

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208147Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 9, 2015
Application Type and Number:	NDA 208147
Product Name and Strength:	Dyanavel XR (amphetamine) Extended-Release Oral Suspension 2.5 mg amphetamine base per mL
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Tris Pharma Inc.
Submission Date:	December 19, 2015
Panorama #:	2014-46334
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Dyanavel XR, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, (b) (4), on July 14, 2014. However, this name was found unacceptable because it (b) (4) in OSE Review 2014-25868 dated October 9, 2014.

Thus, the sponsor submitted the name, Dyanavel XR, for review on December 19, 2014.

1.2 PRODUCT INFORMATION

The following product information was provided in the December 19, 2014 proprietary name submission.

- Intended Pronunciation: dya-na-vel
- Active Ingredient: amphetamine and dextroamphetamine
- Indication of Use: Treatment of Attention Deficit Hyperactivity Disorder (ADHD)
- Route of Administration: Oral
- Dosage Form: Extended-Release Oral Suspension
- Strength: 2.5 mg amphetamine base per mL
- Dose and Frequency: Start at 2.5 mg to 5 mg once daily in the morning. Dose can be titrated in 2.5 mg to 10 mg increments every 4-7 days. Doses greater than 20 mg are not recommended.
- How Supplied: 464 mL bottles
- Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)
- Container and Closure Systems: Child-resistant closure; Amber (b) (4) oblong bottle

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Psychiatry Products (DPP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name¹.

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name contains two components: 1) the proposed root name, Dyanavel, and 2) the modifier XR. Tris Pharma indicated in their submission that the proposed root name, Dyanavel, has no derivation and the modifier “XR” is intended to mean “extended-release.” An analysis of the appropriateness of the modifier “XR” is discussed in Section 2.2.5.

2.2.3 FDA Name Simulation Studies

Eighty-six practitioners participated in DMEPA’s prescription studies. 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 verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 19, 2015 e-mail, the Division of Psychiatry Products (DPP) did not provide any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Analysis of the Modifier “XR”

In our evaluation of the proposed name Dyanavel XR, we considered the following:

- Whether a modifier is necessary
 - Whether the modifier proposed is appropriate
1. We considered whether a modifier is necessary for this product. There are currently no immediate-release amphetamine/dextroamphetamine oral liquid products in the marketplace. However, immediate-release solid oral dosage forms of amphetamine/dextroamphetamine are currently available (e.g., Adderall). Extended-release solid oral dosage forms of amphetamine/dextroamphetamine (e.g., Adderall XR) are also currently marketed, which distinguish themselves from the immediate-release dosage forms by the use of a modifier (e.g., XR or ER). Although there is no currently marketed product that has the name Dyanavel from which Dyanavel XR needs to distinguish itself, we considered whether the lack of a modifier raises a potential safety concern.

DMEPA previously researched extended-release products approved without a modifier in the proprietary name and reviewed documented errors relating to

¹USAN stem search conducted on January 16, 2015.

wrong technique and wrong frequency of administration. Wrong technique errors involved patients or practitioners, chewing, splitting, opening, or crushing the extended-release solid, oral dosage forms when these products were intended to be administered intact. This same risk does not exist for Dyanavel XR as it is a liquid formulation. Wrong frequency errors involved the administration of the extended-release dosage form at intervals more frequent than labeled, (e.g. taking a once daily drug twice a day). Wrong technique and wrong frequency errors occurred despite the presence of clear labeling directives to administer the products intact and at the given intervals. Based on the case narratives we were unable to determine a definitive root cause of the errors. We then considered whether the lack of a modifier may actually contribute to practitioners' and patients' knowledge deficit about the extended-release properties of Dyanavel XR.

The immediate-release solid oral dosage forms of amphetamine/dextroamphetamine products are indicated for once or twice daily frequency of administration versus once daily for Dyanavel XR. In this circumstance, Dyanavel XR has direct overlapping doses with the immediate-release solid oral dosage forms of amphetamine/dextroamphetamine. We are concerned that without a modifier to indicate otherwise, practitioners and patients may assume Dyanavel is an immediate-release product, and practitioners may overlook the differing product characteristics (e.g., frequency of administration). Therefore, we believe a modifier is needed to convey the extended-release nature of the product helping to distinguish it from immediate-release products containing similar ingredients. We recognized there were limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked; however, we believe the addition of the modifier could add an incremental measure of safety.

2. We considered whether the proposed modifier is appropriate. According to Tris Pharma, the modifier XR is intended "to connote 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 "XR" can communicate other information about the product as well. The modifier "XR" has been used to communicate once or twice daily administration, although most products with the XR modifier are dosed once daily². Additionally, to our knowledge the modifier "XR" has not been cited as a source of confusion postmarketing. Therefore, the use of the modifier "XR", in this circumstance, is consistent with the majority of other XR products that are currently marketed.

Given the totality of factors considered above, we believe that the use of a modifier is appropriate for this name and that the proposed modifier, XR, is acceptable.

² ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010 [cited 2015 Feb 09]. Available from: <http://www.ismp.org/tools/drugnamesuffixes.pdf>.

2.2.6 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search³ organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	290
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 293 names contained in Table 1 determined all 293 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on February 19, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPP on March 2, 2015, they stated no additional concerns with the proposed proprietary name, Dyanavel XR.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE project manager, at 240-402-5035.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 19, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

³ POCA search conducted on January 29, 2015.

4 REFERENCES

1. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

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 DNCE. OPDP or DNCE 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 DNCE 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.⁴

⁴ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there medical and/or coined abbreviations in the proprietary name?
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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.

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

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

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

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

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

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

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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 as 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 $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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
<p>Step 2</p>	<p>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.</p>

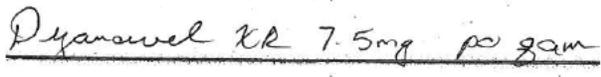
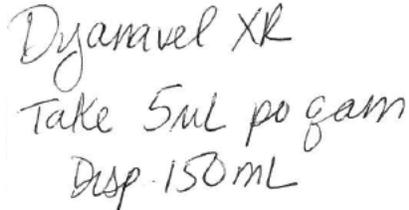
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Dyanavel XR Study (Conducted on January 9, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p data-bbox="188 764 428 800"><u>Medication Order:</u></p>  <p data-bbox="188 974 500 1010"><u>Outpatient Prescription:</u></p> 	<p data-bbox="953 764 1133 800">Dyanavel XR</p> <p data-bbox="953 816 1200 852">Take 5 mL po qam</p> <p data-bbox="953 869 1133 905">Disp. 150 mL</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

				253 People Received Study
				86 People Responded
Study Name: Dyanavel XR				
Total	26	28	32	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DIANAFIL XR	0	1	0	1
DIANAVAL XR	0	2	0	2
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	8	0	8
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	2	0	2
DIANAVAL XR	0	2	0	2
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	2	0	2
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	2	0	2
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	1	0	1
DIANAVAL XR	0	0	1	1
DIANAVAL XR	0	0	1	1
DIANAVAL XR	0	0	5	5
DIANAVAL XR	0	0	1	1
DIANAVAL XR	0	0	2	2
DIANAVAL XR	1	0	0	1
DIANAVAL XR	19	0	8	27
DIANAVAL XR	0	1	0	1

DYANCIVEL XR	0	0	1	1
DYANORVEL XR	0	0	1	1
DYANOUEVEL XR	0	0	1	1
DYANOVAL XR	0	0	1	1
DYANOVEL XR	0	0	4	4
DYANUVEL XR	0	0	1	1
DYNAGEL XR	1	0	0	1
DYNAMEL XR	0	0	1	1
DYNAOVEL	0	0	1	1
DYNAVEL XR	5	0	0	5
PYAMAVEL XR	0	0	1	1
PYANAVEL XR	0	0	1	1

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

No.	<p><u>Proposed name:</u> Dyanavel XR</p> <p><u>Established name:</u> Amphetamine</p> <p><u>Dosage form:</u> Extended-Release Oral Suspension</p> <p><u>Strength:</u> 2.5 mg/mL</p> <p><u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 mg increments</p>	POCA Score (%)	<p>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</p> <p>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</p>
1.	Dyanavel XR ^{***}	74	This name is the subject of this review.
2.	Danazol	74	<p>The prefixes of the root name Dyanavel have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel sound different and the root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
3.	Donnagel	72	<p>The prefixes of the root name Dyanavel have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel sound different and the root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p> <p>Donnagel has been discontinued. There are no generics available. The product contained atapugite. Products containing this ingredient were removed from the market in 2003 because atapugite was found to be generally not recognized as safe or effective.</p>

***** This document contains proprietary information that cannot be released to the public*****

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Denavir	66
2.	Dentagel	64
3.	Dermasil	63
4.	Beta-Val	58
5.	Di-Dak-Sol	58
6.	Dynashield	58
7.	Dianeal PD-2/1.5	56
8.	Dianeal PD-2/3.5	56
9.	Dianeal PD-2/4.25	56
10.	Duo-Vil	56
11.	Dermasav	54
12.	Dermatol 10	54
13.	Durasal	54
14.	Desonil	52
15.	Dynafreeze	52
16.	Sanafitil	52
17.	Docosanol	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	<p><u>Proposed name:</u> Dyanavel XR</p> <p><u>Established name:</u> Amphetamine</p> <p><u>Dosage form:</u> Extended-Release Oral Suspension</p> <p><u>Strength:</u> 2.5 mg/mL</p> <p><u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 mg increments</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	Menaval-20	68	<p>The prefixes of the root name Dyanavel and the root name Menaval have sufficient orthographic differences.</p> <p>The first syllables of the root name Dyanavel and the root name Menaval sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
2.	Daptacel	66	<p>The prefixes/infixes of the root name Dyanavel and the name Daptacel have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Daptacel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
3.	Banaril	64	<p>The prefixes of the root name Dyanavel and the name Banaril have sufficient orthographic differences.</p> <p>The first syllables of the root name Dyanavel and the name Banaril sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
4.	Donnatal	64	<p>The prefixes/suffixes of the root name Dyanavel and the name Donnatal have sufficient orthographic differences.</p> <p>The first syllables of the root name Dyanavel and the name Donnatal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
5.	Dynafed	64	The suffixes of the root name Dyanavel and the name Dynafed have sufficient orthographic differences. The last syllables of the root name Dyanavel and the name Dynafed sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
6.	Vanachol	64	The prefixes/suffixes of the root name Dyanavel and the name Vanachol have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Vanachol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken..
7.	Bunavail***	64	The prefixes of the root name Dyanavel and the name Bunavail*** have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Bunavail*** sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
8.	Guanadrel	64	The prefixes and suffixes of the root name Dyanavel and the name Guanadrel have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Guanadrel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

*** This document contains proprietary information that cannot be released to the public***

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
9.	Panasal	63	The prefixes of the root name Dyanavel and the name Panasal have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Panasal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
10.	Banzel	63 (Phonetic Score: 70%)	The prefixes/infixes of the root name Dyanavel and the name Banzel have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Banzel sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
11.	Panadol	62	The prefixes/suffixes of the root name Dyanavel and the name Panadol have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Panadol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
12.	Minoval	62 (Phonetic Score: 70%)	The prefixes of the root name Dyanavel and the name Minoval have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Minoval sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
13.	Prinivil	62 (Phonetic Score: 76%)	The prefixes of the root name Dyanavel and the name Prinivil have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Prinivil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
14.	Avanafil	61	The prefixes/suffixes of the root name Dyanavel and the name Avanafil have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Avanafil sound different.
15.	DDAVP Nasal	60	The prefixes/infixes/suffixes of the root name Dyanavel and the root name DDAVP have sufficient orthographic differences. The first/second/fourth syllables of the root name Dyanavel and the root name DDAVP sound different. The root name DDAVP contains an extra syllable which helps this name pair sound different when spoken.
16.	Sumavel	60	The prefixes of the root name Dyanavel and the name Sumavel have sufficient orthographic differences. The first syllables of the root name Dyanavel and the name Sumavel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
17.	Divigel	60	The prefixes/infixes/suffixes of the root name Dyanavel and the name Divigel have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Divigel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
18.	Diphemanil	60	The prefixes/infixes of the root name Dyanavel and the name Diphemanil pair have sufficient orthographic differences. The second/fourth syllables of the root name Dyanavel and the name Diphemanil sound different.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
19.	Tri-Nasal	59 (Phonetic Score: 74%)	The prefixes/infixes of the root name Dyanavel and the name Tri-Nasal have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Tri-Nasal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
20.	Genasal	59 (Phonetic Score: 71%)	The prefixes/ of the root name Dyanavel and the name Genasal have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Genasal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
21.	Genedel	59 (Phonetic Score: 71%)	The prefixes/infixes/suffixes of the root name Dyanavel and the name Genedel have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Genedel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
22.	Dioval 40	58	The prefixes/infixes of the root name Dyanavel and the root name Dioval have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the root name Dioval sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
23.	Dibenil	58	The prefixes/infixes of the root name Dyanavel and the name Dibenil have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the name Dibenil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
24.	Dimacol	58	<p>The prefixes/infixes of the root name Dyanavel and the name Dimacol have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dimacol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
25.	Hypnovel	58	<p>The prefixes of the root name Dyanavel and the name Hypnovel have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Hypnovel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
26.	Vanacet	58	<p>The prefixes of the root name Dyanavel and the name Vanacet have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Vanacet sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
27.	Darunavir	58	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Darunavir have sufficient orthographic differences.</p> <p>The second/fourth syllables of the root name Dyanavel and the name Darunavir sound different.</p>
28.	Didronel	58	<p>The prefixes/infixes of the root name Dyanavel and the name Didronel have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Didronel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
29.	Climaval	58 (Phonetic Score: 72%)	<p>The prefixes of the root name Dyanavel and the name Climaval have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Climaval sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
30.	Dynapen	58	<p>The suffixes of the root name Dyanavel and the name Dynapen have sufficient orthographic differences.</p> <p>The second/third syllables the root name Dyanavel and the name Dynapen sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
31.	Tramadol	58 (Phonetic Score: 73%)	<p>The prefixes/suffixes of the root name Dyanavel and the name Tramadol have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Tramadol sound different. The root name Dyanavel contains an extra syllable.</p>
32.	Diphenadryl	57	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Diphenadryl have sufficient orthographic differences.</p> <p>The second/third/fourth syllables of the root name Dyanavel and the name Diphenadryl sound different.</p>
33.	Donepezil	57	<p>The prefixes/infixes of the root name Dyanavel and the name Donepezil have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Donepezil sound different.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
34.	Granisol	57 (Phonetic Score: 72%)	The prefixes/infixes of the root name Dyanavel and the name Granisol have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Granisol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
35.	Dianeal PD-2/2.5	56	The prefixes of the root name Dyanavel and the root name Dianeal have sufficient orthographic differences. The third syllables of the root name Dyanavel and the root name Dianeal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
36.	Dronabinol	56	The prefixes/infixes of the root name Dyanavel and the name Dronabinol have sufficient orthographic differences. The first/second/third/fourth syllables of the root name Dyanavel and the name Dronabinol sound different.
37.	Diclovol	56	The prefixes/infixes of the root name Dyanavel and the name Diclovol have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the name Diclovol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
38.	Digenac XL	56	The prefixes/infixes/suffixes of the root name Dyanavel and the root name Digenac have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the root name Digenac sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
39.	Dovaril	56	<p>The prefixes/infixes of the root name Dyanavel and the name Dovaril have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Dovaril sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
40.	Dymenate	56	<p>The infixes/suffixes of the root name Dyanavel and the name Dymenate have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dymenate sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
41.	Minivelle	56	<p>The prefixes/infixes of the root name Dyanavel and the name Minivelle have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Minivelle sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
42.	Dymelor	55	<p>The infixes/suffixes of the root name Dyanavel and the name Dymelor have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dymelor sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
43.	Tavegil	55	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Tavegil have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Tavegil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
44.	Dynacirc	55	<p>The suffixes of the root name Dyanavel and the name Dynacirc have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dynacirc sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
45.	Daonil	54	<p>The prefixes/infixes of the root name Dyanavel and the name Daonil have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Daonil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
46.	Dicarbosil	54	<p>The prefixes/infixes of the root name Dyanavel and the name Dicarbosil have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dicarbosil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
47.	Dicopanol	54	<p>The prefixes/infixes of the root name Dyanavel and the name Dicopanol have sufficient orthographic differences.</p> <p>The second/third/fourth syllables of the root name Dyanavel and the name Dicopanol sound different.</p>
48.	Dicumarol	54	<p>The prefixes/infixes of the root name Dyanavel and the name Dicumarol have sufficient orthographic differences.</p> <p>The second/third/fourth syllables of the root name Dyanavel and the name Dicumarol sound different.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
49.	Dimotal	54	<p>The prefixes/infixes of the root name Dyanavel and the name Dimotal have sufficient orthographic differences.</p> <p>The second/third syllables of the root name Dyanavel and the name Dimotal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
50.	Dogmatil	54	<p>The prefixes/infixes of the root name Dyanavel and the name Dogmatil have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Dogmatil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
51.	Donnaphen	54	<p>The prefixes/suffixes of the root name Dyanavel and the name Donnaphen have sufficient orthographic differences.</p> <p>The first and last syllables of the root name Dyanavel and the name Donnaphen sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
52.	Dytan-AT	54	<p>The infixes/suffixes of the root name Dyanavel and the root name Dytan have sufficient orthographic differences.</p> <p>The second syllables of the root name Dyanavel and the root name Dytan sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.</p>
53.	Tanafed	54	<p>The prefixes/suffixes of the root name Dyanavel and the name Tanafed have sufficient orthographic differences.</p> <p>The first and last syllables of the root name Dyanavel and the name Tanafed sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
54.	Demerol	54	<p>The prefixes/infixes of the root name Dyanavel and the name</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
			Demerol have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Demerol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
55.	Dynacin	54	The suffixes of the root name Dyanavel and the name Dynacin have sufficient orthographic differences. The last syllables of the root name Dyanavel and the name Dynacin sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
56.	Panfil	54 (Phonetic Score: 73%)	The prefixes/infixes of the root name Dyanavel and the name Panfil have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Panfil sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
57.	Dexasol	53	The prefixes/infixes of the root name Dyanavel and the name Dexasol have sufficient orthographic differences. The first/third syllables of the root name Dyanavel and the name Dexasol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
58.	Diazemuls	53	The prefixes/infixes/suffixes of the root name Dyanavel and the name Diazemuls have sufficient orthographic differences. The third/fourth syllables of the root name Dyanavel and the name Diazemuls sound different.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
59.	Dynex LA	53	The infixes/suffixes of the root name Dyanavel and the root name Dynex have sufficient orthographic differences. The second syllable of the root name Dyanavel and the root name Dynex sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
60.	Indinavir	53	The prefixes/infixes/suffixes of the root name Dyanavel and the name Indinavir have sufficient orthographic differences. The first/second/fourth syllables of the root name Dyanavel and the name Indinavir sound different.
61.	Desyrel	53	The prefixes/infixes of the root name Dyanavel and the name Desyrel have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Desyrel sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
62.	Denaze	52	The prefixes/suffixes of the root name Dyanavel and the name Denaze have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Denaze sound different. The root name Dyanavel contains two extra syllables which helps this name pair sound different when spoken.
63.	Diamode	52	The prefixes/infixes/suffixes of the root name Dyanavel and the name Diamode have sufficient orthographic differences. The last syllables of the root name Dyanavel and the name Diamode sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
64.	Dicel	52	The prefixes/infixes of the root name Dyanavel and the name Dicel have sufficient orthographic differences. The second syllables of the root name Dyanavel and the name Dicel sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
65.	Diphendryl	52	The prefixes/infixes/suffixes of the root name Dyanavel and Diphendryl have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the name Diphendryl sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
66.	Diphenyl	52	The prefixes/infixes/suffixes of the root name Dyanavel and the name Diphenyl have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the name Diphenyl sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
67.	Diuresal	52	The prefixes/infixes of the root name Dyanavel and the name Diuresal have sufficient orthographic differences. The second/third syllables of the root name Dyanavel and the name Diuresal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
68.	Duradryl	52	The prefixes/infixes/suffixes of the root names Dyanavel and Duradryl have sufficient orthographic differences. The first/third syllables of the root name Dyanavel and the name Duradryl sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
69.	Dyline GG	52	<p>The infixes/suffixes of the root name Dyanavel and the root name Dyline have sufficient orthographic differences.</p> <p>The second syllable of the root name Dyanavel the root name Dyline sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.</p>
70.	Guanabenz	52	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Guanabenz have sufficient orthographic differences.</p> <p>The first/third syllables of the root name Dyanavel and the name Guanabenz sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
71.	Panacet	52	<p>The prefixes of the root name Dyanavel and the name Panacet have sufficient orthographic differences.</p> <p>The first/third syllables of the root name Dyanavel and the name Panacet sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
72.	Anadrol-50	52	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the root name Anadrol have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the root name Anadrol sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
73.	Dyna-Hex	52	<p>The infixes/suffixes of the root name Dyanavel and the name Dyna-Hex have sufficient orthographic differences.</p> <p>The last syllables of the root name Dyanavel and the name Dyna-Hex sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
74.	Navstel	52	The prefixes/infixes of the root name Dyanavel and the name Navstel have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Navstel sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
75.	Dynabac	52	The suffixes of the root name Dyanavel and the name Dynabac have sufficient orthographic differences. The last syllables of the root name Dyanavel and the name Dynabac sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
76.	Disipal	51	The prefixes/infixes of the root name Dyanavel and the name Disipal have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Disipal sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
77.	Duraphyl	51	The prefixes/infixes/suffixes of the root name Dyanavel and the name Duraphyl have sufficient orthographic differences. The first/third syllables of the root name Dyanavel and the name Duraphyl sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
78.	Doans Pills	51	The prefixes/infixes/suffixes of the root name Dyanavel and the name Doans Pills have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Doans Pills sound different. The root name Dyanavel contains two extra syllables which helps this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
79.	Donnamar	51	The prefixes/infixes/suffixes of the root name Dyanavel and the name Donnamar have sufficient orthographic differences. The first/third syllables of the root name Dyanavel and the name Donnamar sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
80.	Dynex VR	51	The infixes/suffixes of the root name Dyanavel and the root name Dynex have sufficient orthographic differences. The second syllables of the root name Dyanavel and the root name Dynex sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.
81.	Panaleve	51	The prefixes/infixes/suffixes of the root name Dyanavel and the name Panaleve have sufficient orthographic differences. The first/third syllables of the root name Dyanavel and the name Panaleve sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.
82.	Docetaxel	51	The prefixes/infixes of the root name Dyanavel and the name Docetaxel have sufficient orthographic differences. The first/second/third syllables of the root name Dyanavel and the name Docetaxel sound different.
83.	Dactil	50	The prefixes/infixes of the root name Dyanavel and the name Dactil have sufficient orthographic differences. The first/second syllables of the root name Dyanavel and the name Dactil sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
84.	Zenavod ^{***}	50	<p>The prefixes of the root name Dyanavel and the name Zenavod^{***} have sufficient orthographic differences.</p> <p>The first/third syllables of the root name Dyanavel and the name Zenavod^{***} sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
85.	Dexall	50	<p>The prefixes/infixes of the root name Dyanavel and the name Dexall have sufficient orthographic differences.</p> <p>The first/second syllables of the root name Dyanavel and the name Dexall sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.</p>
86.	Diabetuss	50	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Diabetuss have sufficient orthographic differences.</p> <p>The third/fourth syllables of the root name Dyanavel and the name Diabetuss sound different.</p>
87.	Di-Gel	50	<p>The prefixes/infixes of the root name Dyanavel and the name Di-Gel have sufficient orthographic differences.</p> <p>The second syllables of the root name Dyanavel and the name Di-Gel sound different. The root name Dyanavel contains two extra syllables which help this name pair sound different when spoken.</p>
88.	Dimaphen	50	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Dimaphen have sufficient orthographic differences.</p> <p>The last syllables of the root name Dyanavel and the name Dimaphen sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>

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No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
89.	Docusil	50	<p>The prefixes/infixes of the root name Dyanavel and the name Docusil have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Docusil sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
90.	Domical	50	<p>The prefixes/infixes of the root name Dyanavel and the name Domical have sufficient orthographic differences.</p> <p>The first/second/third syllables of the root name Dyanavel and the name Domical sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
91.	Donnazyme	50	<p>The prefixes/infixes/suffixes of the root name Dyanavel and the name Donnazyme have sufficient orthographic differences.</p> <p>The first and last syllables of the root name Dyanavel and the name Donnazyme sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
92.	Tanafed DM	50	<p>The prefixes/infixes of the root name Dyanavel and the root name Tanafed have sufficient orthographic differences.</p> <p>The first and last syllables of the root name Dyanavel and the root name Tanafed sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>
93.	Tanafed DP	50	<p>The prefixes/infixes of the root name Dyanavel and the root name Tanafed have sufficient orthographic differences.</p> <p>The first and last syllables of the root name Dyanavel and the root name Tanafed sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.</p>

No.	<u>Proposed name:</u> Dyanavel XR <u>Established name:</u> Amphetamine <u>Dosage form:</u> Extended-Release Oral Suspension <u>Strength:</u> 2.5 mg/mL <u>Usual Dose:</u> 2.5 mg (1 mL) to 20 mg (8 mL)—in 2.5 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
94.	Diabinese	50	The prefixes/infixes/suffixes of the root name Dyanavel and the name Diabinese have sufficient orthographic differences. The third/fourth syllables of the root name Dyanavel and the name Diabinese sound different.
95.	Diflunisal	50	The prefixes/infixes of the root name Dyanavel and the name Diflunisal have sufficient orthographic differences. The first/second/fourth syllables of the root name Dyanavel and the name Diflunisal sound different.
96.	Dycill	50	The infixes of the root name Dyanavel and the name Dycill have sufficient orthographic differences. The second syllables of the root name Dyanavel and the name Dycill sound different. The root name Dyanavel contains an extra syllable which helps this name pair sound different when spoken.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 49\%$)

No.	Name	POCA Score (%)
1.	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
1.	(b) (4)***	65	This was an alternate name not reviewed by DMEPA.
2.	Diagesil	64	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
3.	Panafil	64 (Phonetic Score: 73%)	This product has been discontinued. It contained papain. The FDA ordered all companies to stop manufacturing topical products containing papain as of November 24, 2008 and they must not be shipped after January 21, 2009. After this time, all topical products containing papain must obtain FDA approval prior to resuming manufacturing or shipping.
4.	Deanol	62	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
5.	Decanal	62	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
6.	Davana Oil	60	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
7.	Deanase	60	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
8.	Diphenidol	57	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
9.	Drontal	57	This is a veterinary product.
10.	Nonanal	56	This is a colorless, oily liquid that is a component of perfumes. It is not a drug product.
11.	(b) (4)***	55	This name was withdrawn by the sponsor and was not reviewed by DMEPA.
12.	(b) (4)***	54	This name was found unacceptable in OSE Review 2011-3054. The product was approved under the name Stendra.
13.	Dimyрил	54	This name was identified in RxNorm. The product characteristics were not found in commonly used drug

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No.	Name	POCA Score (%)	Failure preventions
			databases.
14.	Dritail	53	This is a veterinary product.
15.	Nuvel	53	This is a family tradename for a number of OTC antiperspirant/deodorant products. It is not the name of a drug.
16.	Travenol	53	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
17.	Dienestrol	53	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
18.	Denaverine	52	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
19.	De-Nol	52	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
20.	Duadacin	52	This product has been discontinued. It contained phenylpropanolamine which was withdrawn from the market for safety reasons.
21.	Dermazole	50	This is a veterinary product.
22.	Doak Tar Oil	50	There is no strength overlap with Dyanavel XR. Dosage information was not found in commonly used (or external) databases.
23.	Dodecanol	50	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.
24.	Dynaxin	50	This name was identified in RxNorm. The product characteristics were not found in commonly used drug databases.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Synarel	64
2.	Vansil	63
3.	(b) (4)***	61
4.	Adacel	60
5.	Cinnsasil	60
6.	Gardasil	60
7.	Gardasil 9	60
8.	Vyndaqel***	60
9.	Pentacel	59
10.	Pyrantel	59
11.	Renagel	59
12.	Zidoval	59
13.	1,10-decanediol	58
14.	Bentasil	58
15.	Gamanil	58
16.	Magagel	58
17.	Mylaval	58
18.	Nasarel	58
19.	Pandel	58
20.	(b) (4)***	58
21.	Vanceril	58
22.	Zamadol	58
23.	Kera Nail	56
24.	Mantadil	56
25.	Menadol	56
26.	Tiadenol	56

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No.	Name	POCA Score (%)
27.	Travasol	56
28.	Travasol 10	56
29.	Travasol 2.75	56
30.	Travasol 2.75/5	56
31.	Travasol 3.5	56
32.	Travasol 4.25/10	56
33.	Travasol 4.25/25	56
34.	Travasol 4.25/5	56
35.	Travasol 5.5	56
36.	Travasol 8.5%	56
37.	Tygacil	56
38.	(b) (4) ***	56
39.	10 Benzagel	55
40.	5 Benzagel	55
41.	Benadryl	55
42.	Benzagel	55
43.	Frenadol	55
44.	Gantanol	55
45.	Nicazel	55
46.	Pediagel	55
47.	Triavil	55
48.	Triavil 2-10	55
49.	Triavil 2-25	55
50.	Triavil 4-10	55
51.	Triavil 4-25	55
52.	Triavil 4-50	55
53.	Basaljel	54
54.	Bedranol	54

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No.	Name	POCA Score (%)
55.	Bromanyl	54
56.	Genacol	54
57.	Menadiol	54
58.	Miranel	54
59.	Monojel	54
60.	Nasin Nasal	54
61.	Naxcel	54
62.	Nidazol	54
63.	Pramegel	54
64.	Tanderil	54
65.	Tanoral	54
66.	Vagisil	54
67.	Vandazole	54
68.	(b) (4) ***	54
69.	Benz-All	53
70.	Ed-In-Sol	53
71.	(b) (4) ***	53
72.	Morantel	53
73.	Mylagel	53
74.	Naquival	53
75.	Novasal	53
76.	Phenobel	53
77.	Vardenafil	53
78.	Amabelz***	52
79.	Betasal	52
80.	B-Natal	52
81.	Bone Meal	52
82.	Calagel	52

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No.	Name	POCA Score (%)
83.	Febantel	52
84.	Gynazole-1	52
85.	Novarel	52
86.	Nrs Nasal	52
87.	Paxarel	52
88.	Pridinol	52
89.	Pseudoval	52
90.	Sildenafil	52
91.	Venomil	52
92.	Conacetol	51
93.	Lamisil	51
94.	Mandol	51
95.	Panoxyl	51
96.	Panoxyl 10	51
97.	Panoxyl 5	51
98.	Paynocil	51
99.	Pedesil	51
100.	Perampanel	51
101.	Prantal	51
102.	Tabradol	51
103.	Vaginyl	51
104.	Viranol	51
105.	Vitazol	51
106.	Acnegel	50
107.	Advil	50
108.	Afrin Nasal	50
109.	Anbesol	50
110.	Benoral	50
111.	Benzo-Jel	50
112.	Brevidil	50

No.	Name	POCA Score (%)
113.	Brondil	50
114.	Cannabinol	50
115.	Cantil	50
116.	Clearasil	50
117.	Clindagel	50
118.	(b) (4)***	50
119.	Farnesal	50
120.	Idenal	50
121.	(b) (4)***	50
122.	Lenzagel	50
123.	Linalool, ()-	50
124.	Linalool, (-)-	50
125.	Linalool, (+)-	50
126.	Linalool, (+-)-	50
127.	Mannitol	50
128.	Mannitol 10%	50
129.	Mannitol 15%	50
130.	Mannitol 20%	50
131.	Mannitol 25%	50
132.	Mannitol 5%	50
133.	Minodyl	50
134.	Mintezol	50
135.	Nadolol	50
136.	Nuvigil	50
137.	Patanol	50
138.	Pentasol	50
139.	Pharmasal	50
140.	Pramimil	50

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No.	Name	POCA Score (%)
141.	Premasol	50
142.	Pyridamal 100	50
143.	Quinapril	50
144.	Seba-Gel	50
145.	Synemol	50
146.	Tadalafil	50
147.	Tandearil	50
148.	Tannate 12 S	50
149.	Tindal	50
150.	(b) (4)***	50
151.	Verapamil	50
152.	Virasal	50
153.	Zinacef	50

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/s/

LORETTA HOLMES
03/09/2015

DANIELLE M HARRIS
03/10/2015

IRENE Z CHAN
03/11/2015