CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216016Orig1s000
216017Orig1s000

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:	August 5, 2024
Application Type and Number:	NDA 216016 and NDA 216017
Product Name, Dosage Form, and Strength:	Iomervu (iomeprol) injection, 250 mg Iodine/mL, 300 mg Iodine/mL, 350 mg Iodine/mL and 400 mg Iodine/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bracco Diagnostics Inc. (Bracco)
PNR ID #:	2024-1044725777 and 2024-1044725778
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Iomervu, 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. Bracco submitted the results of an internal analysis for this proposed name.[a]

1.1 REGULATORY HISTORY

Bracco previously submitted the proposed proprietary name, (b) (4)*** under NDA 216017 on November 30, 2023 and under NDA 216016 on December 14, 2023. However, on February 28, 2024, we found the name, (b) (4)*** unacceptable due to orthographic and phonetic similarities and overlapping product characteristics with the proprietary name (b) (4) and unacceptable due to orthographic and phonetic similarities and overlapping product characteristics with the proprietary name, (b) (4)[b]

Thus, Bracco submitted the proposed proprietary name, Iomervu, for review on May 9, 2024 under NDA 216016 and NDA 216017.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 9, 2024.[a]

Table 1. Relevant Product Information for Iomervu	
Intended pronunciation:	eye-OH-murr-view
Active ingredient:	iomeprol

[a] Request for Proprietary Name Review – Iomervu (NDA 216016 and NDA 216017). Monroe Township (NJ): Bracco Diagnostics Inc.; 2024 May. Available from: \\CDSESUB1\EVSPROD\nda216016\0018\m1\us\118-proprietary-name\118-req-proprietary-name-review-iomervu-primary-seq-0018.pdf and \\CDSESUB1\EVSPROD\nda216017\0024\m1\us\118-proprietary-name\118-seq-0024-req-proprietary-name-review-iomervu-primary.pdf

[b] Kane, D. Proprietary Name Review for (b) (4)*** (NDA 216016 and NDA 216017). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 FEB 28. PNR ID No. 2023-1044725592 and 2023-1044725493.

Table 1. Relevant Product Information for Iomervu	
Indication:	The proposed indication of this product is as a radiographic contrast agent with intravenous and intraarterial administration in both adults and pediatric patients as follows: • Intravenous Procedures o CT imaging of the head and body o Coronary CT Angiography o CT Angiography o (b) (4) o CT Urography • Intraarterial Procedures o Coronary arteriography and ventriculography, (b) (4) o Cerebral, peripheral and visceral arteriography and aortography, including digital subtraction angiography (DSA)
Dosage Form:	injection
Strength:	250 mg Iodine/mL, 300 mg Iodine/mL, 350 mg Iodine/mL and 400 mg Iodine/mL
Route of administration:	Intravenous and Intraarterial
Dose and frequency[c]:	The recommended dose for this product will be dependent on procedure being performed and weight and age of patient.

[c] We note the proposed dosing tables for Iomervu include the previously proposed proprietary name, (b) (4)***". However, we note at the time of approval of NDA 216016 and NDA 216017 the dosing tables will be revised to include the appropriate proprietary name.

Table 1. Relevant Product Information for Iomervu	
	(b) (4)
	For NDA 216016 ONLY:

Table 1. Relevant Product Information for Iomervu	
	(b) (4)

Table 1. Relevant Product Information for Iomervu	
How Supplied:	IOMERVU is supplied in (b) (4) clear glass vials or bottles with elastomeric closures and flip-off caps. IOMERVU is supplied in the following configurations: • IOMERVU-250 (Iomeprol Injection (b) (4)) o Ten 100 mL single dose bottles (NDC 0270-7015-14) • IOMERVU-300 (Iomeprol Injection (b) (4)) o Ten 50 mL single dose vials (NDC 0270-7016-15) o Ten 100 mL single dose bottles (NDC 0270-7016-17) o Ten 150 mL single dose bottles (NDC 0270-7016-18) o Ten 200 mL single dose bottles (NDC 0270-7016-19) • IOMERVU-350 (Iomeprol Injection (b) (4)) o Ten 50 mL single dose vials (NDC 0270-7017-20) o Ten 100 mL single dose bottles (NDC 0270-7017-21) o Ten 150 mL single dose bottles (NDC 0270-7017-24) o Ten 200 mL single dose bottles (NDC 0270-7017-25) • IOMERVU-400 (Iomeprol Injection (b) (4)) o Ten 50 mL single dose vials (NDC 0270-7018-26) o Ten 100 mL single dose bottles (NDC 0270-7018-27) o Ten 150 mL single dose bottles (NDC 0270-7018-28) o Ten 200 mL single dose bottles (NDC 0270-7018-29)
Storage:	Store at 20° to 25°C (68°F to 77°F) [See USP controlled room temperature]. Protect from light. Do not freeze. Although the sensitivity of iomeprol injection to x-rays is low, it is advisable to store the product out of reach of ionizing radiation.

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Iomervu 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 Iomervu. The Division of Imaging and Radiation Medicine (DIRM) did not comment on the findings of OPDP's assessment for Iomervu.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

The proposed proprietary name, Iomervu, contains the United States Adopted Name (USAN) stem 'io-' in the prefix position of the name.[d] The USAN stem 'io-' is used by the USAN Council to indicate iodine-containing contrast media products. Proprietary names should not incorporate USAN stems in the position that USAN designates for the stem.[e] The use of a USAN stem within proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names.

However, we determined that the two-letter stem 'io' is often not distinct enough to be recognized as an USAN stem. We also note that USAN has used the stem 'io' in established names (e.g., vortioxetine) as well as in other USAN stems (-tioxetine). This has resulted in conflicting stems, and therefore in those instances, the stem does not support the USAN Council naming system or accurately indicate the pharmacological or chemical trait of the drug. Additionally, based on our post marketing experience, we do not have the same safety concerns with the two-letter stems, including 'io', that we have identified with three or more letter USAN stems.[f,g]

Therefore, we do not object to the inclusion of the two-letter USAN stem 'io', incorporated into the proposed proprietary name Iomervu.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Bracco indicated in their submission that the proposed proprietary name, Iomervu, is "derived using the 'Io' letter string from the first two letters in Iodine, the element giving the active ingredient (iomeprol) its radiographic property." In fact, the proposed proprietary name and established name share the same four letters in the same order (I, o, m, e). However, we have no concerns with the shared letters.

This proprietary name is comprised of a single word, [redacted] (b) (4) The request for PNR was for "Iomervu" [redacted] (b) (4) as such, we did not consider [redacted] (b) (4)

[d] USAN stem search conducted on January 25, 2024.

[e] Guidance for Industry: Developing Proprietary Names for Human Prescription Drug Products. Guidance December 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry.

[f] Institute for Safe Medication Practices. Safety briefs: Aripiprazole or rabeprazole? ISMP Med Saf Alert Acute Care. 2003;8(8):1-3.

[g] Institute for Safe Medication Practices. Safety Briefs. ISMP Med Saf Alert Acute Care. 2002;7(17):1-2.

(b) (4) as part of this review. This will be addressed via our forthcoming label and labeling review.

Additionally, Iomervu contains the letter string 'er', which is the medical abbreviation for 'extended release', that is used as a modifier in drug nomenclature. We typically discourage the inclusion of medical abbreviations in proprietary names; however, we determined that the location of the abbreviation 'er' in the infix as the fourth and fifth letters of the name makes it unlikely that the letter string 'er' within the proprietary name, Iomervu, could lead to confusion in this case.

Thus, we do not object to the inclusion of the letter string 'er' in this case. Beyond this abbreviation, we note that Iomervu does not contain any additional components (i.e. a 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

As of June 12, 2024, the Division of Imaging and Radiation Medicine (DIRM) did not forward any comments or concerns relating to Iomervu at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-nine (99) practitioners participated in DMEPA's prescription studies for Iomervu.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name Amilomer from a "dynamic contains" picklist. The sans serif font used in the software of the CPOE study did not adequately distinguish between an uppercase "I" and a lowercase "L". Thus, in this case, the participants saw Iomervu however, typed "Iom" (with a lowercase letter "L" instead of the uppercase letter "I"). As a result, the CPOE generated picklist did not contain, Iomervu, as a choice and instead only generated a picklist with names that contained a "LOM" letter string. The participant proceeded to incorrectly select 'Amilomer' as their response after 117 seconds in order to proceed with the FDA prescription simulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk, rather, we determined this is an artifact related to the sans serif font used in the software, which did not adequately distinguish between an uppercase "I" and a lowercase "L" (i.e., I vs. l). Further, Amilomer is the name of the active moiety in Spherex which is an international drug product formerly marketed in Germany (see Appendix G). As such, we conclude the risk for a medication error to occur between this name pair is unlikely.

Additionally, one participant in the CPOE study incorrectly selected the name Loestrin from a "dynamic begins" picklist. The sans serif font used in the software of the CPOE study did not adequately distinguish between an uppercase "I" and a lowercase "L". In this case, the participant typed "loe" (with a lowercase letter "L" instead of the uppercase letter "I" and an "e" instead of an "m"). As a result, the CPOE generated picklist did not contain, Iomervu, as a choice and instead only generated a picklist with names that began with a "LOE" letter string. The participant proceeded to incorrectly select 'Loestrin' as their response after 20 seconds in order to proceed with the FDA prescription simulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. We did not evaluate this result further given the response is an artifact related to the sans serif font used in the

software, which did not adequately distinguish between an uppercase "I" and a lowercase "L" (i.e., I vs. l). As such, we conclude the risk for a medication error to occur between this name pair is unlikely (see Appendix F).[h]

The remaining 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[i] identified 31 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search, FDA Prescription Simulation Study, and the Bracco Diagnostics Inc. internal analysis. 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
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	21
Low similarity name pair: combined match percentage score ≤54%	11

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 33 names contained in Table 2 determined none of the names will pose a risk for confusion with Iomervu as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On August 5, 2024, DMEPA 2 communicated our determination to the Division of Imaging and Radiation Medicine (DIRM).

3 CONCLUSION

The proposed proprietary name, Iomervu, is conditionally acceptable.

[h] Direct POCA search for Iomervu versus Loestrin conducted on July 8, 2024 in version 5.9.

[i] POCA search conducted on May 15, 2024 in version 5.8.

3.1 COMMENTS TO BRACCO DIAGNOSTICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 9, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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.[j]

*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.

[j] 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 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, Purple Book, 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[k]. 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.

c. FDA Prescription Simulation Studies: DMEPA also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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-

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

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 OPQ 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 Safety Evaluator 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?		

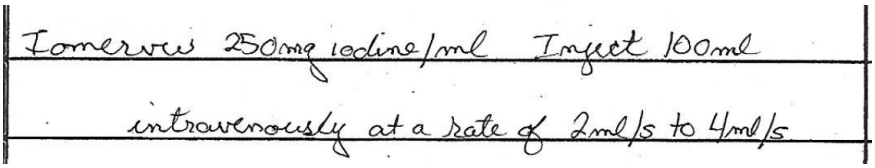
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

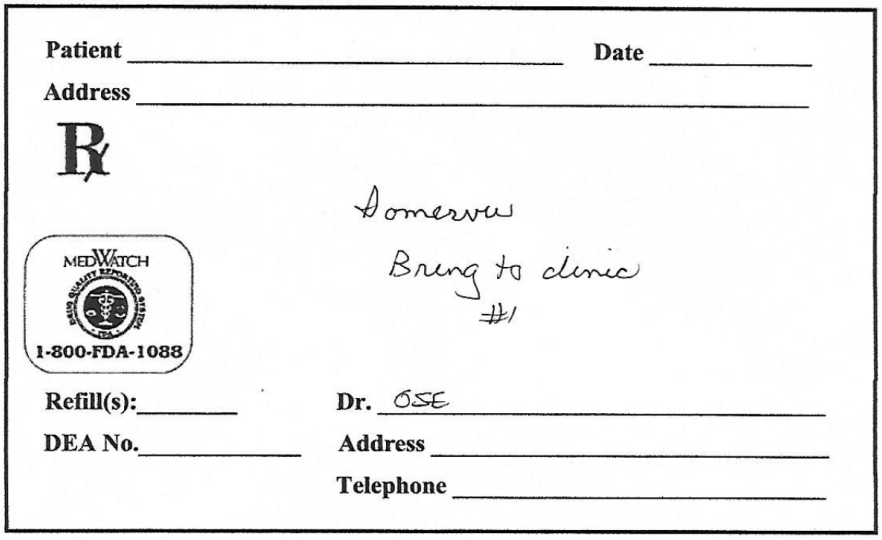
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

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. Iomervu Study (Conducted on 5/21/2024)

<table>
<tr><th>Handwritten Medication Order Prescription</th><th>Verbal Prescription</th></tr>
<tr><td><u>Medication Order:</u>
 

<u>Outpatient Prescription:</u>
 
</td><td>Iomervu
Bring to clinic
#1</td></tr>
<tr><th>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</th><th></th></tr>
<tr><td>Iomervu</td><td></td></tr>
</table>

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Iomervu People Received Study: 198 People Responded: 99					
Total	26	29	16	28	99
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
AMILOMER	0	0	0	1	1
AOMERVA	0	1	0	0	1
AOMERVAI	0	1	0	0	1
AOMERVUI	0	1	0	0	1
DOMERVA	0	2	0	0	2
DOMERVIC	0	1	0	0	1
DOMERVU	0	1	0	0	1
EYEOMORVIEW	0	0	1	0	1
EYOMERVIEW	0	0	2	0	2
EYOMERVUE	0	0	1	0	1
IOMER VIEW	0	0	1	0	1
IOMERIVU	1	0	0	0	1
IOMERVA	0	1	0	0	1
IOMERVEI	3	0	0	0	3
IOMERVEU	2	0	0	0	2
IOMERVEW	1	0	0	0	1
IOMERVI	1	0	0	0	1
IOMERVIE	1	0	0	0	1
IOMERVIEW	0	0	9	0	9
IOMERVII	1	0	0	0	1
IOMERVIO	1	0	0	0	1
IOMERVIU	1	0	0	0	1
IOMERVRIS	1	0	0	0	1
IOMERVU	4	5	0	26	35
IOMERVUE	0	0	1	0	1
IOMERVUI	1	0	0	0	1
IOMERVUS	5	0	0	0	5
IOMERVW	2	0	0	0	2
IOMORAVIEW	0	0	1	0	1
IONERVU	1	0	0	0	1
LOESTRIN	0	0	0	1	1
SOMERVA	0	4	0	0	4
SOMERVAI	0	2	0	0	2
SOMERVU	0	8	0	0	8
SOMERVUI	0	1	0	0	1
SOMERVUS	0	1	0	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Iomervu Pronunciation: eye-OH-murr-view Established name: iomeprol Dosage form: injection Strength(s): 250 mg Iodine/mL, 300 mg Iodine/mL, 350 mg Iodine/mL and 400 mg Iodine/mL Dosage: (b) (4) (b) (4)	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.	Iomervu	100	This name is the subject of this review.

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: Iomervu Pronunciation: eye-OH-murr-view Established name: iomeprol Dosage form: injection Strength(s): 250 mg Iodine/mL, 300 mg Iodine/mL, 350 mg Iodine/mL and 400 mg Iodine/mL Dosage: (b) (4) (b) (4)	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.	Ioversol	62	Orthographically, the suffixes (-vu vs. -sol) look different. Specifically, the upstroke letter "l" in the eighth (last) position of Ioversol provides some difference not seen in Iomervu. Phonetically, the beginning of the third syllable ("mer" vs. "ver") and the fourth syllable ("view" vs. "sol") sound different. Ioversol is the active moiety for Optiray, a radiographic iodinated contrast agent.

No.	Proposed name: Iomervu Pronunciation: eye-OH-murr-view Established name: iomeprol Dosage form: injection Strength(s): 250 mg Iodine/mL, 300 mg Iodine/mL, 350 mg Iodine/mL and 400 mg Iodine/mL Dosage: (b) (4) (b) (4)	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
2.	Cimerli	60	This name pair has sufficient orthographic and phonetic differences.
3.	Iomeprol	60	Iomeprol is the active moiety for Iomervu, which is the subject of this review.
4.	Iqirvo***	59	This name pair has sufficient orthographic and phonetic differences.
5.	Amerge	58	This name pair has sufficient orthographic and phonetic differences.
6.	Merzee	58	This name pair has sufficient orthographic and phonetic differences.
7.	Emerphed	56	This name pair has sufficient orthographic and phonetic differences.
8.	Izervay	56	This name pair has sufficient orthographic and phonetic differences.
9.	Mipomersen	56	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 (%)
1.	Ofirmev	54
2.	Riomet Er	54
3.	Prometrium	50
4.	Isovue	46
5.	Isovue-M 200	45
6.	Isovue-M 300	45

No.	Name	POCA Score (%)
7.	Isovue-M-200	45
8.	Isovue-M-300	45
9.	Loestrin	29

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
1.	Disomer	58	Brand discontinued with no generic equivalents available. NDA 011814 withdrawn FR effective May 6, 1985.
2.	(b) (4) ***	58	(b) (4)
3.	Vio-Moore	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Aservo	56	Veterinary product.
5.	Benerva	56	International product marketed in Mexico, Brazil, Italy, Belgium, France, Spain, and Switzerland, and formerly marketed in Sweden, the United Kingdom, and Ireland.
6.	Metro I.V.	54	Brand discontinued with no generic equivalents available. NDA 018674 withdrawn FR effective August 13, 2018.
7.	Amilomer	52	Active moiety for Spherex, an international product formerly marketed in Germany.

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

No.	Name	POCA Score (%)
1.	Entero Vu 24%	61
2.	Dioderm	60

[I] 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 (%)
3.	(b) (4) ***	60
4.	Viberzi	59
5.	Mirvaso	56
6.	Ormalvi	56
7.	Emverm	55

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HINA S MEHTA
08/05/2024 08:53:48 PM

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:	February 28, 2024
Application Type and Number:	NDA 216016 and NDA 216017
Product Name, Dosage Form, and Strength:	(b) (4) (iomeprol) Injection, 250 mg iodine/mL, 300 mg iodine/mL, 350 mg iodine/mL, and 400 mg Iodine/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bracco Diagnostic Inc. (Bracco)
PNR ID #:	2023-1044725592 and 2023-1044725493
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Associate Director for Nomenclature & Labeling (Acting):	Hina Mehta, PharmD

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STEPHANIE L DEGRAW
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DANIELLE M HARRIS on behalf of HINA S MEHTA
02/28/2024 12:25:02 PM
Signed on behalf of Hina Mehta