CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213227Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	August 18, 2020
Application Type and Number:	NDA 213227
Product Name and Strength:	Detectnet (copper Cu 64 Dotatate) Injection, 37 MBq/mL (1 mCi/mL)
Total Product Strength:	148 MBq/4 mL (4 mCi/4 mL) at calibration date and time
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	RadioMedix Innovating Theranostics (RadioMedix Inc.)
Panorama #:	2020-40390727
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Detectnet, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. RadioMedix Inc. submitted an external name study, conducted (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

RadioMedix Inc. previously submitted the proposed proprietary name, (b) (4) *** on January 22, 2019 under IND 131797. DMEPA found the proposed name, (b) (4) ***, conditionally acceptable on July 21, 2019.[a] However, in their letter dated December 31, 2019 RadioMedix Inc. decided not to submit this proprietary name for review under NDA 213227 due to trademark issues.

On February 27, 2020, RadioMedix Inc. submitted the proposed proprietary name, (b) (4) ***, for review under NDA 213227. DMEPA found the proposed proprietary name, (b) (4) ***, conditionally acceptable on May 19, 2020.[b] RadioMedix Inc. withdrew (b) (4) *** on June 3, 2020.

Thus, RadioMedix Inc. submitted the name, Detectnet, for review on June 3, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 3, 2020.

- Intended Pronunciation: dɪ'tekt ˌnet
- Active Ingredient: copper Cu 64 Dotatate
- Indication of Use: (b) (4) is a radioactive diagnostic agent indicated for use with positron emission tomography (PET) for (b) (4) localization (b) (4) of somatostatin receptor positive neuroendocrine tumors (NETs) in adults.
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 148 MBq/4 mL (4 mCi/4 mL) at calibration date and time
- Dose and Frequency: 4 mCi (148 MBq) administered as an intravenous bolus injection
- How Supplied: sterile, (b) (4) clear, colorless to yellow solution (b) (4) (b) (4) in a (b) (4) 10 mL single-dose vial.
- Storage: (b) (4)

[a] Ogbonna, C. Proprietary Name Review for (b) (4) (IND 131797). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 July 21. Panorama No. 2019-28783182.

[b] Kane, D. Proprietary Name Review for (b) (4) (NDA 213227). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAY 19. Panorama No.: 2020-38136014.

(b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Detectnet 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 Detectnet.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Detectnet.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[c].

2.2.2 Components of the Proposed Proprietary Name

RadioMedix Inc. indicated in their submission that the proposed proprietary name, Detectnet, is derived from the word "detect". This refers to the indication of the product, which is to detect tumors. This proprietary name is comprised of a single word 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, June 25, 2020 e-mail, the Division of Medical Imaging and Radiation Medicine (DMIRM) did not forward any comments or concerns relating to Detectnet at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-four practitioners participated in DMEPA's prescription studies for Detectnet. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

[c] USAN stem search conducted on June 25, 2020.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 193 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	173
Low similarity name pair: combined match percentage score ≤54%	18

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 193 names contained in Table 1 determined none of the names will pose a risk for confusion with Detectnet as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Medical Imaging and Radiation Medicine (DMIRM) via e-mail on August 14, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Medical Imaging and Radiation Medicine (DMIRM) on August 17, 2020, they stated no additional concerns with the proposed proprietary name, Detectnet.

3 CONCLUSION

The proposed proprietary name, Detectnet, is acceptable.

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

[d] POCA search conducted on June 17, 2020 in version 4.3.

3.1 COMMENTS TO RADIOMEDIX INNOVATING THERANOSTICS

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

We note that the presentation of the name in the proprietary name request that you submitted had the letter string "net" (b) (4) However, as noted above we have evaluated and found your name, Detectnet, conditionally acceptable. The Agency will provide additional comments on the formatting of the name at the time of Agency review of labels and labeling.

If any of the proposed product characteristics as stated in your submission, received on June 3, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

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.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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. [e]

[e] 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.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Detectnet Study (Conducted on June 26, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: (b) (4) Inject 4 mCi (148 MBq) intravenously Outpatient Prescription: Patient _____ Date 6/26/20 Address _____ ℞ (b) (4) MEDWATCH 1-800-FDA-1088 Bring to clinic #1 Refill(s):_____ Dr. Ose DEA No._____ Address _____ Telephone _____ **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** (b) (4)	Detectnet Bring to Clinic #1

FDA Prescription Simulation Responses (Aggregate Report)

207 People Received Study
84 People Responded

Study Name: Detectnet

Total	**17**	**23**	**15**	**29**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
DEFECTNET	0	0	0	2	2
DEJECT NET	6	0	0	0	6
DEJEET NET	2	0	0	0	2
DETECT MED	0	0	1	0	1
DETECT NET	5	0	1	5	11
DETECTNED	0	0	1	0	1
DETECTNET	3	23	8	21	55
DETECTNET INJECTION	0	0	0	1	1
DETEET NET	1	0	0	0	1
DETEXMED	0	0	1	0	1
DETEXNET	0	0	3	0	3

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	(b) (4) ***	100	Name being evaluated by study.
2.	Neo Tect Kit	71	Proprietary name for NDA 021012 withdrawn FR effective December 7, 2007. No generic equivalents available.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
3.	Deponit	60
4.	Depotest	60
5.	Dibent	57
6.	Dimetane-Ten	59
7.	Dtic-Dome	56
8.	Entercote	56
9.	Kaopectate 1-D	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
10.	Anectine	55	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
12.	Bendectin	68	Orthographically, the prefix (‘Ben’ vs ‘Det”), infix (‘dec’ vs ‘ect’) and suffix

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
			('tin' vs 'net') provides some differences. Phonetically, the first ('Ben' vs. 'De') and third syllables ('tin' vs. 'net') provide some differences. Although Bendectin and Detectnet are similar in frequency of administration (one tablet orally once daily at bedtime *versus* once), this name pair differs in strength (10 mg/10 mg and 20 mg/20 mg *versus* 148 MBq (4 mCi)). Additionally, these products differ in dosage form (tablet versus injection), and route of administration (oral *versus* intravenous). We note that Detectnet will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for positron emission tomography (PET) and is limited to specialized handling, preparation, and dispensing. Thus, these product characteristic differences provide additional differentiation if included on a prescription.
13.	Decaject	61	Orthographically, the downstroke from the letter 'j' in Decaject and the upstrokes from the letter 't' in the third and sixth positions of Detectnet provide sufficient differences. Phonetically, the second ('ca' vs. 'tect') and third syllables ('ject' vs. 'net') provide sufficient differences.

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
			Although Decaject and Detectnet can be similar in strength (4 mg/mL *versus* 4 mCi/4 mL (148 MBq/4 mL)), this name pair differs in frequency of administration (First day, 4 to 8 mg intramuscularly; second and third days, dexamethasone (base) 4 tablets (0.75 mg each) in 2 divided doses each day; fourth day, 2 tablets in 2 divided doses; fifth and sixth days, 1 tablet each day; seventh day, no treatment *versus* once). Additionally, this name pair differs in the route of administration (intramuscularly *versus* intravenously). We note that Detectnet will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for positron emission tomography (PET) and is limited to specialized handling, preparation, and dispensing. Thus, these product characteristic differences provide additional differentiation if included on a prescription.
14.	Decitabine	58	This name pair has sufficient orthographic and phonetic differences.
15.	Decongest	62	This name pair has sufficient orthographic and phonetic differences.
16.	(b) (4) ***	62	(b) (4)

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
			(b) (4)
17.	Definity	56	This name pair has sufficient orthographic and phonetic differences.
18.	Delta-Cortef	58	This name pair has sufficient orthographic and phonetic differences.
19.	Depakote	56	This name pair has sufficient orthographic and phonetic differences.
20.	Depakote Er	57	This name pair has sufficient orthographic and phonetic differences.
21.	Depletite	58	This name pair has sufficient orthographic and phonetic differences.
22.	Depoject-80	59	This name pair has sufficient orthographic and phonetic differences.
23.	Dermtex Hc	56	This name pair has sufficient orthographic and phonetic differences.
24.	Desenex	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
25.	Desitin	56	This name pair has sufficient orthographic and phonetic differences.
26.	Desonate	58	This name pair has sufficient orthographic and phonetic differences.
27.	Despec Tablet	64	This name pair has sufficient orthographic and phonetic differences.
28.	Detane	56	This name pair has sufficient orthographic and phonetic differences.
29.	Dexacorten	56	This name pair has sufficient orthographic and phonetic differences.
30.	Dextenza	60	This name pair has sufficient orthographic and phonetic differences.
31.	Dextran	57	This name pair has sufficient orthographic and phonetic differences.
32.	Dextran 1	57	This name pair has sufficient orthographic and phonetic differences.
33.	Dextran 110	57	This name pair has sufficient orthographic and phonetic differences.
34.	Dextran 40	57	This name pair has sufficient orthographic and phonetic differences.
35.	Dextran 70	57	This name pair has sufficient orthographic and phonetic differences.
36.	Dextran 75	57	This name pair has sufficient orthographic and phonetic differences.
37.	Dexycu Kit	56	This name pair has sufficient orthographic and phonetic differences.
38.	Dimetapp Nd	60	This name pair has sufficient orthographic and phonetic differences.
39.	Dipentum	56	This name pair has sufficient orthographic and phonetic differences.
40.	Doptelet	56	This name pair has sufficient orthographic and phonetic differences.
41.	Dostinex	56	This name pair has sufficient orthographic and phonetic differences.
42.	Duetact	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	**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**
43.	Dupixent	66	This name pair has sufficient orthographic and phonetic differences.
44.	Duramectin	56	This name pair has sufficient orthographic and phonetic differences.
45.	Dytan-At	56	This name pair has sufficient orthographic and phonetic differences.
46.	Edetate	56	This name pair has sufficient orthographic and phonetic differences.
47.	Entrectinib	62	This name pair has sufficient orthographic and phonetic differences.
48.	Ethedent	58	This name pair has sufficient orthographic and phonetic differences.
49.	Gattex Kit	64	This name pair has sufficient orthographic and phonetic differences.
50.	Ide-Cet	58	This name pair has sufficient orthographic and phonetic differences.
51.	Medent C	60	This name pair has sufficient orthographic and phonetic differences.
52.	Netupitant	60	This name pair has sufficient orthographic and phonetic differences.
53.	Nurtec Odt	58	This name pair has sufficient orthographic and phonetic differences.
54.	Pectin	56	This name pair has sufficient orthographic and phonetic differences.
55.	Pytest Kit	60	This name pair has sufficient orthographic and phonetic differences.
56.	Tecentriq	63	This name pair has sufficient orthographic and phonetic differences.
57.	Technescan	55	This name pair has sufficient orthographic and phonetic differences.
58.	Tencet	60	This name pair has sufficient orthographic and phonetic differences.
59.	Teveten	55	This name pair has sufficient orthographic and phonetic differences.
60.	Tolectin	59	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Detectnet **Established name:** copper Cu 64 Dotatate **Dosage form:** Injection **Strength(s):** 37 MBq/mL (1 mCi/mL) **Usual Dose:** 4 mCi (148 MBq) as a single intravenous bolus injection.	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**
61.	Tolectin 600	59	This name pair has sufficient orthographic and phonetic differences.
62.	Tolectin Ds	58	This name pair has sufficient orthographic and phonetic differences.
63.	Totect	57	This name pair has sufficient orthographic and phonetic differences.
64.	Trabectedin	60	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
65.	Deet	41
66.	Ectoine	45
67.	Endocet	54
68.	Etanercept	52
69.	Nordette	51
70.	(b) (4) ***	51
71.	Nordette-28	51
72.	Octadecene	49
73.	Technelite	54
74.	Tencon	50
75.	Tetcaine	52
76.	Tetradecane	54
77.	Undeceth-5	54
78.	Undeceth-7	54

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
79.	1-Decene	52	Product is not a drug. Decene is an alkene with the formula $C_{10}H_{20}$.
80.	(b) (4) ***	66	(b) (4)
81.	Bimectin	60	Veterinary product.
82.	Cydectin	68	Veterinary product.
83.	Decazate	58	International product formerly marketed in the United Kingdom.
84.	Deceth-6	53	Product is not a drug. It is an ingredient for cosmetic formulations.
85.	Deceth-8	53	Product is not a drug. It is an ingredient for cosmetic formulations.
86.	Decohistine Dh	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
87.	Deconex	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
88.	Decongest-B	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
89.	Deconsal Ct	55	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
90.	Decoquinate	56	Veterinary product.
91.	Dectomax	58	Veterinary product.
92.	Defencin Cp	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
93.	Delhistine D	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
94.	Depakote Cp	61	Withdrawn FR Effective 6/18/2009; sponsor voluntarily requested withdrawal of approval of this application because they have no plan to market the drug product under the NDA 019794.
95.	Depandrate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
96.	Depestrate	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
97.	Depocyt	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
98.	Desenex Foot	60	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
99.	Despec Pd	56	International drug product marketed in Puerto Rico.
100.	Despec-Pdc	64	International drug product marketed in Puerto Rico.
101.	Dexaject	58	Veterinary product.
102.	Dextrates	57	Product is not a drug. Product is (b) (4)
103.	Dextraven-110	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
104.	Diatensec	64	International drug product formerly marketed in the United Kingdom.
105.	Diet Caplets	57	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
106.	Dimetane	60	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
107.	Dimetane Dc	60	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
108.	Diphentann	56	Product contained an active ingredient that was in tannate salt form. FDA determined these ingredients are not generally recognized as safe and effective (FR effective 3/3/2011). The Agency took enforcement action against such products and those who manufactured them or caused them to be manufactured or shipped in interstate commerce.

No.	Name	POCA Score (%)	Failure preventions
109.	Diphentann D	60	Product contained an active ingredient that was in tannate salt form. FDA determined these ingredients are not generally recognized as safe and effective (FR effective 3/3/2011). The Agency took enforcement action against such products and those who manufactured them or caused them to be manufactured or shipped in interstate commerce.
110.	Direct Black 19	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
111.	Ditate-Ds	58	Brand discontinued with no generic equivalent available. ANDA 086423 withdrawn FR effective 01/24/1989.
112.	Doconexent	62	Not a drug. It is a component of dietary supplements.
113.	Doramectin	56	Veterinary product.
114.	Dotatate	57	Active ingredient for several drug products. Not available as a standalone product.
115.	Doxatet	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
116.	Edetic Acid	60	Compounding ingredient. Not available for commercial sale.
117.	Emete-Con	57	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
118.	Endo-Mectin	57	Veterinary product.
119.	Entyce	46	Veterinary product.
120.	Ketaject	56	International drug product formerly marketed in the Philippines.
121.	Medent	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
122.	Nordette-21	51	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
123.	Perfect Coat	56	Veterinary product.
124.	Pet Pectillin	56	Veterinary product.
125.	Spectamine	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
126.	Tetradecene	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
127.	Teveten Hct	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
128.	Xpect Pe	58	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
129.	Xpect-At	62	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.
130.	Zaptec Pse	56	Name identified in RxNorm database. Per Redbook, drug product is deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g].

No.	Name	POCA Score (%)
131.	Beractant	64
132.	Betadren	56
133.	Betanate	58
134.	Beta-Pinene	57
135.	Betastat	60
136.	Betavent	60
137.	Betaxon	56
138.	Betoptic	58
139.	Canesten	57
140.	Canesten Af	58
141.	Cefetamet	64
142.	Cefotetan	57
143.	Cenestin	58
144.	Cepastat	55
145.	Cetazone T	64
146.	Citanest	59
147.	C-Phed Tannate	58

[g] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
148.	Emtexate	58
149.	Entex Pse	55
150.	Entex T	59
151.	Entocort Ec	55
152.	Etretinate	58
153.	Gadoxetate	56
154.	Genestin	56
155.	Gentex Hc	55
156.	Intestinex	56
157.	Lethechniq	56
158.	Mastic Dent	62
159.	Medent Ld	57
160.	Medent-Pe	58
161.	Mentadent	61
162.	Mentax-Tc	59
163.	Metadate Cd	55
164.	Metandren	56
165.	Meticorten	58
166.	Nebupent	55
167.	Neutracett	56
168.	Neutrexin	56
169.	Nicotinex	55
170.	Nuedexta	56
171.	Pediatex Ct	56
172.	Pentetate	59
173.	Pepsodent	55
174.	Peptones	56
175.	Podactin	55
176.	Qternmet***	59
177.	Ridactate	58
178.	Take Action	56
179.	Tetraxetan	57
180.	Tinactin	56
181.	Treximet	56
182.	Trideceth-10	55
183.	Trideceth-12	55
184.	Trideceth-3	55
185.	Trideceth-5	55
186.	Trideceth-6	55
187.	Trideceth-8	55
188.	Trideceth-9	55
189.	Vetaket	56
190.	Videx Ec	58

No.	Name	POCA Score (%)
191.	Zenchent	56
192.	Zetacet	62
193.	Zotex C	55

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/

DEVIN R KANE
08/18/2020 09:19:48 AM

HINA S MEHTA
08/18/2020 11:08:06 AM

PROPRIETARY NAME REVIEW

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*****

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

Date of This Review:	May 15, 2020
Application Type and Number:	NDA 213227
Product Name and Strength:	(b) (4) (copper Cu 64 dotatate) injection, 37 MBq/mL (1 mCi/mL)
Total Product Strength:	148 MBq/mL (4 mCi/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	RadioMedix Innovating Theranostics (RadioMedix Inc.)
Panorama #:	2020-38136014
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

22 Pages have been Withheld in Full as B4 (CCI/TS) immediately following this page

---

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/

DEVIN R KANE
05/15/2020 02:49:03 PM

HINA S MEHTA
05/18/2020 03:37:12 PM