CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204326Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	January 13, 2016
Application Type and Number:	NDA 204326
Product Name and Strength:	Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets) 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neos Therapeutics, Inc.
Panorama #:	2016-2484884
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Adzenys XR-ODT, NDA 204326. This name was found conditionally acceptable in a previous review.[1] We note that there is a change in the product strengths and dose. The previously proposed strengths and doses were: [redacted] The newly proposed strengths and doses are: 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

The product strengths were changed [redacted] However, in our previous review of the name[1], we evaluated the strengths proposed by the Applicant as well as the corresponding strength based on the amount of amphetamine base. Thus, we previously evaluated the following strengths [redacted] (3.1 mg), [redacted] (6.3 mg), [redacted] (9.4 mg), [redacted] (12.5 mg), [redacted] (15.7 mg), and [redacted] (18.8 mg)] and found the name conditionally acceptable. We maintain our decision to accept the name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any 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, Adzenys XR-ODT, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your January 6, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[1] Holmes L. Proprietary Name Review for Adzenys XR-ODT (NDA 204326). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Oct 28. 28 p. Panorama No.: 1120661.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LORETTA HOLMES
01/13/2016

DANIELLE M HARRIS
01/14/2016

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)

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Date of This Review:	October 28, 2015
Application Type and Number:	NDA 204326
Product Name and Strength:	Adzenys XR-ODT (amphetamine) Extended Release Orally Disintegrating Tablets (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neos Therapeutics, Inc.
Panorama #:	2015-1120661
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS
DMEPA Deputy Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Adzenys XR-ODT, 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 submitted an external name study, conducted by (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) on January 4, 2013. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) unacceptable due to orthographic or phonetic similarities and shared product characteristics with the proprietary name, (b) (4) in OSE Review #2013-104, dated April 4, 2013. Subsequently, the name (b) (4) XR-ODT was submitted but later withdrawn prior to our review of the name. The NDA received a Complete Response (CR) action on September 24, 2013. The Applicant resubmitted the NDA application on July 27, 2015 in response to the CR. Subsequently, the Applicant submitted the name, Adzenys XR-ODT, for review on August 5, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 5, 2015 proprietary name submission.

- Intended Pronunciation: add-ZEN-iss ex are oh dee tee
- Active Ingredient: amphetamine
- Indication of Use: Treatment of attention deficit hyperactivity disorder (ADHD)
- Route of Administration: Oral
- Dosage Form: extended release orally disintegrating tablet
- Strengths[1]: (b) (4)
- Dose and Frequency: (b) (4) orally once daily in the morning
- How Supplied: Cartons containing 5 blister cards of 6 tablets each, for a total of 30 tablets

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[1] The Applicant originally submitted the Proprietary Name Request on August 5, 2015 with the strength statements of (b) (4). The Office of Pharmaceutical Quality (OPQ) has recommended that the (b) (4) (b) (4) A final determination on the matter has not been reached by the review team. Thus, the proposed strengths and the strengths based on the free base (in parentheses) were evaluated in this review as follows: (b) (4) (3.1 mg) (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), and (b) (4) (18.8 mg).

- Storage: Store at 25º C (77º F). Excursions permitted to 15-30º C (59-86º F) [see USP Controlled Room Temperature]. Store blister packages in the rigid, plastic travel case provided after removal from the carton.

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 name[2].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Adzenys XR-ODT, was not derived from any one particular concept. This proprietary name is comprised of the root name, Adzenys, and the modifier "XR-ODT". According to the applicant, the modifier "XR-ODT" accurately represents the extended release and orally disintegrating characteristics of the formulation. The modifier is discussed further in Section 2.2.8.

2.2.3 FDA Name Simulation Studies

Seventy-seven practitioners participated in DMEPA's prescription studies. Participants in the voice studies misinterpreted the root name as "Adcentis" (n=1) and "Adzentis" (n=1) which both sound similar to the marketed name, Adcetris. However, these phonetic variations are not compelling. Additionally, the modifier "XR-ODT" adds an additional measure of phonetic differentiation if included. This name pair is discussed further in Appendix E. 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, August 12, 2015 e-mail, the Division of Psychiatry Products (DPP) stated: "No problems are likely from an OPQ perspective; however note that the extended release "XR" and orally disintegrating tablet "ODT" claims will be OPQ review issues."

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[2]USAN stem search conducted on August 10, 2015.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[3] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	89
Low similarity name pair: combined match percentage score ≤49%	11

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Adzenys XR-ODT will potentially be available in strengths of 3.1 mg, 6.3 mg, 9.4 mg, 15.7 mg, and 18.8 mg. Since these are not typical strengths, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Adzenys XR-ODT that were not identified in POCA, and found to have an overlap in strength with Adzenys XR-ODT.

Table 1A. eDRLS Search Results	POCA score
N/A	

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

Our analysis of the 101 names contained in Table 1 determined these names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Safety Analysis of the Modifier "XR-ODT"

Neos Therapeutics has proposed to use the modifier "XR-ODT" to represent their amphetamine extended-release orally disintegrating tablets. According to Neos, "the proposed modifier for Adzenys will be XR-ODT, which accurately represents the extended-release and orally disintegrating tablet formulation."

[3] POCA search conducted on August 10, 2015.

Safety Assessment of XR

Individually, the modifier XR is not new and is currently utilized in the marketplace. The modifier XR is typically used to convey the meaning "extended-release" for products with modified-release formulations.[4] Provided that OPQ determines that the product meets criteria for a modified dosage form, the modifier may serve as a signal to health care practitioners that this product differs from the currently marketed immediate-release products on the market, which may reduce the potential for wrong frequency errors. Although we acknowledge that modifiers may be omitted or overlooked, we believe a modifier signaling the extended-release properties of this drug provides an incremental level of safety. Therefore, the modifier XR is appropriate for conveying this characteristic of the product formulation.

Safety Assessment of ODT

Individually, the modifier ODT is not new and is currently utilized in the marketplace. The modifier ODT is typically used to convey the meaning "orally disintegrating tablet" for products designed to disintegrate or dissolve rapidly on contact with saliva[5]. Provided that OPQ determines that the product meets the criteria for an orally disintegrating product, the modifier may help to communicate the intended method of administration for the product, which may reduce the potential for errors related to wrong administration technique. Therefore, the modifier ODT is appropriate for conveying this characteristic of the product formulation.

Safety Assessment of XR-ODT

Neos has combined two familiar modifiers to make a single modifier "XR-ODT". This modifier is not currently in the marketplace. However, for a product formulation that is extended-release as well as an orally disintegrating tablet, the single modifier XR-ODT appears appropriate. While there are other options for a modifier (e.g., use of a nonsensical modifier) the use of the XR-ODT modifier, each with pre-existing connotation, more accurately conveys the product formulation characteristics using language that healthcare practitioners have likelihood of best interpreting and may therefore be less confusing. We considered the risk of medication error in the event the modifier was dropped. Dropping of the entire modifier would not be unique to this product, however, dropping part of the combined "XR-ODT" modifier would be. We determined that, dropping of part of the modifier may cause confusion leading healthcare practitioners or pharmacists to think that there are two different products in the marketplace. However, as there are no other products on the market with the root name Adzenys, we believe this confusion is likely to occur when the product is first marketed and diminish with uptake of the product. Additionally, we do not think this initial

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[4] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010 [cited 2015 Oct 08]. Available from: http://www.ismp.org/tools/drugnamesuffixes.pdf.

[5] Guidance for Industry: Orally Disintegrating Tablets. Food and Drug Administration. 2008. Available from http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070578.pdf.

confusion will lead to harm of a patient, especially as this product is not utilized for emergency indications where time delay may be more critical. While there may be some initial confusion if this modifier is introduced, we believe that some of this risk can be mitigated through appropriate labeling interventions.

Given the totality of information considered, we believe that adding a modifier to convey the extended release and orally disintegrating properties of the drug is acceptable. Additionally, we believe the modifier XR-ODT is able to convey this information. Thus, we find the modifier XR-ODT acceptable for this product.

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 27, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on October 28, 2015, they stated we should keep in mind that the acceptability of the "XR" and "ODT" designations is currently under review by the Office of Pharmaceutical Quality (OPQ).

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any 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, Adzenys XR-ODT, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your August 5, 2015 submission 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.

6. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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. [6]

[6] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors.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 ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤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 ≥ 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 ≥50% to ≤69%).

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

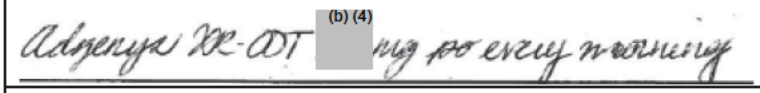
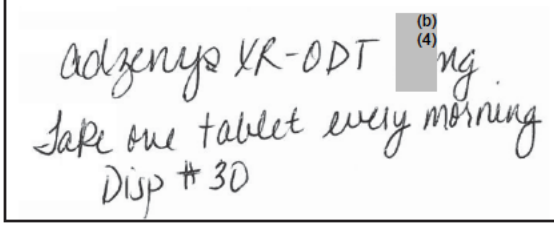
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Adzenys XR-ODT Study (Conducted on August 14, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Adzenys XR-ODT Take 1 tablet by mouth every morning
Outpatient Prescription:  	Disp. #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

			244 People Received Study **77 People Responded**
Study Name: Adzenys XR ODT			
Total	**30**	**22**	**25**
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**
ADCENTIS XR ODT	0	1	0
ADDZENNIS XR ODT	0	1	0
ADEZENYS DR ODT	1	0	0
ADGENYA XR ODT	0	0	1
ADGENYS XR ODT	0	0	2
ADGENYS XR-ODT	0	0	3
ADGENYS XR-OOT	0	0	1
ADGENZS XR ODT	0	0	1
ADOFENYA XE OOT	0	0	1
ADVENYS XR ODT	0	0	1
ADYENYS XR-OOT	0	0	1
ADZENIF XR ODT	0	1	0
ADZENIP XR-ODT	1	0	0

ADZENIS XR ODT	0	9	0
ADZENIS XR-ODT	0	1	0
ADZENOS XR ODT	0	1	0
ADZENOUS XR ODT	0	1	0
ADZENTIS XR ODT	0	1	0
ADZENYA XE ODT	0	0	1
ADZENYA XR ODT	1	0	1
ADZENYA XR-ODT	1	0	3
ADZENYS SR-OCT	0	0	1
ADZENYS XR ODT	3	0	5
ADZENYS XR -ODT	1	0	0
ADZENYS XR-ODT	21	0	2
ADZENYS XT-ODT	1	0	0
ADZENZA TOC-ODT	0	0	1
ADZONIS XR	0	1	0
ASVENTIS XR ODT	0	1	0
HADZENIS XR ODT	0	4	0

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

No.	**Proposed name:** **Adzenys XR-ODT** **Established name: Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths: (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), and (b) (4) (18.8 mg)** **Usual Dose: (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), or (b) (4) (18.8 mg) 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.	Adzenys XR-ODT***	54	This is the name currently under review. The POCA score generated is the root name "Adzenys" vs. the entire name "Adzenys XR-ODT."

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

No.	Name	POCA Score (%)
1.	Aminess	59
2.	Aminess 5.2	59
3.	Ammens	57
4.	Anti-Gas	56
5.	Anti-Gas-80	56
6.	Ed Cyte F	56
7.	Advantage-S	51
8.	Anacin AF	51
9.	Allfen CX	50

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

No.	**Proposed name:** **Adzenys XR-ODT** **Established name:** **Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), and** (b) (4) **(18.8 mg)** **Usual Dose:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), or** (b) (4) **(18.8 mg) 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.	Adcetris	64	The infixes/suffixes ('zenys' vs 'cetris') of the root name Adzenys and the name Adcetris have sufficient orthographic differences. The /third syllables ('nis' vs 'tris') of the root name Adzenys and the name Adcetris sound different with distinct differences of the onsets. Additionally, the modifier "XR-ODT" adds a measure of phonetic differentiation, if included. The products differ in frequency of administration (once daily vs. every 3 weeks), and there are no direct overlaps in dose (b) (4), and (b) (4) vs. 1.8 mg/kg (indicated for adult patients)].
2.	Anzemet	64	The suffixes of the root name Adzenys and the name Anzemet have sufficient orthographic differences. The first/third syllables of the root name Adzenys and the name Anzemet sound different.
3.	Ambenyl	62	The infixes and suffixes of the root name Adzenys and the name Ambenyl have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Ambenyl sound different.

No.	**Proposed name:** **Adzenys XR-ODT** **Established name:** **Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), and** (b) (4) **(18.8 mg)** **Usual Dose:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), or** (b) (4) **(18.8 mg) 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**
4.	Adempas	60	The infixes/suffixes of the root name Adzenys and the name Adempas have sufficient orthographic differences. The second/third syllables of the root name Adzenys and the name Adempas sound different.
5.	Adphen	58	The infixes/suffixes of the root name Adzenys and the name Adphen have sufficient orthographic differences. The root name Adzenys contains an extra syllable which helps to differentiate the name pair.
6.	Advate	58	The infixes/suffixes of the root name Adzenys and the name Advate have sufficient orthographic differences. The second syllables of the root name Adzenys and the name Advate sound different. Adzenys contains an extra syllable.
7.	Antinaus	57	The prefixes/infixes/suffixes of the root name Adzenys and the name Antinaus have sufficient orthographic differences. The first syllables of this name pair sound different.
8.	Antinaus 50	57	The prefixes/infixes/suffixes of the root name Adzenys and the root name Antinaus have sufficient orthographic differences. The first syllables of this name pair sound different.

No.	**Proposed name:** Adzenys XR-ODT **Established name:** Amphetamine **Dosage form:** Extended-release Orally Disintegrating Tablets **Strengths:** (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), and (b) (4) (18.8 mg) **Usual Dose:** (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), or (b) (4) (18.8 mg) 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**
9.	Arsenic	56	The infixes of the root name Adzenys and the name Arsenic have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Arsenic sound different.
10.	Adagen	56	The infixes/suffixes of the root name Adzenys and the name Adagen have sufficient orthographic differences. The second/third syllables of this name pair sound different.
11.	Antrenyl	55	The prefixes/infixes of the root name Adzenys and the name Antrenyl have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Antrenyl sound different.
12.	Diphenyl	55	The prefixes/infixes of the root name Adzenys and the name have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Diphenyl sound different.
13.	(b) (4)	54	The infixes/suffixes of the root name Adzenys and the name (b) (4) have sufficient orthographic differences. The second syllables of the root name Adzenys and the name (b) (4) sound different.

No.	**Proposed name:** **Adzenys XR-ODT** **Established name:** **Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), and** (b) (4) **(18.8 mg)** **Usual Dose:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), or** (b) (4) **(18.8 mg) 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**
14.	Antatens	54	The prefixes/infixes/suffixes of the root name Adzenys and the name Antatens have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Antatens sound different.
15.	Antituss	54	The prefixes/infixes/suffixes of the root name Adzenys and the name Antituss have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Antituss sound different.
16.	Anti-Tuss	54	The prefixes/infixes/suffixes of the root name Adzenys and the name Anti-Tuss have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Anti-Tuss sound different.
17.	Aventyl	54	The prefixes/suffixes of the root name Adzenys and the name Aventyl have sufficient orthographic differences. The third syllables of the root name Adzenys and the name Aventyl sound different.
18.	Aczone	53	The infixes/suffixes of the root name Adzenys and the name Aczone have sufficient orthographic differences. The second syllables of the root name Adzenys and the name Aczone sound different. The root name Adzenys contains an extra syllable.

No.	**Proposed name:** **Adzenys XR-ODT** **Established name:** **Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), and** (b) (4) **(18.8 mg)** **Usual Dose:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), or** (b) (4) **(18.8 mg) 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**
19.	Abetimus	53	The infixes/suffixes of the root name Adzenys and the name Abetimus have sufficient orthographic differences. The second/third syllables of the root name Adzenys and the name Abetimus sound different. The name Abetimus contains an extra syllable.
20.	Adbeon	52	The infixes/suffixes of the root name Adzenys and the name Adbeon have sufficient orthographic differences. The second/third syllables of the root name Adzenys and the name Adbeon sound different.
21.	Antabuse	51	The prefixes/infixes/suffixes of the root name Adzenys and the name Antabuse have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Antabuse sound different.
22.	Adprin B	50	The infixes/suffixes of the root name Adzenys and the root name Adprin have sufficient orthographic differences. The root name Adzenys contains an extra syllable which helps to differentiate the name pair.
23.	Actinex	50	The infixes/suffixes of the root name Adzenys and the name Actinex have sufficient orthographic differences. The first/third syllable of the root name Adzenys and the Actinex sound different.

No.	**Proposed name:** **Adzenys XR-ODT** **Established name:** **Amphetamine** **Dosage form:** **Extended-release Orally Disintegrating Tablets** **Strengths:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), and** (b) (4) **(18.8 mg)** **Usual Dose:** (b) (4) **(3.1 mg),** (b) (4) **(6.3 mg),** (b) (4) **(9.4 mg),** (b) (4) **(12.5 mg),** (b) (4) **(15.7 mg), or** (b) (4) **(18.8 mg) 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**
24.	Amphadase	50	The prefixes/infixes/suffixes of the root name Adzenys and the name Amphadase have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Amphadase sound different.
25.	Aranesp	50	The prefixes/infixes of the root name Adzenys and the name Aranesp have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Aranesp sound different.
26.	Atrovent	50	The prefixes/infixes/suffixes of the root name Adzenys and the name Atrovent have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Atrovent sound different.
27.	Avonex	50	The prefixes/infixes/suffixes of the root name Adzenys and the name Avonex have sufficient orthographic differences. The first/second/third syllables of the root name Adzenys and the name Avonex sound different.
28.	Adlone-40	50	The infixes/suffixes of the root name Adzenys and the root name Adlone have sufficient orthographic differences. The second syllables of the root name Adzenys and the root name Adlone sound different. The root name Adzenys contains an extra syllable.

No.	**Proposed name:** Adzenys XR-ODT **Established name:** Amphetamine **Dosage form:** Extended-release Orally Disintegrating Tablets **Strengths:** (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), and (b) (4) (18.8 mg) **Usual Dose:** (b) (4) (3.1 mg), (b) (4) (6.3 mg), (b) (4) (9.4 mg), (b) (4) (12.5 mg), (b) (4) (15.7 mg), or (b) (4) (18.8 mg) 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**
29.	Adlone-80	50	The infixes/suffixes of the root name Adzenys and the root name Adlone have sufficient orthographic differences. The second syllables of the root name Adzenys and the root name Adlone sound different. The root name Adzenys contains an extra syllable.
30.	(b) (4)	56	The prefixes/infixes of the root name Adzenys and the root name (b) (4) have sufficient orthographic differences. The first/second syllables of the root name Adzenys and the root name (b) (4) sound different.
31.	(b) (4)	56	

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

No.	Name	POCA Score (%)
1.	Adipex	49
2.	Adenosine	48
3.	Albenza	48
4.	Lucentis	44
5.	Ativan	43

No.	Name	POCA Score (%)
6.	Advair	42
7.	Advil	39
8.	Azilect	38
9.	Adalat	36
10.	Adderall	36
11.	Zenatane	34

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.	Adizem-SR	62	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
2.	Adidas	58	This is a family tradename. The product line included multiple deodorant products, some with different ingredients; would have to specify the specific product; all of the names have a modifier; no Adidas root name only
3.	Atenix	58	This is a foreign name.
4.	Adizem	56	This is a foreign name.
5.	(b) (4)	52	This is an alternate name that was not submitted for our review. The NDA was approved under the name Basaglar.
6.	Adgan	52	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
7.	Adizem-XL	52	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
8.	Advocin	52	This is a veterinary product.
9.	Angeze	52	This is a foreign name.

No.	Name	POCA Score (%)	Failure preventions
10.	Angeze SR	52	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
11.	Adenine	51	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
12.	Arsenate	51	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
13.	Anisate	50	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.

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

No.	Name	POCA Score (%)
1.	E-Glades	60
2.	Eze D.S.	59
3.	Eczemin	54
4.	Exodus	54
5.	Heptanes	54
6.	Vancenase	54
7.	Zavedos	54
8.	Endotuss	53
9.	Diphen Af	52
10.	(b) (4)	52
11.		52
12.	Edronax	52
13.	End-Zit	52
14.	Exetuss	52

No.	Name	POCA Score (%)
15.	(b) (4)	52
16.		52
17.	Ursinus	52
18.	Cancidas	51
19.	Desenex	51
20.	(b) (4)	51
21.	Dutrebis	50
22.	Edurant	50
23.	E-Gems	50
24.	Entex S	50
25.	Estinyl	50
26.	Excenel	50
27.	Handclens	50
28.	Iodides	50
29.	Obenix	50
30.	Omontys	50
31.	Onsolis	50
32.	Pentids '200'	50
33.	Pentids '250'	50
34.	Pentids '400'	50
35.	Pentids '800'	50
36.	Xartemis	50

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/s/

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10/28/2015

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10/28/2015

IRENE Z CHAN
10/28/2015

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	April 4, 2013
Reviewer:	Loretta Holmes, BSN, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	(b) (4) (Amphetamine (b) (4) Extended-release Orally Disintegrating Tablets 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 mg
Application Type/Number:	NDA 204326
Applicant:	Neos Therapeutics, Inc.
OSE RCM #:	2013-104

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04/04/2013

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