CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022335Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 5, 2023
Application Type and Number:	NDA 022335
Product Name and Strength:	Technegas (kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol) for oral inhalation, 1.25 g
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Cyclomedica Australia Pty Ltd (Cyclomedica)
PNR ID #:	2023-1044725089
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Technegas, 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. Cyclomedica did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Cyclomedica previously submitted the proposed proprietary name, Technegas, on March 26, 2020 under NDA 022335. However, we found the name Technegas unacceptable due to orthographic similarity and overlapping product characteristics with the Technescan products (Technescan HDP, Technescan MAG3, Technescan PYP kits)[a].

On August 31, 2020, Cyclomedica submitted a request for reconsideration of the proposed proprietary name, Technegas, with additional information for the reconsideration submitted on November 17, 2020. Based on the information included in the reconsideration request, the proposed name Technegas was found conditionally acceptable on November 25, 2020.[b] However, on June 25, 2021, NDA 022335 received a Complete Response (CR) letter.[c]

On March 29, 2023, Cyclomedica resubmitted the marketing application for NDA 022335 and thus resubmitted the proposed proprietary names, Technegas, and (b) (4) for consideration.

During the current review cycle, several internal discussions with the review team have led to significant changes in the proposed product characteristics and proposed labeling. Due to ongoing internal discussion and regulatory decision making, DMEPA 2 did not issue a determination on the proposed names within the PDUFA goal date for the name submission. On May 31, 2023 the Office of Pharmaceutical Quality (OPQ) issued an information request (IR) to Cyclomedica that, among other matters, proposed certain relabeling strategies for NDA 022335 with respect to drug substance characterization and drug product specifications. With this proposal, the proposed proprietary name, Technegas, would be assigned to the carbon crucible and a second name (i.e., (b) (4)) would not be necessary, nor appear on approved labels and labeling. On June 30, 2023, Cyclomedica acknowledged the IR from OPQ and agreed with their proposal. Thus, the product characteristics for Technegas have changed since the original review of the proposed name (see Table 1 below) and since the aforementioned March 29, 2023 submission.

To align with the agreed upon relabeling strategies, on August 8, 2023, DMEPA 2 sent an IR to Cyclomedica requesting an amendment to their proposed proprietary name submission. The requested amendment includes the removal of the proposed name "(b) (4)" from the Request for Proprietary Name Review such that the name "(b) (4)" is no longer proposed and only

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[a] Kane, D. Proprietary Name Review for Technegas (NDA 022335). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUN 22. Panorama No. 2020-38417209 and 2020-39052490.

[b] Kane, D. Proprietary Name Review for Technegas (NDA 022335). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 NOV 24. Panorama No. 2020-42607425.

[c] June 25, 2021 CR letter available from:
https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af805fcbf6

"Technegas" is requested for agency review as the proprietary name for the carbon crucible. On August 14, 2023, Cyclomedica submitted an **AMENDMENT TO REQUEST FOR PROPRIETARY NAME REVIEW: TECHNEGAS** under NDA 022335 and aligned with the Agency's request. Furthermore, the cover page of the aforementioned amendment states that Cyclomedica agrees with the Agency's request and no longer plans to include "(b) (4)" as a proprietary name to represent the carbon crucible. (b) (4) However, the Agency has proposed labeling that does not include the name "(b) (4) to which Cyclomedica has agreed. Thus, this review evaluates the proposed proprietary name Technegas, and does not further consider or evaluate the previously proposed name, (b) (4).

Table 1 below reflects the product characteristic history from the first proprietary name review, to the most recent information included in the August 14, 2023 proprietary name amendment submission, whereas Section 1.2 provides the currently available product characteristics based on iterations proposed by the review team and negotiated with Cyclomedica.

Table 1. Product Information Comparison

	NDA 022335 (August 2023)	**NDA 022335 (June 2023)**	**NDA 022335 (November 2020)**
Established Name	Kit for the preparation of technetium Tc 99m labeled inhalation aerosol	Kit for the Preparation of technetium Tc 99m labeled carbon aerosol	Technetium Tc-99m Labeled Carbon
Indication	TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m labeled carbon inhalation aerosol (Technegas Aerosol), a radioactive diagnostic agent for use in adults and pediatric patients aged 6 years and older for:	Technegas is a diagnostic imaging agent indicated for functional lung ventilation imaging (b) (4) in adult and pediatric patients.	

	• visualization of pulmonary ventilation • evaluation of pulmonary embolism when paired with perfusion imaging	
Strength	1.25 g per crucible	N/A (b) (4)
Dose and Frequency	For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas Crucible is 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) to achieve a lung count rate between 1,500 counts per second (cps) and 2,500 cps at the end of the last respiration. For pediatric patients aged 6 years and older, a sufficient amount of Technegas Aerosol should be inhaled to	(b) (4)

	achieve between 500 cps and 1,000 cps at the end of last respiration. The radioactivity to be loaded in the Technegas Crucible is a fraction of the recommended activity for adults adjusted by body weight.	
How Supplied	TECHNEGAS (kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol) is a 1.25 gram single-use black to dark grey oval shape graphite carbon crucible packaged into thermoformed blister packs. Each carton contains five blister packs of 10 single-use Technegas Crucibles (NDC 73814-986-20).	(b) (4)

1.2 PRODUCT INFORMATION

The following product information provides the currently available product characteristics based on iterations proposed by the review team and agreed upon with Cyclomedica during labeling negotiations within the review cycle.

- Intended Pronunciation: Tech' nah gas
- Active Ingredient: kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol
- Indication of Use: TECHNEGAS, when used with sodium pertechnetate Tc 99m in the Technegas Plus System, provides technetium Tc 99m labeled carbon inhalation aerosol (Technegas Aerosol), a radioactive diagnostic agent for use in adults and pediatric patients aged 6 years and older for:

    - visualization of pulmonary ventilation
    - evaluation of pulmonary embolism when paired with perfusion imaging
- Route of Administration: Inhalation
- Dosage Form: for oral inhalation
- Strength: 1.25 g per crucible
- Dose and Frequency:
    - For adult patients, the recommended activity of sodium pertechnetate Tc 99m injection to be loaded in the Technegas Crucible is 400 MBq to 1,000 MBq (10.8 mCi to 27 mCi) to achieve a lung count rate between 1,500 counts per second (cps) and 2,500 cps at the end of the last respiration.
    - For pediatric patients aged 6 years and older, a sufficient amount of Technegas Aerosol should be inhaled to achieve between 500 cps and 1,000 cps at the end of last respiration. The radioactivity to be loaded in the Technegas Crucible is a fraction of the recommended activity for adults adjusted by body weight.
- How Supplied: TECHNEGAS (kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol) is a 1.25 gram single-use black to dark grey oval shape graphite carbon crucible packaged into thermoformed blister packs. Each carton contains five blister packs of 10 single-use Technegas Crucibles (NDC 73814-986-20).
- Storage: Store Technegas Crucibles at 15° to 30°C (59° to 86° F). Store unused crucibles in the original package to prevent contamination of crucibles.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Technegas would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Technegas. The Division of Medical Imaging and Radiation Medicine (DIRM) did not comment on the findings of OPDP's assessment for Technegas.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Cyclomedica indicated in their submission that the proposed proprietary name, Technegas, is an acronym composed of two components. Per the Applicant:

"*The prefix "Techne-" identifies the agent as a product that contains radioactive technetium Tc-99m, a mono-energetic gamma emitting isotope with an ideal energy and physical half-life for nuclear medicine imaging. Technetium-99m enjoys a versatile chemistry such that it can readily be reacted with a variety of ligands and as such it is commonly estimated that various chemical complexes of Tc-99m are used to perform over 80% of nuclear medicine diagnostic exams. The suffix "gas" is added because the ultrafine particles produced by the TechnegasPlus Technegas™ Generator distribute within the lungs as if it were a gas and is often referred to as a pseudogas.*

Thus the "Techne" and "gas" taken together provides a readily recognized identification of this radioactive aerosol with gas-like distribution in the lungs. However, unlike a gas, the small particulates will deposit in the alveolar regions of the lung periphery and are retained in the lungs for a sufficient time to permit multiple views and projections of the lung permitting the reconstruction of 3-dimensional lung images that accurately define well ventilated regions of the lungs from poorly ventilated or non-ventilated regions."

We generally recommend the avoidance of incorporating product-specific attributes as part of the proprietary name. In this instance, we note that although the product is an aerosol for inhalation, per the applicant, the product distributes within the lungs as if it were a gas. Additionally, OPDP did not object to the proposed proprietary name from a misbranding perspective when considering the inclusion of this products specific attribute. In this instance, we do not think that the inclusion of the product-specific attribute 'gas' poses additional risks for medication errors and thus, do not object to its inclusion in the proprietary name at this time. We discussed this matter internally and obtained alignment with the review team to allow 'gas' in the proposed proprietary name, in this instance.

This proprietary name is comprised of a single word that contains the letter string 'as', which is a medical abbreviation for 'left ear', in the suffix, and 'ec', which is a medical abbreviation for 'enteric coated', in the infix. We typically discourage the inclusion of medical abbreviations in proprietary names; however, we determined that the location of the abbreviation 'ec' in the middle of the name makes it unlikely that the letters 'ec' within the proposed proprietary name, Technegas, could lead to confusion in this case.

For the 'as' abbreviation, we evaluated the potential risk of misinterpreting the proposed proprietary name Technegas as "[drug name similar to Techneg] + AS" and did not identify any concern.[e] Additionally, the proposed product is a carbon crucible required for the production of Technetium Tc 99m labeled carbon aerosol and could not be administered via the otic route.

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[d] USAN stem search conducted on May 10, 2023.

[e] POCA search for "Techneg" conducted on June 5, 2023 in version 5.2.

Thus, we do not object to the inclusion of the letter string 'as' and 'ec' in this case. Beyond these abbreviations, we note that Technegas does not contain any additional components (i.e. a modifier, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On May 19, 2023, the Division of Medical Imaging and Radiation Medicine (DIRM) did not forward any comments or concerns relating to Technegas at the initial phase of the review. However, during ongoing labeling meetings with DIRM and Office of Pharmaceutical Quality (OPQ) for this NDA, concerns were expressed with the proposed proprietary name and how to name each of the individual components involved in the production of the Technegas Aerosol. Ultimately, the review Divisions and DMEPA agreed on assigning the proposed name, Technegas, to the carbon crucible and then utilizing descriptive labeling modifiers for the other components (i.e. Technegas Plus System, Technegas Contacts, Technegas Aerosol) within other aspects of the labeling to which Cyclomedica has agreed.

2.2.4 FDA Name Simulation Studies

Eighty-eight (88) practitioners participated in DMEPA's prescription studies for Technegas. 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 124 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-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 name. We note there was a change in the proposed established name and strength (See Table 1 above). All other product characteristics remain the same. Upon re-evaluation, we agree with the findings from our previous review for the names previously evaluated.

Therefore, we identified 8 names not previously analyzed. These names are included in Table 2 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 2 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**

[f] POCA search conducted on April 5, 2023 in version 5.2.

Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	8
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 8 names contained in Table 2 determined none of the names will pose a risk for confusion with Technegas as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On September 5, 2023, DMEPA 2 communicated our determination to the Division of Medical Imaging and Radiation Medicine (DIRM).

3 CONCLUSION

The proposed proprietary name, Technegas, is conditionally 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 CYCLOMEDICA AUSTRALIA PTY LTD

We have completed our review of the proposed proprietary name, Technegas, and have concluded that this name is conditionally acceptable. We also acknowledge your comments in your **AMENDMENT TO REQUEST FOR PROPRIETARY NAME REVIEW: TECHNEGAS** dated August 14, 2023 pertaining to the use of an alternative proprietary name in scientific literature and by various regulatory authorities in foreign markets. However, in alignment with the previously agreed-upon changes to your product labeling, no alternative proprietary names were considered for inclusion in your product labeling as part of this Proprietary Name Review.

If any of the proposed product characteristics as stated in your submission, received on March 29, 2023, 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 3*. 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. [g]

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 3- 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, Cerner RxNorm, 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 4-6) 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 4).
- 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[h]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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.

[h] 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.

   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 4. 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 5: 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.

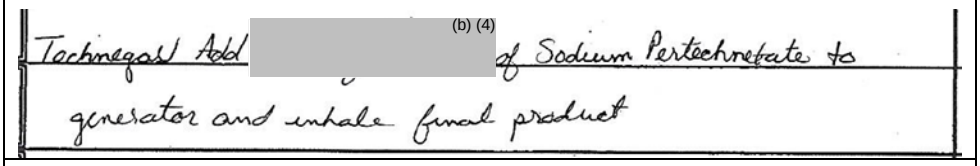
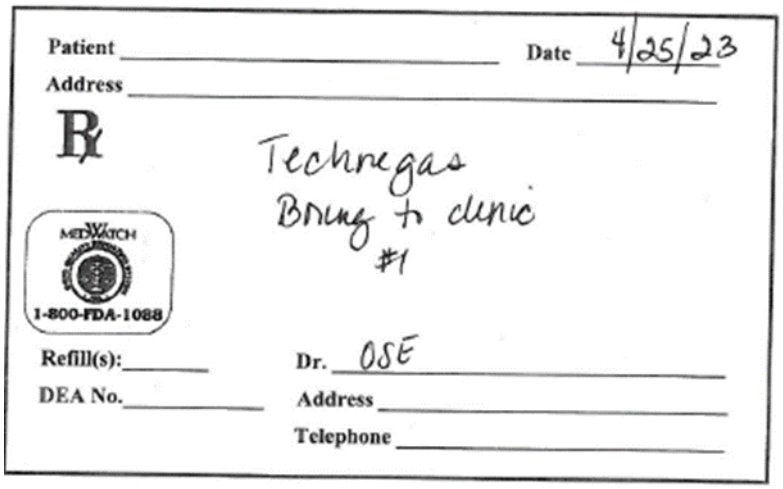
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 6: 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. Technegas Study (Conducted on April 25, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order[i]:  	Technegas Bring to clinic #1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Technegas	

[i] We note some of the product characteristics for Technegas have changed since the original review of the proposed name (see Table 1 above) and since the March 29, 2023 proprietary name submission. Specifically, the loading dose of Sodium Pertechnetate Tc 99m added to the Technegas Crucible evaluated in the Inpatient Prescription Study is no longer reflective of the loading dose included in the proposed labeling. However, this change did not preclude our review of the study results.

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Technegas

256 People Received Study

88 People Responded

Total	21	23	19	25	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
SODIUM PERTECHNETATE (ADD TO TECHNIGAS)	1	0	0	0	1
TACHNEGALL	1	0	0	0	1
TACHNEGAU	1	0	0	0	1
TACHNEQAS	1	0	0	0	1
TECHNAGAS	0	0	4	0	4
TECHNEGAL	1	0	0	0	1
TECHNEGAR	1	0	0	0	1
TECHNEGAS	10	23	0	23	56
TECHNEQALL ADD	1	0	0	0	1
TECHNEQAS	1	0	0	0	1
TECHNEQASL	1	0	0	0	1
TECHNEQGAS	0	0	1	0	1
TECHNIGAS	0	0	10	0	10
TECHREGAS	0	0	0	2	2
TECKNEGAS	0	0	1	0	1
TECNEGAS	0	0	1	0	1
TEKNAGAS	0	0	1	0	1
TEKNAGAST	0	0	1	0	1
TOCHNEGAS	1	0	0	0	1
TOCHNEGASL	1	0	0	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%) – **N/A**

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 – **N/A**

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:** Technegas **Established name:** kit for the preparation of technetium Tc 99m labeled carbon inhalation aerosol **Dosage form:** for oral inhalation **Strength(s):** (b) (4) **Usual Dose:** Inhale approximately 40 MBq (1.08 mCi) once as needed for functional lung imaging.	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**
1.	Tavneos	60	This name pair has sufficient orthographic and phonetic differences.
2.	Tecartus	59	This name pair has sufficient orthographic and phonetic differences.
3.	Tascenso ODT	58	This name pair has sufficient orthographic and phonetic differences.
4.	Detectnet	57	This name pair has sufficient orthographic and phonetic differences.
5.	Tascenso (root name for Tascenso ODT)	56	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%) – **N/A**

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

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	59
2.	Dectogard	58
3.	Bexacat	56

[j] 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

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/s/

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09/06/2023 08:36:47 AM
Signed on behalf of Danielle Harris

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:	November 24, 2020
Application Type and Number:	NDA 022335
Product Name and Strength:	Technegas (Technetium Tc-99m labeled carbon) aerosol for inhalation, and (b) (4) (kit for the preparation of technetium Tc-99m carbon inhalation) for inhalation
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Cyclomedica Australia Pty Ltd (Cyclomedica)
Panorama #:	2020-42607425 and 2020-42480722
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review responds to an August 31, 2020 request from Cyclomedica Australia Pty Ltd to reconsider the proposed proprietary names, Technegas and (b) (4) for NDA 022335 from a safety and misbranding perspective. Cyclomedica did not submit an external study for these proposed proprietary names.

1.1 REGULATORY HISTORY

Cyclomedica previously submitted the proposed proprietary names, Technegas and (b) (4) on March 26, 2020 under NDA 022335. However, we found the name Technegas unacceptable due to orthographic similarity and overlapping product characteristics with the Technescan products (Technescan HDP, Technescan MAG3, Technescan PYP kits).[a] (b) (4) (b) (4) Cyclomedica was informed of our decisions in writing on June 24, 2020.[c,d]

Thus, Cyclomedica submitted a request for reconsideration of the proposed proprietary names, Technegas and (b) (4) on August 31, 2020 with additional information for the reconsideration submitted on November 17, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 31, 2020.

- Intended Pronunciation:
  - Tech' nah gas
  - (b) (4)
- Active Ingredient:
  - Technegas: Technetium Tc-99m labeled carbon
  - (b) (4) kit for the preparation of technetium 99m Carbon inhalation
- Indication of Use:

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[a] Kane, D. Proprietary Name Review for Technegas (NDA 022335). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUN 22. Panorama No. 2020-38417209 and 2020-39052490.

[b] Kane, D. Proprietary Name Review for (b) (4) (NDA 022335). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUN 22. Panorama No. 2020-38443115 and 2020-39072612.

[c] Harris, D. Proprietary Name Denied for Technegas. Silver Spring (MD): FDA, CDER, OSE (US); 2020 JUN 24. NDA 022335.

[d] Harris, D. Proprietary Name Denied for (b) (4) Silver Spring (MD): FDA, CDER, OSE (US); 2020 JUN 24. NDA 022335.

- Technegas: Indicated for functional lung ventilation imaging [redacted] in adult patients.
- [redacted]

- Route of Administration:
  - Technegas: inhalation
  - [redacted]
- Dosage Form: aerosol for inhalation
- Strength: determined by quantity of sodium pertechnetate Tc-99m added to crucible, which is in range of [redacted]
- Dose and Frequency:
  - Technegas: Inhale approximately 40 MBq (1.08 mCi) as needed for functional lung ventilation imaging (until a lung count rate of between 1,500 cps and 2,500 cps is obtained).
  - [redacted]
- How Supplied:
  - Technegas (kit for the preparation of Technetium Tc 99m labeled carbon aerosol for inhalation) is supplied as a multiple dose kit consisting of 10 single-use [redacted]*** crucibles. Each crucible contains [redacted] high purity graphite for use in the TechnegasPlus Technegas Generator. Each kit consists of five thermoformed blister packs of 10 crucibles in a cardboard box.
  - [redacted]
- Storage: Store the crucibles under ambient temperature. Store the crucibles in the original package.

2 MATERIALS REVIEWED AND METHODS

We used Failure Mode and Effects Analysis (FMEA) in our review of Cyclomedica's request for reconsideration. We also considered the safety concerns described in our previous review of the proposed proprietary names, Technegas and [redacted] as well as information provided by Cyclomedica, which included additional information regarding the intended ordering process for Technegas, preparation and administration of Technegas, Technegas' intended diagnostic medical imaging procedure, and the intended dosage form and route of administration for Technegas.

In the August 31, 2020 request for reconsideration, Cyclomedica stated:

1. Physicians do not write traditional prescriptions for radiopharmaceutical drug products but rather write orders for a specific diagnostic imaging scans or procedures.

2. Pharmacists do not dispense radiopharmaceutical drug products. Rather, specially trained nuclear medicine professionals prepare and administer depending on the type of diagnostic imaging procedure or scan that was ordered.
3. The diagnostic medical imaging procedure ordered by a physician that involves the administration of Technegas (i.e., lung ventilation) is different from the types of imaging procedures that involve the use of Technescan agents (i.e., skeletal, renal, and cardiac imaging) (b) (4).
4. The dosage form and route of administration preclude the possibility that specially trained nuclear medicine professionals could inadvertently prepare and administer an injectable radiopharmaceutical agent indicated for skeletal, renal, or cardiac imaging when performing a lung ventilation scan that requires inhalation of a radiopharmaceutical ventilatory agent such as Technegas or vice versa.
5. Longstanding use and recognition of the proprietary name Technegas in the United States, including recognition by nuclear medicine clinicians in the U.S.

The following sections provide information obtained and considered in the overall reconsideration of the proposed proprietary names, Technegas and (b) (4)

2.1.1 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] for Technegas identified 117 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. (b) (4) We had identified and evaluated some of the names in our previous proprietary name reviews. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. We did not identify any names that were not previously analyzed.

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

Our analysis of the names determined none of the names will pose a risk for confusion with Technegas or with (b) (4)

3 DISCUSSION

This section summarizes our evaluation of the information provided by Cyclomedica in support of a reconsideration of the proposed proprietary names, Technegas and (b) (4)

PHYSICIANS ORDER IMAGING SCANS, NOT THE IMAGING AGENTS OR KITS

Cyclomedica states that "*Physicians do not write traditional prescriptions for radiopharmaceutical drug products imaging agents such as Technegas, for the Technescan*

[e] POCA search conducted on November 24, 2020 in version 4.4.

[f] POCA search conducted on November 24, 2020 in version 4.4.

HDP, Technescan MAG3, Technescan PYP, [redacted] used to prepare such drugs. Nor do physicians write prescriptions for any of the components supplied to prepare these imaging agents, such as the [redacted] crucible. Rather, physicians write orders for the diagnostic imaging procedure scans which require the administration of diagnostic radiopharmaceutical imaging agents such as Technegas or the agents prepared using the Technescan HDP, MAG3, PYP kits, [redacted]."

We acknowledge that the proposed indication for Technegas is functional lung ventilation imaging [redacted]. Additionally, we acknowledge that the high purity graphite crucible, [redacted], is intended for use in the production of Technegas and is not for direct patient administration nor would it be ordered as an individual product. We note that Technescan HDP is indicated for diagnostic skeletal imaging, Technescan MAG3 is indicated for diagnostic renal imaging, and Technescan PYP is a skeletal imaging agent.

Based on the product information for Technegas, [redacted] Technescan HDP, Technescan MAG3, and Technescan PYP, we agree that there is no direct overlap in product indications/diagnostic imaging procedure scans. We confirmed with our colleague in the Division of Medical Imaging and Radiation Medicine (DMIRM) that radiopharmaceutical prescription orders, such as those that would be placed for Technegas, would include the indication for use as part of the prescription order. An order placed based on indication/ diagnostic imaging procedure scan would help to mitigate the risk of product name confusion between Technegas and Technescan (HDP, MAG3, PYP kits).

Additionally, we acknowledge that [redacted]

Thus, we agree with Cyclomedica's statement that proprietary name confusion between Technegas and Technescan (HDP, MAG3, PYP kit) [redacted] would be mitigated by differing indications/diagnostic imaging procedure scans.

TRAINED NUCLEAR MEDICINE PROFESSIONALS RECEIVE IMAGING ORDERS, PREPARE AND ADMINISTER RADIOPHARMACEUTICAL IMAGING AGENTS, AND TAKE IMAGES

We acknowledge that radiopharmaceuticals are a unique class of medications and are ordered through the nuclear medicine department or radiology clinic, instead of being sent to a retail or hospital pharmacy. We note that Technegas and Technescan (HDP, MAG3, PYP kits) are all radiopharmaceutical products, and orders would be placed by a nuclear medicine physician through the nuclear medicine department, radiology clinic, or nuclear pharmacy, and prepared by a specialized nuclear technologist or nuclear pharmacist for each of these products. We also note that orders for radiopharmaceuticals are accompanied by the indication for use for the product (see our discussion in the above section). We acknowledge that the healthcare professionals

ordering, preparing, and administering radiopharmaceuticals are highly trained professionals and would be familiar with various products and their appropriate indications. Thus, we agree with Cyclomedica that having highly trained nuclear medicine healthcare professionals handling the receipt, preparation, and administration for Technegas and other radiopharmaceutical products would help to mitigate the risk of confusion between these products.

UNIQUE PREPARATION AND ADMINISTRATION OF TECHNEGAS

We acknowledge that Technegas is prepared through the use of the TechnegasPlus Technegas Generator where the generator is brought to the patient's bedside, and the patient inhales Technegas directly from the generator for ventilation imaging of the lungs. Additionally, we acknowledge that the TechnegasPlus Technegas Generator requires the addition of an Argon gas source, a (b) (4) crucible, and a dose of Sodium Pertechnetate Tc 99m loaded into the (b) (4) crucible in order to successfully produce Technegas. We note that Technescan HDP, MAG3, and PYP kits are prepared in the nuclear pharmacy or by a nuclear medicine technologist, and the individual doses for these products are withdrawn into single patient use syringes. The single patient use syringe is then brought to the patient's bedside in the imaging suite and administered intravenously. Thus, we acknowledge that Technegas is unique in its product preparation and route of administration compared to Technescan HDP, MAG3, and PYP kit. Additionally, we acknowledge that (b) (4)

Furthermore, we re-evaluated the product characteristics of Technegas, (b) (4) Technescan (HDP, MAG3, PYP Kit), and (b) (4) as noted in the Applicant's reconsideration request. Technegas and Technescan (HDP, MAG3, PYP Kit) products differ in dosage form (aerosol *versus* injection), route of administration (inhalation *versus* intravenous), and indication (lung ventilation imaging *versus* diagnostic skeletal, renal, and cardiac imaging). (b) (4)

Given the unique product preparation and administration for Technegas (b) (4), we agree with Cyclomedica that these properties would mitigate the risk of product confusion.

POSTMARKET REPORTS OF NAME CONFUSION INVOLVING THE PREFIX 'TECHNE-'

Additionally, Cyclomedica states they are "unaware of a single reported clinical instance or expression of regulatory concern about any potential or actual prescribing or medication errors" involving the prefix 'Techne-'. On September 22, 2020, we conducted a FAERS search[g] for postmarketing error reports involving product name confusion caused by the prefix 'Techne-'. Our search did not identify any case reports involving product name confusion caused by the

[g] FAERS search conducted on September 22, 2020. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

prefix ‘Techne-‘. We acknowledge that product name confusion involving the prefix ‘Techne’ has not been reported.

THE TECHNEGAS NAME IS WELL ESTABLISHED AND WIDELY RECOGNIZED WORLDWIDE

Per Cyclomedica, Technegas is marketed under the proposed proprietary name in multiple countries and has been the focus of many clinical investigations since first being introduced in Australia in 1986. Cyclomedica states that in the United States, the Technegas system has been clinically assessed for ventilation imaging under IND 62660 since 2011, and the investigational studies have recruited over 200 patients at eight US clinical trial sites. We acknowledge that the proprietary name Technegas is recognized in other countries, and we acknowledge Cyclomedica’s concern that “*nuclear medicine physicians and technologists in the U.S. would be confused by a change in the globally established and recognized nomenclature for the imaging agent that is generated using the Technegas System for ventilation imaging*”. Additionally, we acknowledge Cyclomedica’s concern that the proposed proprietary name, Technegas, is well-established in other countries and using a different proprietary name in the United States may cause confusion. However, the medication use system may be different in the United States as compared to other countries. Furthermore, the products Technescan (HDP, MAG3, and PYP) (b) (4) may not be marketed in countries outside the United States; therefore, the risk of name confusion error may not exist in those countries as it does in the United States.

LONGSTANDING USE AND RECOGNITION OF THE PROPRIETARY NAME, TECHNEGAS, IN THE UNITED STATES

We acknowledge the supplemental information submitted by Cyclomedica on November 17, 2020 under NDA 022335 for the reconsideration of the proposed proprietary name, Technegas. We acknowledge that Cyclomedica states the National Library of Medicine’s clinical trials database includes five clinical trials with Technegas as the intervention/treatment being studied, Technegas is the only name used to refer to the drug on informed consent forms for the clinical trials, and that there are over 430 published articles that reference Technegas. We note, as stated above, that in the United States the Technegas system has been clinically assessed for ventilation imaging under IND 62660 since 2011, and the investigational studies have recruited over 200 patients at eight US clinical trial sites. We also acknowledge Cyclomedica’s concern that “*confusion over the use of an alternate proprietary name other than Technegas would not facilitate more efficient access to safe and effective new medications for the American public*”. Although we acknowledge Cyclomedica’s argument on the use of the name Technegas as it pertains to the clinical trials, wrong drug errors may still occur as clinical studies are typically tightly controlled conditions.

SUMMARY OF OUR EVALUATION

We carefully considered the rationale raised by Cyclomedica in the supporting documentation on each of the points above, and when all of the mitigations described above are considered in totality, we find that the proposed mitigations minimize the risk of name confusion between the name pairs, Technegas and Technescan (HDP, MAG3, PYP Kit), (b) (4) to an acceptable level.

4 CONCLUSIONS

The proposed proprietary names, Technegas and [redacted] are acceptable.

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

4.1 COMMENTS TO CYCLOMEDICA AUSTRALIA PTY LTD

We have completed our review of the proposed proprietary name, Technegas, and the proposed proprietary name, [redacted] and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your submission, received on August 31, 2020, are altered prior to approval of the marketing application, the names must be resubmitted for review.

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/s/

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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)

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Date of This Review:	June 22, 2020
Application Type and Number:	IND 062660 and NDA 022335
Product Name and Strength:	(b) (4) (kit for the preparation of technetium 99m Carbon inhalation) for inhalation
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Cyclomedica Australia Pty Ltd (Cyclomedica)
Panorama #:	2020-38443115 and 2020-39072612
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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