

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203159Orig1s000

PROPRIETARY NAME REVIEW(S)

**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 Review--Final

Date: October 22, 2012

Reviewer(s): Alison Park, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, PharmD, Team Leader
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Skyla (Levonorgestrel-Releasing Intrauterine System)
13.5 mg

Application Type/Number: NDA 203159

Applicant: Bayer Healthcare Pharmaceuticals Inc.

OSE RCM #: 2012-2111

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Skyla, is written in response to the anticipated approval of this NDA 203159 within 90 days from the date of this review. The review clock for this NDA has been extended from the original date of October 9, 2012 to the new PDUFA date of January 9, 2013 due to a Major Amendment. DMEPA found the proposed name, Skyla, acceptable in OSE Review# 2012-1521 dated July 19, 2012, OSE Review# 2011-4639 dated March 7, 2012, and OSE Review# 2011-1208 dated September 30, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (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. For this review we used the same search criteria described in OSE Review 2011-4639 and OSE Review 2011-1208. We note that none of the proposed product characteristics were altered. However, 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. The searches of the databases yielded two new names (b) (4) thought to look or sound similar to Skyla and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Skyla and lead to medication errors. This analysis determined that the name similarity between Skyla and the identified names was unlikely to result in medication error for the reasons presented in Appendix A and Appendix B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of September 18, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on September 26, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Skyla, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Skyla, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Reproductive and Urologic Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Marcus Cato, OSE project manager, at 301-796-3903.

4 REFERENCES

1. **Park, A., OSE Review # 2012-1521**, Proprietary name review for Skyla (NDA 203159, Pre-action), July 19, 2012.
Park, A., OSE Review # 2011-4639, Proprietary name review for Skyla (NDA 203159), March 7, 2012.
Abate, R., OSE Review # 2011-1208, Proprietary name review for Skyla (IND 073505), September 30, 2011.
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved 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](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **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.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Skyla	Failure Preventions
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Appendix B: FMEA Table

PROPOSED NAME: Skyla (Levonorgestrel-releasing Intrauterine System)	STRENGTH: 13.5 mg	USUAL DOSE: One system to be inserted by a healthcare provider and remains in place for up to 3 years.
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)

(b) (4)



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/s/

ALISON J PARK
10/22/2012

ZACHARY A OLESZCZUK
10/23/2012

**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 Review--Final

Date: July 19, 2012

Reviewer(s): Alison Park, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, PharmD, Team Leader
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Skyla (Levonorgestrel-Releasing Intrauterine System)
13.5 mg

Application Type/Number: NDA 203159

Applicant: Bayer Healthcare Pharmaceuticals Inc.

OSE RCM #: 2012-1521

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1 INTRODUCTION

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2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (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. For this review we used the same search criteria described in OSE Review 2011-4639 and OSE Review 2011-1208. We note that none of the proposed product characteristics were altered. However, 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. The searches of the databases yielded seven new names (b) (4) thought to look or sound similar to Skyla and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Skyla and lead to medication errors. This analysis determined that the name similarity between Skyla and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 12, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on July 12, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Skyla, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Skyla, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Reproductive and Urologic Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Marcus Cato, OSE project manager, at 301-796-3903.

4 REFERENCES

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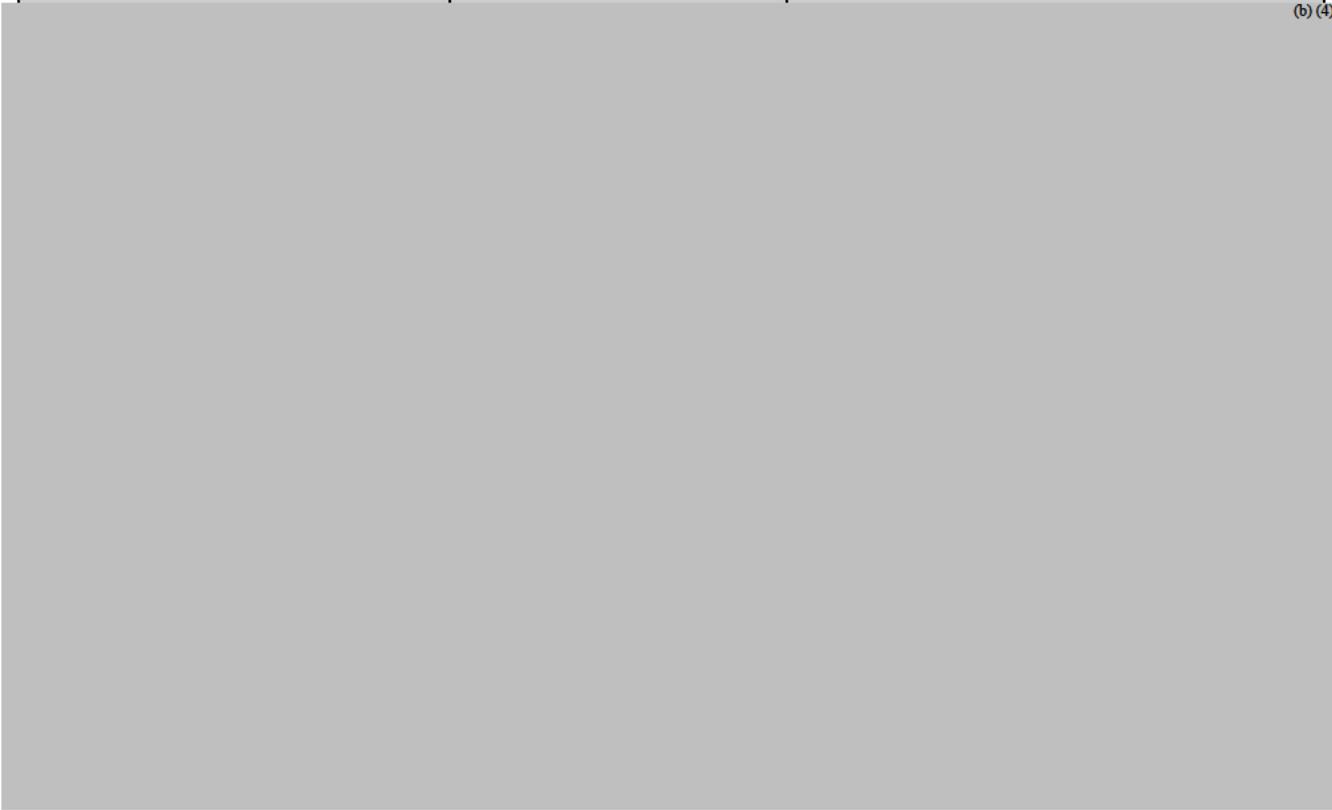


(b) (4)

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(b) (4)



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/s/

ALISON J PARK
07/19/2012

ZACHARY A OLESZCZUK
07/20/2012