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RESEARCH**

APPLICATION NUMBER:

208224Orig1s000

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:	February 16, 2016
Application Type and Number:	NDA 208224
Product Name and Strength:	Kyleena (Levonorgestrel-releasing Intrauterine System) 19.5 mg
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bayer Healthcare Pharmaceuticals
Panorama #:	2015-2206092
DMEPA Primary Reviewer:	Walter Fava, RPh. MSED., Safety Evaluator
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

1 INTRODUCTION

The proposed proprietary name, Kyleena, was reviewed by DMEPA on September 9, 2015 under IND 73505 and was found conditionally acceptable.¹ We note that the product characteristics are the same. This memorandum is to re-assess the proposed proprietary name, Kyleena, under the NDA 208224.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA searched the POCA databases for “names entered by safety evaluators” to identify any new names with orthographic and phonetic similarity to the proposed name not identified in the previous OSE proprietary name review #2015-244304. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN update.²

Our re-assessment identified three new names with the combined orthographic and phonetic score of $\geq 50\%$, however, none of the three names pose a risk for confusion as described in Appendix A. Finally, the January 25, 2016 search of the USAN stems did not find any USAN stems in the proposed proprietary name.

Thus, our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name and we maintain the name is acceptable.

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 Bone, Reproductive, and Urologic Products (DBRUP) concurred with the findings of OPDP’s assessment of the proposed name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name is acceptable from both a promotional and safety perspective under the NDA 208224.

If you have further questions or need clarifications, please contact Shawnetta Jackson, OSE project manager at 301-796-4952.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 08, 2015 submission are altered, the name must be resubmitted for review.

¹ Fava, W. Proprietary Name Review for Kyleena (levonorgestrel-releasing Intrauterine System), (IND 073505). 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). 2015 SEP 09. Panorama No. 2015-244304: 2015 SEP 09.

² USAN stem search conducted on January 25, 2016

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. 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.

APPENDICES

Appendix A: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Kyleena Established name: Levonorgestrel Strength(s): 19.5 mg Usual Dose: Place one system into uterus one time for up to five years.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	(b) (4)	66	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair have sufficient phonetic differences.
2.	(b) (4)	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair have sufficient phonetic differences. Kyleena contains an additional syllable which also helps to differentiate this name pair when spoken.

No.	Proposed name: Kyleena Established name: Levonorgestrel Strength(s): 19.5 mg Usual Dose: Place one system into uterus one time for up to five years.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	(b) (4)	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic differences.</p>

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/s/

WALTER L FAVA
02/16/2016

DANIELLE M HARRIS
02/17/2016