CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217645Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	October 20, 2023
Application Type and Number:	NDA 217645
Product Name and Strength:	Onyda XR (clonidine hydrochloride) extended-release oral suspension, 0.1 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Tris Pharma, Inc. (Tris)
PNR ID #:	2023-1044725252
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onyda XR, 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. Tris submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 24, 2023, and amendment received on August 14, 2023.

- Intended Pronunciation: oh-nee'-dah XR
- Active Ingredient: clonidine hydrochloride
- Indication of Use: treatment of attention-deficit/hyperactivity disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications
- Route of Administration: oral
- Dosage Form: extended-release oral suspension
- Strength: 0.1 mg/mL
- Dose and Frequency: Dosing should be initiated with one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses should be taken once a day at bedtime. Doses higher than 0.4 mg/day were not evaluated in clinical trials for ADHD and are not recommended.
- How Supplied: NDC 24478-148-02; 120 mL oral suspension supplied in 5 fl oz bottle packaged with two oral dosing dispensers and two press in bottle adapters in a carton.
- Storage: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Onyda XR would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Onyda XR. The Division of Psychiatry (DP) did not comment on the findings of OPDP's assessment for Onyda XR.

2.2 SAFETY ASSESSMENT

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

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

The proposed proprietary name, Onyda XR, is comprised of two components: 1) the root name, Onyda, and 2) the modifier, XR. According to Tris, 1) there is no specific derivation of the proposed root name, and 2) the modifier, XR, is intended to connote "extended-release". An analysis of the appropriateness of the modifier is discussed in Section 2.2.4. This proposed name does not contain any other components (i.e., route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 23, 2023, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Onyda XR at the initial phase of the review.

2.2.4 Safety Assessment of the Modifier "XR"

According to Tris, the intended meaning of the modifier, XR, is *extended-release*. We note that the use of a modifier to convey that the product is an extended-release dosage form is contingent upon the product meeting the Agency's criteria for this designation. Assuming these criteria are met, we note that the modifier "XR" has been used for other modified-release formulations to communicate an "every 12-hour", "twice daily", or "once daily" dosing schedule for an extended-release formulation product. Based on the Institute for Safe Medication Practices (ISMP) List of Products with Drug Name Suffixes, the modifier "XR" is typically used to convey the meaning "extended-release" for products with modified-release formulations.[b] We note that this proposed product is an extended-release formulation with a once daily frequency of administration. Therefore, the use of the modifier "XR" is consistent with its existing meaning and current use in the marketplace. Additionally, to our knowledge, the modifier "XR" has not been cited as a source of confusion in postmarket reports. Therefore, the use of the modifier "XR" is acceptable in this case.

2.2.5 FDA Name Simulation Studies

Sixty-eight (n=68) practitioners participated in DMEPA's prescription studies for Onyda XR. The responses did not overlap with any currently marketed products; however, two respondents in the verbal portion of the FDA Name Simulation Studies responded "Bonita XR". We note that "Bonita" is similar to the name Boniva (retrieved in our POCA search). Boniva is the tradename of a formerly marketed product that is currently available as a generic product (see Appendix E for our evaluation of the name pair). Appendix B contains the results from the prescription simulation studies.

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[a] USAN stem search conducted on September 20, 2023.

[b] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We conducted a POCA search of the root name, Onyda, and the root name plus modifier, "Onydaxr". Our POCA search[c] identified 121 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.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 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%	108
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 121 names contained in Table 1 determined none of the names will pose a risk for confusion with Onyda XR as described in Appendices C through H.

2.2.9 Communication of DMEPA's Determination

On October 20, 2023, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Onyda XR, is conditionally acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Safety Regulatory Project Manager, at 240-402-5827.

3.1 COMMENTS TO TRIS PHARMA, INC.

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

[c] POCA search conducted on September 20, 2023 in version 5.2.

If any of the proposed product characteristics as stated in your submission, received on July 24, 2023, and amended on August 14, 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.

3. ***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).

4. ***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).

5. ***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 201.10I(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. [d]

***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)).

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

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[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 are 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.

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.

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

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

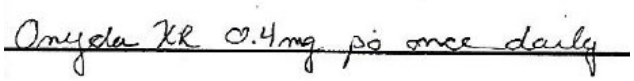
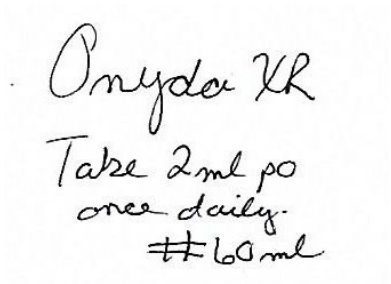
<table>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping 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 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?</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: 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. Onyda XR Study (Conducted on September 1, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Onyda XR Take 2 mL by mouth once daily Dispense 60 mL
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Onyda XR	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Onyda XR People Received Study: 253 People Responded: 68					
Total	15	21	13	19	68
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ALEEDA XR	0	0	1	0	1
BELITA XR	0	0	1	0	1
BONITA XR	0	0	2	0	2
ELNIDA XC	0	0	1	0	1

OMEDIA XR	0	0	1	0	1
OMIDA XR	0	0	1	0	1
OMYDA XR	0	1	0	0	1
ONEDA XR	0	0	2	0	2
ONEEDA XR	0	0	3	0	3
ONETA XR	0	0	1	0	1
ONYDA XL	0	1	0	0	1
ONYDA XR	11	17	0	19	47
ONYDO XR	0	2	0	0	2
ONYELA XR	3	0	0	0	3
ONYSLA XR	1	0	0	0	1

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

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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.**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
1.	Onyda XR	100	66	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

No.	Name	POCA Score (%)	
		POCA Search "Onydaxr"	**POCA Search "Onyda"**
1.	Opana		61
2.	Onglyza		60

Appendix E: Moderately Similar Names (e.g., combine oh-'ee'-dah XR d POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
1.	Nydamax	67	49	This name pair has sufficient orthographic and phonetic differences.
2.	Anorex-SR	64		This name pair has sufficient orthographic and phonetic differences.
3.	Konyne 80		62	This name pair has sufficient orthographic and phonetic differences.
4.	(b) (4) ***		62	(b) (4)

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
				(b) (4) When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
5.	Onivyde		62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
6.	Yonsa		61	This name pair has sufficient orthographic and phonetic differences.
7.	Odactra	60		This name pair has sufficient orthographic and phonetic differences.
8.	(b) (4) ***		60	This name pair has sufficient orthographic and phonetic differences.
9.	Ontak		60	This name pair has sufficient orthographic and phonetic differences.
10.	Boniva		58	This name pair has sufficient orthographic differences. Onyda XR and Boniva have product characteristics that differ which further help to differentiate the name pair. There is no overlap in strength (0.1 mg/mL vs. 2.5 mg and 150 mg) – strength must be included on a prescription for Boniva. If dose for Boniva is written as 2.5 mg or 150 mg, there is no overlap in dose with that of Onyda XR (0.1 mg to 0.4 mg [1 mL to 4 mL, respectively].

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
				When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
11.	Oncaspar	58		This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***		58	(b) (4)

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
				(b) (4) When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
13.	(b) (4) ***	57		This name pair has sufficient orthographic and phonetic differences.
14.	(b) (4) ***		55	(b) (4)

No.	**Proposed name:** Onyda XR **Established name:** clonidine hydrochloride **Dosage form:** extended-release oral suspension **Strength(s):** 0.1 mg/mL **Usual Dose:** one 1 mL (0.1 mg) dose at bedtime. The daily dose should be adjusted in increments of 0.1 mg/day (1 mL/day) at weekly intervals until the desired response is achieved. Doses higher than 0.4 mg/day are not recommended.	**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**
		POCA Search "Onydaxr"	**POCA Search "Onyda"**	
				(b) (4) When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
15.	(b) (4) ***		56	This name pair has sufficient orthographic and phonetic differences.
16.	Ony-Clear	56		This name pair has sufficient orthographic and phonetic differences.
17.	Ozobax	55		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 (%)	
		POCA Search "Onydaxr"	POCA Search "Onyda"
1.	Today		54
2.	Nydrane		52
3.	Oxy Gard	52	
4.	Anhydron	50	
5.	Norinyl 1+35 21-Day	46	50
6.	Norinyl 1+35 28-Day	46	50
7.	Norinyl 1+50 21-Day	46	50
8.	Norinyl 1+50 28-Day	46	50
9.	Norinyl 1+80 21-Day	46	50
10.	Norinyl 1+80 28-Day	46	50
11.	Oxandrin	50	
12.	Voydeya***		48

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
		POCA Search "Onydaxr"	POCA Search "Onyda"	
1.	(b) (4) ***	69		Proposed proprietary name for NDA 214621 found unacceptable by DMEPA (OSE# 2020-39342225). NDA 214621 approved under the proprietary name Orgovyx.
2.	Monomax SR	68		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Rondec-TR	67		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Androxy	66		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Onydaxr"	POCA Search "Onyda"	
5.	Lodrane XR	66		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Dynex VR	65		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Andec-TR	64		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	(b) (4) ***	64		Proposed proprietary name withdrawn by the Applicant. NDA 213218 approved under the proprietary name, Soaanz.
9.	Edronax	63		International product marketed in Australia, Austria, Belgium, Denmark, and other foreign countries.
10.	(b) (4) ***		63	Proposed proprietary name for NDA (b) (4) found to be unacceptable (OSE # (b) (4)). The unapproved application was withdrawn by the Applicant on (b) (4).
11.	(b) (4) ***		62	Proposed proprietary name for IND (b) (4) found to be acceptable (OSE # (b) (4)), however, the application has been on inactive status since (b) (4).
12.	Onbody***		61	Onbody is the proposed modifier that represents the device portion of the proposed name "Udenyca Onbody"*** [proposed proprietary name for BLA 761039/S-015 found to be acceptable (OSE # 2022-1044724871)]. "Udenyca" is a currently marketed product. Onbody alone does not exist as a proprietary name on the market.
13.	(b) (4) ***	61		Proposed proprietary name for NDA (b) (4) found to be acceptable (OSE # (b) (4)), however, the entire application was withdrawn by the Applicant on (b) (4).

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Onydaxr"	POCA Search "Onyda"	
14.	Omedia		60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
15.	Omeza		60	This is not a drug. Omeza is the name of a company that markets wound care products (i.e., Omeza Collagen Matrix, Omeza Lidocaine Lavage, and Omeza Skin Protectant). Omeza alone does not exist as a proprietary name on the market.
16.	(b) (4) ***		60	Proposed proprietary name for NDA 212608 found unacceptable by DMEPA (OSE# 2018-26498771). NDA 212608 approved under the proprietary name Ayvakit .
17.	Ponderax	60		International product marketed in the United Kingdom and Australia.
18.	Entex ER	58		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	(b) (4) ***	56		Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (OSE # (b) (4) dated (b) (4)). The Applicant withdrew the name (b) (4) *** on (b) (4) and submitted the name Bonjesta*** for review under NDA 021876. Due to the change in product characteristics of the proposed doxylamine succinate and pyridoxine hydrochloride product, the submission was assigned a new NDA number (NDA 209661). Subsequently, NDA 209661 was approved under the proprietary name Bonjesta.
20.	(b) (4) ***		56	Proposed proprietary name withdrawn by the Applicant. BLA 761161 approved under the proprietary name, Elfabrio.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Onydaxr"	POCA Search "Onyda"	
21.	(b) (4) ***		56	Proposed proprietary name for IND (b) (4) found to be acceptable (OSE # (b) (4)), however, the name was withdrawn by the Applicant on (b) (4) and no new names have been submitted.
22.	Doxylar	55		International product marketed in the United Kingdom.
23.	(b) (4) ***	55		Proposed proprietary name for IND (b) (4) found to be acceptable (OSE # (b) (4)), however, the entire application has been on inactive status since (b) (4).

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

No.	Name	POCA Score (%)	
		POCA Search "Onydaxr"	POCA Search "Onyda"
1.	Namenda XR	66	
2.	Rondex	65	
3.	Ganda		63
4.	Monodox	63	
5.	Symax SR	62	
6.	Naproxrn	61	
7.	Endal		60
8.	Enzymax	60	
9.	Gfn DXR 00	60	
10.	(b) (4) ***	60	
11.	Xanax XR	60	
12.	Dynaxin	59	
13.	Indomax	59	

[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

No.	Name	POCA Score (%)	
		POCA Search "Onydaxr"	POCA Search "Onyda"
14.	Nordox	59	
15.	Sonamox	59	
16.	Sonata		59
17.	Adderall XR 10	58	
18.	Adderall XR 15	58	
19.	Adderall XR 20	58	
20.	Adderall XR 25	58	
21.	Adderall XR 30	58	
22.	Adderall XR 5	58	
23.	Adderall-XR	58	
24.	Animax	58	
25.	Dryvax	58	
26.	Endoxan	58	
27.	Neo-Dexair	58	
28.	Robadex	58	
29.	Ryanodex	58	
30.	Anaprox	57	
31.	Anndexa	57	
32.	Drymax	57	
33.	Inlyta		57
34.	Zymine XR	57	
35.	Amidox	56	
36.	Avidoxy	56	
37.	Candex	56	
38.	Dandrex	56	
39.	Dyanavel XR	56	
40.	Dyanavel XR 10	56	
41.	Dyanavel XR 15	56	
42.	Dyanavel XR 20	56	
43.	Dyanavel XR 5	56	
44.	Dynex LA	56	
45.	Dytan		56
46.	Handex	56	
47.	Inomax	56	
48.	Inova		56
49.	Inova 4-1		56
50.	Inova 8-2		56
51.	Lodine XL	56	
52.	Menactra	56	
53.	M-End Max	56	
54.	M-End Max D	56	

No.	Name	POCA Score (%)	
		POCA Search "Onydaxr"	POCA Search "Onyda"
55.	Mydex	56	
56.	Neo-Dex	56	
57.	Pandex	56	
58.	Poly-Dex	56	
59.	Tanacof XR	56	
60.	Trokendi XR	56	
61.	Ventmax SR	56	
62.	Zyban SR	56	
63.	Zymine DXR	56	
64.	(b) (4) ***		55
65.	Hydromox R	55	
66.	Synjardy XR	55	

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/s/

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