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RESEARCH**

APPLICATION NUMBER:

214993Orig1s000

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:	July 15, 2021
Application Type and Number:	NDA 214993
Product Name and Strength:	Nephroskan (kit for the preparation of technetium Tc 99m succimer) for injection, 1 mg succimer per vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Theragnostics Inc (Theragnostics)
Panorama or PNR ID #:	2021-1044724024
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nephroscan, which was found conditionally acceptable under IND 145176 on March 29, 2021.^a Thus, Theragnostics submitted the name, Nephroscan, under NDA 214993 for review on May 19, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nephroscan would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Medical Imaging and Radiation Medicine (DMIRM) concurred with the findings of OPDP's assessment for Nephroscan.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, 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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The June 29, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Nephroscan.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Medical Imaging and Radiation Medicine (DMIRM). At that time we also requested additional information or concerns that could inform our review. On July 14, 2021, the Division of Medical Imaging and Radiation Medicine (DMIRM) stated no additional concerns with the proposed proprietary name, Nephroscan.

3 CONCLUSION

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, Nephroscan, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO THERAGNOSTICS INC

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

^a Kane, D. Proprietary Name Review for Nephroscan (IND 145176). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 26. Panorama No.: 2020-43255895.

If any of the proposed product characteristics as stated in your submission, received on May 19, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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07/15/2021 08:25:08 AM

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07/16/2021 10:13:46 AM