Requesting Office or Division: Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)
Application Type and Number: NDA 207070
Product Name and Strength: Spiriva Respimat (Tiotropium Bromide) Inhalation Spray
1.25 mcg per Actuation
Product Type: Single-ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Boehringer Ingelheim
Submission Date: July 8, 2015
Panorama #: 2015-960680
DMEPA Primary Reviewer: Lissa C. Owens, PharmD
DMEPA Team Leader: Kendra Worthy, PharmD
DMEPA Associate Director: Lubna Merchant, PharmD, MS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Spiriva Respimat under NDA 207070 which was found acceptable under NDA 207070¹. (b) (4)

All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For reassessment of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database (see section 5) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2014-26397. Additionally, we 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 strength. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 29, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Spiriva Respimat, is acceptable from both a promotional and safety perspective under the NDA 207070.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE Project Manager, at 301-796-3904.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 8, 2015 submission are altered, the name must be resubmitted for review.

¹ Owens, Lissa C. Proprietary Name Review for Spiriva Respimat (NDA 207070). 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); 2014 December. 4 OSE RCM No.: 2014-26397.

5 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. **Phonetic and Orthographic Computer Analysis (POCA)**

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

LISSA C OWENS
08/10/2015

KENDRA C WORTHY
08/10/2015

LUBNA A MERCHANT
08/10/2015

**Department of Health and Human Services
Public Health Service
Food and Drug Administration Center for
Drug Evaluation and Research Office of
Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Memorandum

Date: December 4, 2014

Reviewer: Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Kendra Worthy, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Spiriva Respimat (Tiotropium Bromide) Inhalation Spray
(b)(4) mcg per actuation

Application Type/Number: NDA 207070

Applicant: Boehringer Ingelheim

OSE RCM #: 2014-26397

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1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Spiriva Respimat, under NDA 207070 submitted on September 12, 2014 for the indication of long-term, once-daily, add-on maintenance treatment of asthma in patients 12 years of age and older who remain symptomatic on at least inhaled corticosteroids . DMEPA previously found the name acceptable in OSE Review #2014-17214 dated June 30, 2014 under NDA 021936 for the indication of long-term once daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations. We note that all product characteristics are identical to NDA 021936 and that the only change is in the indication.

2 METHODS AND DISCUSSION

For re-assessments of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2014-17214. Additionally, we 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. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The December 1, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE Project Manager, at 301-796-3904.

3.1 Comments to the Applicant

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

If any of the proposed product characteristics as stated in your September 12, 2014 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. Owens, L, Proprietary name review for Spiriva Respimat (NDA 021936). 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); 2014-06-30. OSE RCM No.: 2014-17214.
2. **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.
3. **Phonetic and Orthographic Computer Analysis (POCA)**
POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

LISSA C OWENS
12/04/2014

KENDRA C WORTHY
12/04/2014