CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761122Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	April 22, 2019
Application Type and Number:	BLA 761122
Product Name and Strength:	Nucala (mepolizumab) injection 100 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	GlaxoSmithKline, LLC. (Glaxo)
Panorama #:	2019-28945689
DMEPA Safety Evaluator:	Teresa McMillan, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD
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Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 1
2.1 Misbranding Assessment 1
2.2 Safety Assessment 2
3 CONCLUSION 5
3.1 Comments to the Applicant/Sponsor 5
4 REFERENCES 7
APPENDICES 8

1 INTRODUCTION

This review evaluates the proposed proprietary name, Nucala***, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Glaxo submitted an external name study by (b) (4) for this proposed proprietary name Nucala***[a] and the study was previously reviewed by DMEPA.

1.1 REGULATORY HISTORY

Nucala (mepolizumab) for injection was approved on November 4, 2015 under BLA 125526 for the add-on maintenance treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype (BLA 125526). On December 12, 2017, Nucala (mepolizumab) for injection (BLA 125526) was also approved for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

On January 28, 2019, Glaxo submitted the name, Nucala*** for review under BLA 761122 for a new dosage form (injection), and presentation (autoinjector and pre-filled syringe) of mepolizumab.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 28, 2019.

Table 1. Relevant Product Information for Nucala

Product Name	**Nucala (BLA 761122)**	**Nucala (BLA 125526)**
Intended Pronunciation	new-KAH-lah	
Initial Approval Date	N/A	November 4, 2015
Active Ingredient	mepolizumab	
Indication	• Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. • Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).	
Route of Administration	subcutaneous	
Dosage Form	Injection	For injection
Strength	100 mg/mL	100 mg per vial
Dose and Frequency	• Asthma: 100 mg administered subcutaneously once every 4 weeks.	

[a] Owens, L. Proprietary Name Review for Nucala (mepolizumab) injection (IND 006971). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 MAY 12. Panorama No.: 2013-16533.

Reference ID: 4422455

	• EGPA: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks	
How Supplied	A clear to opalescent, colorless to pale yellow solution for subcutaneous use. Each single-dose prefilled autoinjector or single-dose prefilled syringe is designed to deliver 100 mg of mepolizumab in 1 mL of solution. The autoinjectors and syringes are not made with natural rubber latex. • 100 mg/mL, single-dose, prefilled autoinjector with attached 29-gauge, half-inch needle in cartons of 1 • 100 mg/mL, single-dose, prefilled glass syringe with attached 29-gauge, half-inch needle in cartons of 1	A sterile, preservative-free, lyophilized powder for reconstitution and subcutaneous injection in a single-dose glass vial with a flip-off seal. The vial stopper is not made with natural rubber latex 100-mg single-dose vials in cartons of 1
Storage	*Prior to Dispensing:* Refrigerate prefilled autoinjectors and prefilled syringes at 36°F to 46°F (2°C to 8°C). Keep the product in the original carton to protect from light. Do not freeze. Do not shake. Avoid exposure to heat. *Following Dispensing:* Refrigerate prefilled autoinjectors and prefilled syringes at 36°F to 46°F (2°C to 8°C). Keep the product in the original carton to protect from light until the time of use. Do not freeze. Do not shake. Avoid exposure to heat. If necessary, an unopened carton can be stored outside the refrigerator at up to 86°F (30°C) for up to 7 days. Discard if left out of the refrigerator for more than 7 days.	Store vials below 77°F (25°C)

	NUCALA injection must be administered within 8 hours after removal from the carton. Discard if not administered within 8 hours.	

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Nucala.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nucala would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment for Nucala.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Nucala.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[b].

2.2.2 Components of the Proposed Proprietary Name

Glaxo did not provide a derivation or intended meaning for the proposed proprietary name, Nucala, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. We discuss the use of a single proprietary name for multiple dosage forms in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 8, 2019 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to Nucala at the initial phase of the review.

[b] USAN stem search conducted on February 13, 2019.

2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving ***Nucala*** that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	February 13, 2019
Drug Name	Nucala [mepolizumab]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	N/A

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

The search yielded no cases of name confusion with the proprietary name Nucala.

Reference ID: 4422455

2.2.5 Multiple Dosage Forms under a Single Proprietary Name

Under BLA 761122, Glaxo proposes to introduce an autoinjector and prefilled syringe presentation of mepolizumab injection, to be marketed under the same name as the currently approved product, Nucala. Nucala is currently available as a lyophilized powder for injection in a vial presentation and shares the same strength, dose, frequency, and route of administration as the proposed product (see Table 1). We note that the currently available Nucala for injection should be reconstituted and administered by a healthcare professional and the proposed presentations may be administered by a healthcare professional, patient, or caregiver.

It is a common and accepted practice to have a product line with multiple dosage forms and presentations managed under one proprietary name. We acknowledge that healthcare practitioners would need to specify what presentations the patient should receive. If the presentation were to be omitted, the intended presentation (autoinjector/prefilled syringe or vial) would need to be clarified by the pharmacist prior to dispensing. In the event that the pharmacist does not verify the intended presentation prior to dispensing, we note that the 100 mg product strength is available in both the vial and autoinjector/prefilled syringe presentations (see Table 1) and therefore, the patient would still receive the correct product and dose. Additionally, we have not identified any medication errors with the proprietary name, Nucala. Therefore, we find the Applicant's proposal to market the proposed subcutaneous formulation with the proprietary name Nucala acceptable.

2.2.6 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 April 11, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) on April 15, 2019, they stated no additional concerns with the proposed proprietary name, Nucala.

3 CONCLUSION

The proposed proprietary name, Nucala, 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 GLAXOSMITHKLINE, LLC.

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 submission, received on January 28, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

Reference ID: 4422455

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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