CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212038Orig1s000

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:	October 25, 2018
Application Type and Number:	NDA 212038
Product Name and Strength:	Adhansia XR (methylphenidate hydrochloride) Extended-Release capsules 25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Purdue Pharma (Canada)
Panorama #:	2018-24858045
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Adhansia 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. Purdue Pharma (Canada) resubmitted an external name study previously conducted by [redacted] (b) (4), for the root name, Adhansia. The study was evaluated in our review of the name Adhansia.[a]

1.1 REGULATORY HISTORY

Rhodes Pharmaceuticals L.P. initially submitted the proposed proprietary name, [redacted] (b) (4)*** under IND 118297 on March 4, 2016. However, the name, [redacted] (b) (4)*** was found unacceptable [redacted] (b) (4).[b] Subsequently, the name, Adhansia*** was submitted for review under the IND on May 8, 2017. We found the name, Adhansia*** acceptable[c]; however, we recommended the addition of a modifier to the proposed proprietary name to convey the extended-release nature of the proposed product to help mitigate the potential risk of wrong frequency of administration errors.

Thus, Purdue Pharma (Canada), (a change in sponsor), submitted the name, Adhansia XR***, for review on July 30, 2018 under the NDA. We note that under the IND, [redacted] (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 30, 2018.

- Intended Pronunciation: Not provided
- Active Ingredient: methylphenidate hydrochloride
- Indication of Use: Treatment of Attention Deficit Hyperactivity Disorder (ADHD)
- Route of Administration: Oral
- Dosage Form: Extended-release capsules
- Strengths: 25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg
- Dose and Frequency: 25 mg to 100 mg once daily
- How Supplied: 100-count bottles

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[a] Holmes L Proprietary Name Review for Adhansia IND 118297. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Nov 02. Panorama No. 2017-14893165.

[b] Holmes L Proprietary Name Review for [redacted] (b) (4) IND 118297. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Apr 15. Panorama No. 2016-2986612.

[c] Holmes L Proprietary Name Review for Adhansia IND 118297. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Nov 02. Panorama No. 2017-14893165.

- Storage: Store between 20º C to 25º C (68º F to 77º F); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF) [see USP Controlled Room Temperature]. Protect from light and moisture.

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. The Division of Medication Error Prevention and Analysis (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 name[d].

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name, Adhansia XR, contains two components: 1) the proposed root name "Adhansia" and 2) the modifier "XR". Purdue Pharma (Canada) did not provide a derivation of the root name. The use of the modifier "XR" is evaluated in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 22, 2018 e-mail, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Fifty-four (54) 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.

2.2.5 Analysis of the Proposed Modifier "XR"

The sponsor has proposed the modifier "XR" in the proposed name Adhansia XR, to convey the extended-release nature of the proposed product. There is currently no immediate release product marketed or proposed with only the root name "Adhansia"; however, there are other immediate release methylphenidate products on the market. The use of the modifier "XR" to

[d] USAN stem search conducted on August 21, 2018.

convey that the product is an extended-release dosage form is contingent upon the product meeting the Agency's criteria for this designation. The modifier "XR" has been used for extended-release dosage formulations which have a frequency of administration of "every 12 hours" or "twice daily" or "once daily."

In this case, Adhansia XR has a once daily frequency of administration; therefore, the use of the modifier "XR" is consistent with the dosing frequency associated with other products that have an "XR" modifier. In addition, the modifier "XR" will help differentiate this extended-release formulation from the currently marketed immediate release formulations of methylphenidate. Based on ISMP's 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. We recognize there are limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked. However, after assessing the benefit vs. risk of the use of the modifier, we believe a modifier signaling the extended-release properties of this drug provides an incremental level of safety. Therefore, given the totality of information considered, DMEPA concludes that the use of the modifier "XR" for the proprietary name "Adhansia XR" is appropriate.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We searched the names Adhansia and Adhansia XR in POCA. Our POCA search identified 26 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review of Adhansia. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that (b) (4) ; however, none of the other product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 19 names not previously analyzed. 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. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	15
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 19 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on October 19, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on October 24, 2018, they stated no additional concerns with the proposed proprietary name, Adhansia XR.

3 CONCLUSION

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT/SPONSOR

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

If any of the proposed product characteristics as stated in your submission, received on July 30, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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 DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

***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)).

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.

- Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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.

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

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 ≥ 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.

<table>
<tr><td></td><td colspan="2">

Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
Similar sounding doses: 15 mg is similar in sound to 50 mg

</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <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?

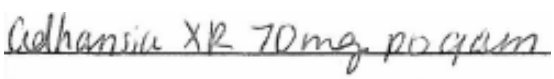
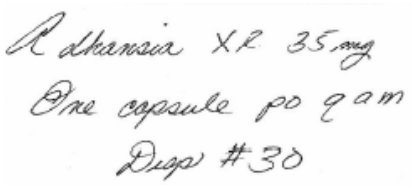
</td></tr>
</table>

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. Adhansia XR Study (Conducted on August 21, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Adhansia XR 35 mg Take one capsule by mouth every morning Dispense #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

			307 People Received Study 54 People Responded	
Study Name: Adhansia XR				
Total	**16**	**19**	**19**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ADDHENSYA XR	0	1	0	1
ADHANCEA XR	0	1	0	1
ADHANCIA XR	0	11	1	12
ADHANSIA XR	12	2	15	29
ADHANSIA XR 35 MG	1	0	0	1
ADHENCIA	0	1	0	1
ADHENCIA XR	0	2	0	2
ADKANSIA XR	1	0	0	1
COLHANSIA XR	0	0	1	1
GELHANSIA XR	0	0	2	2
HADHANCIA XR	0	1	0	1
RDHANSIA XR 35 MG	1	0	0	1
ROLHANSIA XR	1	0	0	1

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

No.	**Proposed name:** **Adhansia XR** **Established name:** **methylphenidate hydrochloride** **Dosage form:** **Extended-release capsules** **Strengths:** **25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg** **Usual Dose:** **25 mg to 100 mg orally once daily**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Adhansia XR***	100	This name is the subject of this review.
2.	(b) (4) ***	75	Proposed proprietary name for NDA 210566 was found unacceptable (OSE Review #2017- 19081749) because, as proposed (b) (4) . NDA 210566, was approved without a proprietary name. Subsequently, a new name, Lexette***, was submitted and is pending review.
3.	Aptensio XR	71	The names Adhansia XR and Aptensio XR differ orthographically due to the fact that the root name "Aptensio" contains the downstroke letter "p" in the second position and the cross-stroke "t" in the second position whereas the root name "Adhansia" does not contain a downstroke letter or cross-stroke letter in those positions. The names differ phonetically due to the fact that the second syllables do not sound similar ("-ten-" vs. "-han"). Additionally, the products differ in strength (25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg vs. 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg) which will help to mitigate the potential for name confusion to occur.

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 (%)
1.	Elepsia XR***	61
2.	Chantix	55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** **Adhansia XR** **Established name:** **methylphenidate hydrochloride** **Dosage form:** **Extended-release capsules** **Strengths:** **25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg** **Usual Dose:** **25 mg to 100 mg orally once daily**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	N/A		

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

No.	Name	POCA Score (%)
1.	Hands First 4 In 1	50

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) ***	68	Proposed proprietary name for IND 116985 was found unacceptable (OSE Review #2014-25868) because (b) (4) The application, NDA 208147, was approved under new proprietary name, Dyanavel XR.
2.	(b) (4) ***	56	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
3.	Adifax	55	International product formerly marketed in Australia, Ireland, South Africa, and the United Kingdom.

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

No.	Name	POCA Score (%)
1.	Namenda XR	62
2.	Xanax XR	60
3.	Dyanavel XR	58
4.	Sanctura XR	58
5.	Dimaphen SR	57
6.	Infanrix	56
7.	Lodrane XR	56
8.	Natrilix SR	56
9.	Nifensar XL	56
10.	Dandrex	55

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

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

/s/

LORETTA HOLMES
10/25/2018

LOLITA G WHITE
10/25/2018