CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214056Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	January 17, 2025
Application Type and Number:	NDA 214056
Product Name, Dosage Form, and Strength:	Onapgo (apomorphine hydrochloride) injection, for subcutaneous infusion, 98 mg/20 mL (4.9 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MDD US Operations, LLC, a subsidiary of Supernus Pharmaceuticals, Inc. (MDD US)
PNR ID #:	2024-1044726175
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Onapgo, which was found conditionally acceptable under IND 052844 and NDA 214056 on January 4, 2022.[a] However, NDA 214056 received a complete response (CR) letter on October 7, 2022, citing product quality and device deficiencies.

Subsequently, MDD US resubmitted the proposed proprietary name, Onapgo, as part of the Class 2 Resubmission for NDA 214056 on October 5, 2023, and we again found the name conditionally acceptable on December 7, 2023.[b] However, NDA 214056 received a second CR letter on April 5, 2024, citing product quality and device deficiencies.

Thus, MDD US resubmitted the proposed proprietary name, Onapgo, under the Class 2 Resubmission for NDA 214056 for re-review on August 1, 2024.[c] We note that all product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Onapgo 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 Onapgo. The Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Onapgo.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Onapgo, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 26, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Onapgo.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On January 17, 2025, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

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[a] Morris, C. Proprietary Name Review for Onapgo (IND 052844, NDA 214056). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 JAN 04. PNR ID No. 2021-1044724319, 2021-1044724087.

[b] Morris, C. Proprietary Name Review for Onapgo (NDA 214056). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2023 DEC 07. PNR ID No. 2023-1044725390.

[c] Cover letter – Resubmission (NDA 214056). Rockville (MD): MDD US Operations, LLC, a subsidiary of Supernus Pharmaceuticals, Inc.; 2024 AUG 01. Available from: \\CDSESUB1\EVSPROD\nda214056\0064\m1\us\cover-letter.pdf

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Onapgo, is conditionally acceptable.

3.1 COMMENTS TO MDD US OPERATIONS, LLC, A SUBSIDIARY OF SUPERNUS PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 1, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

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.

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

/s/

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01/17/2025 10:14:27 AM

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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:	December 7, 2023
Application Type and Number:	NDA 214056
Product Name and Strength:	Onapgo (apomorphine hydrochloride) injection, 98 mg/20 mL (4.9 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MDD US Operations, LLC, a subsidiary of Supernus Pharmaceuticals, Inc. (MDD US)
PNR ID #:	2023-1044725390
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onapgo, 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. MDD US did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

MDD US previously submitted the proposed proprietary name, Onapgo, under NDA 214056 on September 8, 2020. However, the Agency refused to file (RTF) NDA 214056.

Therefore, MDD US resubmitted the name, Onapgo, for review under IND 052844 on July 28, 2021, and with their resubmission after the RTF letter under NDA 214056 on December 7, 2021. We found the proposed name, Onapgo, conditionally acceptable on January 4, 2022[a]. However, NDA 214056 received a complete response (CR) letter on October 7, 2022, citing product quality and device deficiencies.

Thus, MDD US resubmitted the name, Onapgo, for review on October 5, 2023 under NDA 214056. We note that none of the product characteristics have changed since our last review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission and proposed prescribing information received on October 5, 2023.

- Intended Pronunciation: on-AP-goh
- Active Ingredient: apomorphine hydrochloride
- Indication of Use: Continuous treatment of motor fluctuations (OFF episodes) in Parkinson's Disease patients that are not adequately controlled with oral levodopa and one or more adjunct Parkinson's disease medications.
- Route of Administration: subcutaneous infusion
- Dosage Form: injection
- Strength: 98 mg/20 mL (4.9 mg/mL)
- Dose and Frequency: Maximum daily dose: 98 mg
    - Continuous dose over approximately 16 hours to 24 hours: Usual dose is (b) (4) mg/hour. Initial dose of 1 mg/hour, increased by 0.5 mg/hour to 1 mg/hour each day based on patient response and tolerability, to maximum infusion rate of (b) (4) mg/hour .
    - Extra dose: usual dose of 2 mg; initial dose of 1 mg, increased in 0.5 mg or 1 mg increments. Frequency of extra doses should be limited to one dose every 3 hours.

[a] Morris, C. Proprietary Name Review for Onapgo (NDA 214056, IND 052844). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2022 JAN 04. PNR ID No. 2021-1044724319, 2021-1044724087.

- How Supplied: 5-count carton containing 98 mg (20mL) single-patient use glass cartridges; 1-count infusion pump kit (includes pump, pouch, belt, lanyard, spare battery, battery door key, carrying case). Cartridge holder and infusion set to be provided separately.
- Storage: Cartridges should be stored at 25°C (77°F). Excursions permitted between 15°C to 30°C (59°F to 86°F).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Onapgo 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 Onapgo. The Division of Neurology 1 (DN 1) did not comment on the findings of OPDP's assessment for Onapgo.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

MDD US did not provide a derivation or intended meaning for the proposed proprietary name, Onapgo, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On November 9, 2023, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Onapgo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Fifty-seven practitioners participated in DMEPA's prescription studies for Onapgo. 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.

[b] USAN stem search conducted on November 2, 2023.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 21 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated all 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 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 new names that were not previously analyzed; therefore, we did not identify any names that could pose a risk for confusion with Onapgo.

2.2.6 Discussion of Dual Proprietary Name

MDD US proposes to use a dual proprietary name, Onapgo, for apomorphine hydrochloride. MDD US currently markets Apokyn (apomorphine hydrochloride) for a different indication, with a different strength, route of administration, dosing regimen, primary container, device components, and packaging under NDA 021264.

On December 7, 2021, we sent an Information Request asking MDD US to provide their rationale for proposing a dual proprietary name as part of our previous evaluation of the proposed name Onapgo. On December 13, 2021 MDD US amended their previous proprietary name request for review under IND 052844 with justification describing the significant differences in the user interface, dose, dosing units, administration, and packaging. MDD US also states using dual proprietary names will minimize confusion when prescribing and preparing an injection versus an infusion. MDD US noted that patients using the proposed subcutaneous infusion product may also use Apokyn for rescue situations, adding that using different proprietary names many help the user differentiate the products. Furthermore, they provided an example of currently marketed products with dual proprietary names, consistent with MDD US' justification.

Table 1 presents relevant product information for Onapgo and Apokyn.

Table 1. Relevant Product Information for Onapgo and Apokyn

Product Name	**Onapgo**	**Apokyn[d]**
Initial Approval Date	N/A	April 20, 2004
Intended Pronunciation	on-AP-goh	AY-po-kin
Active Ingredient	apomorphine hydrochloride	
Indication	Continuous treatment of motor fluctuations (OFF episodes) in Parkinson's Disease patients that are not adequately controlled with	Acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes)

[c] POCA search conducted on November 3, 2023 in version 5.3.
[d] Apokyn product information accessed November 2, 2023, available from: https://fdalabel.fda.gov:8443/fdalabel-r/services/spl/set-ids/3235535d-9ef9-4657-8b2a-176a807d091c/spl-doc?hl=apokyn

Table 1. Relevant Product Information for Onapgo and Apokyn		
Product Name	**Onapgo**	**Apokyn[d]**
	oral levodopa and one or more adjunct Parkinson's disease medications.	associated with advanced Parkinson's disease
Route of Administration	Subcutaneous infusion	Subcutaneous injection
Dosage Form	Injection	
Strength	98 mg/20 mL (4.9 mg/mL)	30 mg/3 mL (10 mg/mL)
Dosing Regimen	Continuous dose over approximately 16 hours to 24 hours: Usual dose is (b) (4) mg/hour. Initial dose of 1 mg/hour, increased by 0.5 mg/hour to 1 mg/hour each day based on patient response and tolerability, to maximum infusion rate of (b) (4) mg/hour. Extra dose: usual dose of 2 mg; initial dose of 1 mg, increased in 0.5 mg or 1 mg increments. Frequency of extra doses should be limited to one dose every 3 hours. Maximum total daily dose: 98 mg	0.2 mL (2 mg) to 0.6 mL (6 mg) per dose as needed, with at least 2 hours between doses, up to a maximum of 2 mL (20 mg) per day
Primary Container	20 mL single-patient use glass cartridges	3 mL single-patient-use cartridges
Device Component and Packaging	Infusion pump kit (includes pump, pouch, belt, lanyard, spare battery, battery door key, carrying case)	Pen injector (include (b) (4) needles and a carrying case)

We have evaluated the risks associated with this naming strategy and do not object to the use of a dual proprietary name, in this case.

2.2.7 Communication of DMEPA's Determination

On December 7, 2023, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

3 CONCLUSION

Our assessment did not identify any new names or error-prone attributes that represent a potential source of drug name confusion. Therefore, the proposed proprietary name, Onapgo, is conditionally acceptable.

If you have any questions or need clarifications, please contact Lopa Thambi, OSE project manager, at 301-796-5354.

3.1 COMMENTS TO MDD US OPERATIONS, LLC.

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

If any of the proposed product characteristics as stated in your submission, received on October 5, 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 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

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

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, 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 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

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

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

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

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

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

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

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

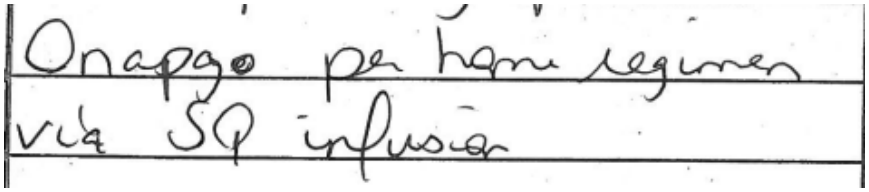
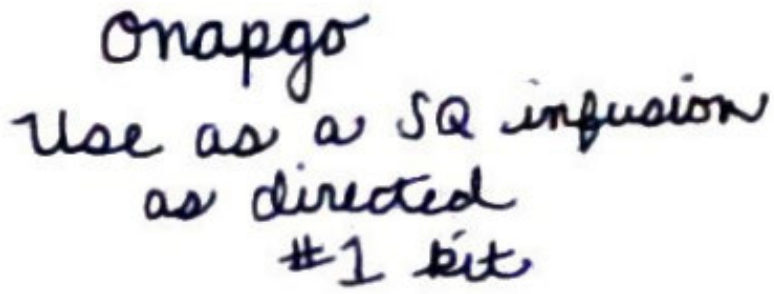
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Onapgo Study (Conducted on October 13, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Onapgo Use as a SQ infusion as directed #1 kit
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Onapgo	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Onapgo People Received Study: 229 People Responded: 57					
Total	14	15	9	19	57
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
IMNAPTO	0	0	1	0	1
OMNAPO	0	0	1	0	1
OMNAPTO	0	0	1	0	1
ONAPDO	0	0	1	0	1
ONAPGO	14	14	0	19	47
ONAPQO	0	1	0	0	1
ONMAPQUO	0	0	1	0	1
UNABGO	0	0	1	0	1
UNAPKO	0	0	1	0	1
UNNAPGO	0	0	1	0	1
UNNAPTO	0	0	1	0	1

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

No.	**Proposed name:** Onapgo **Established name:** apomorphine hydrochloride **Dosage form:** injection **Strength(s):** 98 mg/20 mL (4.9 mg/mL) **Usual Dose:** Continuous: 1 mg/hr to (b)(4) mg/hr increased by 0.5 mg/hr to 1 mg/hr. Extra dose: 1 mg to 2 mg in 0.5 mg increments	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.**
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

No.	Name	POCA Score (%)
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:** Onapgo **Established name:** apomorphine hydrochloride **Dosage form:** injection **Strength(s):** 98 mg/20 mL (4.9 mg/mL) **Usual Dose:** Continuous: 1 mg/hr to (b)(4) mg/hr increased by 0.5 mg/hr to mg/hr. Extra dose: 1 mg to 2 mg in 0.5 mg increments	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**
N/A			

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

No.	Name	POCA Score (%)
N/A		

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
N/A			

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

No.	Name	POCA Score (%)
N/A		

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

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

/s/

JOHN C MORRIS
12/07/2023 10:11:14 AM

STEPHANIE L DEGRAW
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DANIELLE M HARRIS
12/07/2023 11:46:25 AM

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:	January 4, 2022
Application Type and Number:	IND 052844 / NDA 214056
Product Name and Strength:	Onapgo (apomorphine hydrochloride) injection, 98 mg/20 mL (4.9 mg/mL)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MDD US Operations, LLC (MDDUS)
PNR ID #:	2021-1044724087 / 2021-1044724319
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onapgo, 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. MDDUS submitted an internally conducted name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

MDDUS previously submitted the proposed proprietary name, Onapgo, under NDA 214056 on September 8, 2020. However, the Agency refused to file NDA 214056.

Thus, MDDUS submitted the name, Onapgo, for review under IND 052844 on July 28, 2021 and under NDA 214056 on December 7, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proposed Prescribing Information and December 7, 2021.

- Intended Pronunciation: on-AP-goh
- Active Ingredient: apomorphine hydrochloride
- Indication of Use: Continuous treatment of motor fluctuations (OFF episodes) in Parkinson's Disease patients that are not adequately controlled with oral levodopa and one or more adjunct Parkinson's disease medications.
- Route of Administration: subcutaneous infusion
- Dosage Form: injection
- Strength: 98 mg/20 mL (4.9 mg/mL)
- Dose and Frequency: Maximum daily dose, 98 mg
    - Continuous dose over approximately 16 hours to 24 hours: Usual dose is (b) (4) mg/hour. Initial dose of 1 mg/hour, increased by 0.5 mg/hour to 1 mg/hour each day based on patient response and tolerability, to maximum infusion rate of (b) (4) mg/hour .
    - Extra dose: usual dose of 2 mg; initial dose of 1 mg, increased in 0.5 mg or 1 mg increments. Frequency of extra doses should be limited to one dose every 3 hours.
- How Supplied: 5-count 100mg (20mL) single-patient use glass cartridges; 1-count infusion pump kit (includes pump, pouch, belt, lanyard, spare battery, battery door key, carrying case). Cartridge holder and infusion set to be provided separately.
- Storage: 25°C (77°F). Excursions permitted between 15°C to 30°C (59°F to 86°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Onapgo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Onapgo.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

MDDUS did not provide a derivation or intended meaning for the proposed proprietary name, Onapgo, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 18, 2021 and January 3, 2022, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Onapgo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred eighteen practitioners participated in DMEPA's prescription studies for Onapgo. 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[b] identified 20 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and MDDUS's internally conducted name study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

---

[a] USAN stem search conducted on December 7, 2021.

[b] POCA search conducted on December 7, 2021 in version 4.4.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	16
Low similarity name pair: combined match percentage score ≤54%	8

2.2.7 Discussion of Dual Proprietary Name

MDDUS proposes to use a dual proprietary name, Onapgo, for apomorphine hydrochloride. MDDUS currently markets Apokyn (apomorphine hydrochloride) for a different indication, with a different strength, route of administration, dosing regimen, primary container, device components, and packaging under NDA 021264.

On December 7, 2021, we sent an Information Request asking MDDUS to provide their rationale for proposing a dual proprietary name. On December 13, 2021 MDDUS amended their proprietary name request for review under IND 052844 with justification describing the significant differences in the user interface, dose, dosing units, administration, and packaging. MDDUS also states using dual proprietary names will minimize confusion when prescribing and preparing an injection versus an infusion. MDDUS notes that patients using the proposed subcutaneous infusion product may also use Apokyn for rescue situations, adding that using different proprietary names many help the user differentiate the products. Furthermore, they provided an example of currently marketed products with dual proprietary names, consistent with MDDUS's justification.

Table 2 presents relevant product information for Onapgo and Apokyn.

Table 2. Relevant Product Information for Onapgo and Apokyn		
Product Name	**Onapgo**	**Apokyn[c]**
Initial Approval Date	N/A	April 20, 2004
Intended Pronunciation	on-AP-goh	AY-po-kin
Active Ingredient	apomorphine hydrochloride	
Indication	Continuous treatment of motor fluctuations (OFF episodes) in Parkinson's Disease patients that are not adequately controlled with oral levodopa and one or	Acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease

[c] Apokyn product information accessed December 7, 2021, available from: \\CDSESUB1\evsprod\nda021264\0004\m1\us\114-label\1142-final-label\pi.pdf

Table 2. Relevant Product Information for Onapgo and Apokyn		
Product Name	**Onapgo**	**Apokyn[c]**
	more adjunct Parkinson's disease medications.	
Route of Administration	Subcutaneous infusion	Subcutaneous injection
Dosage Form	Injection	
Strength	98 mg/20 mL (4.9 mg/mL)	30 mg/3 mL (10 mg/mL)
Dosing Regimen	Continuous dose over approximately 16 hours to 24 hours: Usual dose is (b) (4) mg/hour. Initial dose of 1 mg/hour, increased by 0.5 mg/hour to 1 mg/hour each day based on patient response and tolerability, to maximum infusion rate of (b) (4) mg/hour. Extra dose: usual dose of 2 mg; initial dose of 1 mg, increased in 0.5 mg or 1 mg increments. Frequency of extra doses should be limited to one dose every 3 hours. Maximum total daily dose: 98 mg	0.2 mL (2 mg) to 0.6 mL (6 mg) per dose as needed, with at least 2 hours between doses, up to a maximum of 2 mL (20 mg) per day
Primary Container	20 mL single-patient use glass cartridges	3 mL single-patient-use cartridges
Device Component and Packaging	Infusion pump kit (includes pump, pouch, belt, lanyard, spare battery, battery door key, carrying case)	Pen injector (includes (b) (4) needles and a carrying case)

We have evaluated the risks associated with this naming strategy and do not object to the use of a dual proprietary name, in this case.

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

Our analysis of the 25 names contained in Table 1 determined none of the names will pose a risk for confusion with Onapgo as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

On January 4, 2022, DMEPA 2 communicated our findings to the Division of Neurology 1 (DN 1).

3 CONCLUSION

The proposed proprietary name, Onapgo, is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO MDD US OPERATIONS, LLC

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

If any of the proposed product characteristics as stated in your submission, received on July 28, 2021 and December 7, 2021, 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. [d]

[d] 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, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

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

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 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[e]. 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

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

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 staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

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

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

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

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

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

Table 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.

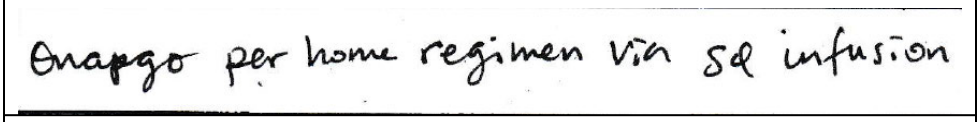
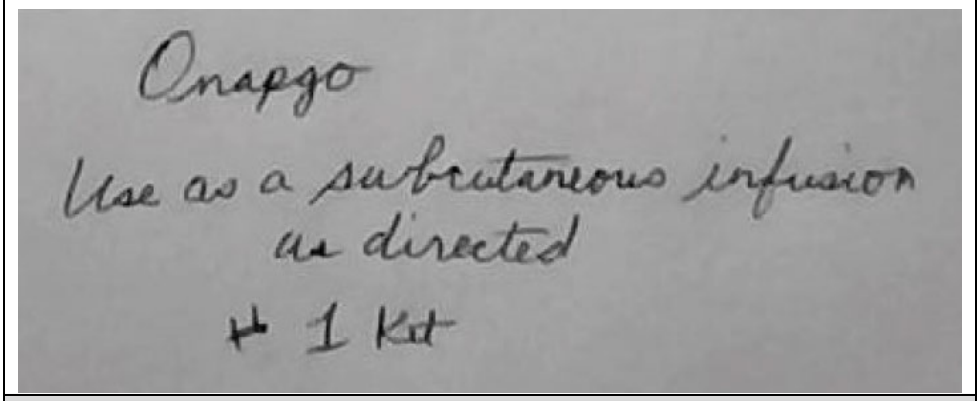
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Onapgo Study (Conducted on August 23, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Onapgo	Onapgo Use as a subcutaneous infusion as directed #1 kit

FDA Prescription Simulation Responses (<u>Aggregate Report</u>)

261 People Received Study
118 People Responded

Study Name: Onapgo

Total	28	35	25	30	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ANAPGO	1	0	0	0	1
AUNAPCO	0	0	1	0	1
ENAPGO	0	0	0	1	1
GNAPGO	0	0	0	1	1
ONACTO	0	0	1	0	1
ONAMCO	0	0	1	0	1
ONAPCO	0	0	7	0	7
ONAPDO	0	0	1	0	1
ONAPGO	27	35	3	26	91
ONAPKGO	0	0	1	0	1
ONAPKO	0	0	4	0	4
ONAPQO	0	0	0	1	1
ONAPTGO	0	0	1	0	1
ONAPTO	0	0	1	0	1
ONEPCO	0	0	1	0	1
ONNAPCO	0	0	1	0	1
ORAPGO	0	0	0	1	1
UNACTO	0	0	1	0	1
UNAPKO	0	0	1	0	1

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

No.	**Proposed name:** Onapgo **Established name:** apomorphine hydrochloride **Dosage form:** injection **Strength(s):** 98 mg/20 mL (4.9 mg/mL) **Usual Dose:** Continuous: 1 mg/hr to (b)(4) mg/hr increased by 0.5 mg/hr to 1 mg/hr. Extra dose: 1 mg to 2 mg in 0.5 mg increments	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.	Onapgo	100	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

No.	Name	POCA Score (%)
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:** Onapgo **Established name:** apomorphine hydrochloride **Dosage form:** injection **Strength(s):** 98 mg/20 mL (4.9 mg/mL) **Usual Dose:** Continuous: 1 mg/hr to (b)(4) mg/hr increased by 0.5 mg/hr to 1 mg/hr. Extra dose: 1 mg to 2 mg in 0.5 mg increments	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.	Antagon	62	This name pair has sufficient orthographic and phonetic differences.
2.	Onpattro	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the infixes (-ap- vs -patt-) and suffixes (-go vs -ro) are sufficiently different.

No.	**Proposed name:** Onapgo **Established name:** apomorphine hydrochloride **Dosage form:** injection **Strength(s):** 98 mg/20 mL (4.9 mg/mL) **Usual Dose:** Continuous: 1 mg/hr to (b)(4)mg/hr increased by 0.5 mg/hr to 1 mg/hr. Extra dose: 1 mg to 2 mg in 0.5 mg increments	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**
			Phonetically, the second syllables (AP vs PAH) and onset of the third syllables (goh vs troh) sound different. Additionally, there is no overlap or similarity among the following product characteristics: strength (4.9 mg/mL vs 2 mg/mL), route of administration (self-administered subcutaneous infusion vs HCP-administered intravenous infusion) or frequency of administration (continuous over 16 hours to 24 hours vs every 3 weeks), which may provide additional differentiation if included on a prescription or medication order.
3.	Fanapt	56	This name pair has sufficient orthographic and phonetic differences.
4.	Sonata	56	This name pair has sufficient orthographic and phonetic differences.
5.	Anaprox	55	This name pair has sufficient orthographic and phonetic differences.
6.	Opana	53	This name pair has sufficient orthographic and phonetic differences.
7.	Apogen	46	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.	Oncaspar	52
2.	Onglyza	41
3.	Olanzapine	40
4.	Ondansetron	38

No.	Name	POCA Score (%)
5.	Ongentys	38

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.	Monaspor	58	International product formerly marketed in Austria, the Netherlands, and the United Kingdom.
2.	Omnopon	56	International product marketed in the United Kingdom and Russia, and formerly marketed in South Africa.
3.	Pongamol	50	Product is not a drug. It is a major bioactive compound present in karanja (Pongamia pinnata) seed oil.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion8F[f].

No.	Name	POCA Score (%)
1.	Naphcon	66
2.	Uni-Pro	61
3.	Naphcon-A	58
4.	(b) (4)***	56
5.	Indigo	56
6.	Nacton	56
7.	Xadago	56
8.	Senna Pod	56
9.	Avapro	55

[f] 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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