CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

2082886Orig1s000

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)

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Date of This Review:	April 3, 2018
Application Type and Number:	NDA 208288
Product Name and Strength:	SoluPrep (Chlorhexidine Gluconate/Isopropyl Alcohol) Topical Solution, 2%/70%
Product Type:	Multi-ingredient Product
Rx or OTC:	OTC
Applicant/Sponsor Name:	3M Healthcare Inc.
Panorama #:	2018- 21245098
DMEPA Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Acting Deputy Director:	Danielle Harris, PharmD, BCPS
DMEPA Division Director:	Todd Bridges, RPh

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, SoluPrep, which was found conditionally acceptable under IND 076549 on March 3, 2015,[a] and under NDA 208288 on October 9, 2015,[b] and on May 19, 2017.[c]

The application received a Complete Response (CR) letter on May 6, 2016 and a second CR letter on September 1, 2017.

The Applicant submitted a Class 2 Resubmission on February 9, 2018, and requested a review of the proposed proprietary name, SoluPrep, on February 23, 2018. We note that all product characteristics in this current submission remain the same since our last May 19, 2017 review.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Division of Nonprescription Drug Products (DNDP) determined that the proposed name would not misbrand the proposed product. DMEPA concurred with the findings of DNDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 19, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the DNDP via e-mail on March 27, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNDP on April 2, 2018, they stated no additional concerns with the proposed proprietary name, SoluPrep.

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[a] Jones, GP. Proprietary Name Review for SoluPrep. IND 076549. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 MAR 03. Panorama No.: 2014-39497.

[b] Jones, GP. Proprietary Name Memorandum for SoluPrep. NDA 208288. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 OCT 09. Panorama No.: 2015-1210657.

[c] Jones, GP. Proprietary Name Review for SoluPrep. NDA 208288. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAY 19. Panorama No.: 2017-13536820.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Abiola Olagundoye-Alawode, OSE project manager, at 301-796-3982.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on February 23, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GRACE JONES
04/03/2018

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