

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**125526Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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**Date of This Review:** January 23, 2015

**Requesting Office or Division:** Division of Pulmonary, Allergy, and Rheumatology Products (DPARP)

**Application Type and Number:** BLA 125526

**Product Name and Strength:** Nucala (Mepolizumab)  
Injection  
100 mg per vial

**Product Type:** Single Ingredient Product

**Rx or OTC:** Rx

**Applicant/Sponsor Name:** GlaxoSmithKline

**Submission Date:** November 7, 2014

**Panorama #:** 2014-42583

**DMEPA Primary Reviewer:** Lissa C. Owens, PharmD

**DMEPA Team Leader:** Kendra Worthy, PharmD

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## **1 INTRODUCTION**

This memorandum is to re-assess the proposed proprietary name, Nucala under BLA 125526, which was found acceptable under IND 006971<sup>1</sup>. We note that there are no changes to the product characteristics.

## **2 METHODS AND DISCUSSION**

For re-assessments 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 # 2013-2703. We also 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 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 19, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## **3 CONCLUSIONS**

DMEPA maintains the proposed proprietary name, Nucala, is acceptable from both a promotional and safety perspective under the BLA 125526.

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, Nucala, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your November 7, 2014 submission are altered, the name must be resubmitted for review.

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<sup>1</sup> Owens, Lissa C. Proprietary Name Review for Nucala (IND 006971). 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 May 12. 26 OSE RCM No.: 2013-2703.

## 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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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LISSA C OWENS  
01/23/2015

KENDRA C WORTHY  
01/23/2015