CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202158Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMO

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:	September 28, 2017
Application Type and Number:	NDA 202158
Product Name:	RadioGenix System
Product Strength:	N/A
Product Type:	Combination Product
Rx or OTC:	N/A
Applicant/Sponsor Name:	NorthStar Medical Radioisotopes, LLC
Panorama #:	2017-16671383
DMEPA Safety Evaluator:	Idalia E. Rychlik, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH
Division Director:	Todd Bridges, RPh

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, RadioGenix System, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 4, 2017 proprietary name submission.

- Intended Pronunciation:\ra-de-o- jen-iks\ \ sis-tem\
- Active Ingredient: Sodium Pertechnetate Tc 99m Injection
- Indication of Use: The RadioGenix System is a closed automated system used to process solutions of non-Uranium sourced potassium Molybdate Mo-99 to produce Sodium Pertechnetate Tc-99m. Sodium Pertechnetate Tc-99m Injection is for use in the preparation of FDA-approved diagnostic radiopharmaceuticals, as described in the labeling of these diagnostic kits.
- Route of Administration: N/A
- Dosage Form: N/A
- Strength: N/A
- Volume Limits:

RadioGenix Eluate Volume Limits	
Radiopharmaceutical	Maximum RadioGenix Tc-99m Eluate
Exametazime	1 mL
MAG3	3 mL
Sestamibi	3 mL

- How Supplied: RadioGenix System is a standalone automated generator.
- Storage: N/A
- Container and Closure Systems: N/A

2 RESULTS

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

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 Medical Imaging Products (DMIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

The proposed proprietary name, RadioGenix System, contains the United States Adopted Name (USAN) stem –io- in the infix position. The stem –io- in the infix position is used by the USAN Council to indicate iodine containing products.[a] Typically, proprietary names should not incorporate USAN stems in the position that USAN designates for the stem. [b] However, the proprietary name, RadioGenix System, is in reference to an automated separation generator used to process solutions of non-Uranium sourced Potassium Molybdate Mo-99 to produce Sodium Pertechnetate Tc-99m Injection. The proposed proprietary name, RadioGenix System, will not be present in the areas of the United States medication-use system (e.g. prescribing, dispensing and administration) in which name confusion typically occurs. Therefore, in this specific instance, we do not believe that the inclusion of the –io- USAN stem will present a risk of name confusion.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, RadioGenix System, is derived from the contracted form of the chemical name, *radio*, and *gen*erator. This proprietary name is comprised of a two word string 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.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 16, 2016 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

3 CONCLUSIONS

The proposed proprietary name 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 THE APPLICANT

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

---

[a] USAN stem search conducted on (8/9/2017).

[b] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM39899

If any of the proposed product characteristics as stated in your August 4, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

/s/

IDALIA E RYCHLIK
09/28/2017

HINA S MEHTA
09/29/2017

MISHALE P MISTRY
09/29/2017

DANIELLE M HARRIS on behalf of TODD D BRIDGES
09/29/2017