CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213026Orig1s000

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 23, 2020
Application Type and Number:	NDA 213026
Product Name and Strength:	Amondys 45 (casimersen) injection, 50 mg/mL
Total Product Strength:	100 mg/2 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sarepta Therapeutics, Inc. (Sarepta)
Panorama #:	2020-37147158
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Amondys 45, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Sarepta submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 14, 2020.

- Intended Pronunciation: ah-MAHN-dis
- Active Ingredient: casimersen
- Indication of Use: Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 50 mg/mL (100 mg/2 mL)
- Dose and Frequency: 30 mg/kg once weekly
- How Supplied: 2 mL single dose vials
- Storage: 2 ºC to 8 ºC (36 ºF to 46 ºF) in its original carton until ready for use to protect from light. Do not freeze.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Amondys 45.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Amondys 45 would not misbrand the proposed product but noted phonetic and orthographic similarities to the approved and marketed names, Exondys 51 and Vyondys 53. We evaluated the name pairs, Amondys 45 and Exondys 51, and Amondys 45 and Vyondys 53 further, and find that there are sufficient orthographic and phonetic differences (See Appendix E). The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's promotional assessment for Amondys 45.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Amondys 45.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Amondys 45, is comprised of a root name, Amondys, and a numeric modifier, 45. Sarepta indicated in their submission the root name, Amondys, is somewhat evocative of "exon" and "dystrophin" or "dystrophy," and the modifier, 45, is intended to identify the exon number in the dystrophin gene that is targeted to be skipped by Amondys 45, and thus identify the Duchenne Muscular Dystrophy (DMD) patient subset, which is amenable to treatment by Amondys 45. We assess the proposed modifier, 45, in Section 2.2.3 below.

2.2.3 Assessment of the Modifier, 45

The strategy to use a numeric modifier to convey the exon to be skipped was previously evaluated in reviews of Exondys 51[b], (b) (4)***[c], and Vyondys 53[d] and we found the use of a numeric modifier to identify the DMD patient subset acceptable. As part of those reviews, we considered the appropriateness of the numerical modifier to denote the exon to be skipped, the presentation and placement of modifier, and the potential for misinterpretation of the modifier as the strength, dose, or route of administration.

We note that omission and oversight of a modifier is cited in literature as a common cause of medication error. We note 20/102 participants (19.6%) in the FDA Prescription Simulation Study (11 in the inpatient written prescription study, 5 in the outpatient written prescription study, and 4 in the verbal prescription study) dropped the modifier, '45' (see Appendix B). However, since there are no other products marketed with the root name, Amondys, we find the risk of name confusion associated with omission of the modifier to be low.

Therefore, we do not object to the use of the numeric modifier, 45, in this case.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 27, 2020 e-mail, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Amondys 45 at the initial phase of the review.

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[a] USAN stem search conducted on January 16, 2020.

[b] Harris, J. Proprietary Name Review for Exondys 51 (eteplirsen) (IND 077429). 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). 2014 OCT 29. Panorama No. 2014-25473.

[c] Morris, C. Proprietary Name Review for (b) (4)*** (golodirsen) (NDA211970). 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). 2019 MAR 19. Panorama No. 2018-28117624.

[d] Morris, C. Proprietary Name Review for Vyondys 53 (golodirsen) (NDA 211970). 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). 2019 MAY 17. Panorama No. 2019-30317423.

2.2.5 FDA Name Simulation Studies

One hundred two practitioners participated in DMEPA's prescription studies for Amondys 45. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the prescription simulation studies.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 88 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	83
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 94 names contained in Table 1 determined none of the names will pose a risk for confusion with Amondys 45 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 Neurology 1 (DN 1) via e-mail on March 20, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 1 (DN 1) on March 23, 2020, they stated no additional concerns with the proposed proprietary name, Amondys 45.

3 CONCLUSION

The proposed proprietary name, Amondys 45, is acceptable.

[e] POCA search conducted on January 16, 2020 in version 4.3.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO SAREPTA THERAPEUTICS, INC.

We have completed our review of the proposed proprietary name, Amondys 45, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on January 14, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

In addition, we have the following comment for your consideration:

As you develop proprietary names for future exon skipping DMD drug candidates, please note the practice of including the identical letter string "-ondys" in the root name can result in creating multiple similar proprietary names, which might increase the risk for name confusion among your products.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

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

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

[f] 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 inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

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

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

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

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

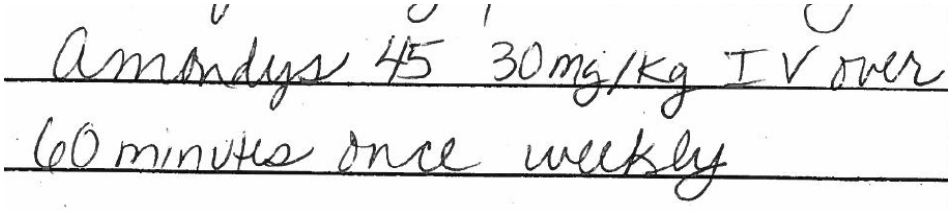
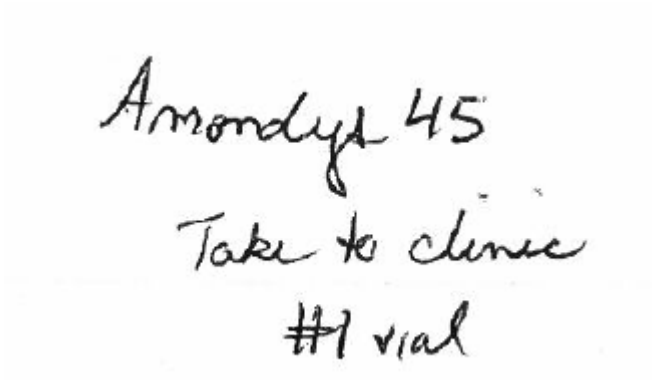
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Amondys 45 Study (Conducted on January 24, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Amondys 45 Take to clinic #1 vial
Outpatient Prescription:  	
CPOE Study Sample (Font: sans-serif, 12 point, bold)	
Amondys 45	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Amondys 45
As of Date 3/4/2020

212 People Received Study
102 People Responded

Study Name: Amondys 45

Total	21	22	18	41	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
AMANDIS 45	0	0	1	0	1
AMANDYS	0	0	0	1	1
AMANDYZ	0	0	0	1	1
AMAUNDAS-45	0	0	1	0	1
AMONDIS	0	0	3	0	3
AMONDIS 45	0	0	5	0	5
AMONDIS-45	0	0	1	0	1
AMONDUS 45	0	0	1	0	1
AMONDYNS 45	0	0	0	1	1
AMONDYS	5	0	0	9	14
AMONDYS 45	14	22	4	29	69
ANORDYL 45	1	0	0	0	1
ANRONDYS 45	1	0	0	0	1
HOMONDIS	0	0	1	0	1
UMANDUS 45	0	0	1	0	1

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

No.	**Proposed name:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	**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.	Omontys	82	Brand withdrawn by the Applicant due to safety reasons (postmarketing reports of serious hypersensitivity reactions including anaphylaxis, which can be life threatening or fatal) and no generic equivalents are available. NDA 202799 withdrawn FR effective 2/13/2019.
2.	Vyondys***	72	This is the root name for the product, Vyondys 53. See below for prevention of failure mode for Vyondys 53.
3.	Vyondys 53	72	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes (‘Am’ vs ’Vy’) provide some orthographic differences. Vyondys contains the downstroke letter ‘y’ in the prefix, whereas Amondys does not contain any downstroke letters in the prefix, which gives the prefixes different shapes when scripted. Phonetically, the 1st syllables (‘ah’ vs ‘vy’) and onset of the second syllables (‘MAHN’ vs ‘ON’) provide sufficient phonetic differences. Additionally, the modifiers (‘45’ vs ‘53’) provide further orthographic and phonetic differences, if used.

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 (%)
4.	Ammens	61
5.	Adzenys	60
6.	Almond Oil	60
7.	Ammonia N 13	57
8.	Ammonia N-13	57
9.	Monistat	56
10.	Monistat 3	56
11.	Monistat 5	56
12.	Monistat 7	56
13.	Monistat-1	56

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:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	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.	Exondys	67	This is the root name for the product, Exondys 51. See below for prevention of failure mode for Exondys 51.
15.	Exondys 51	67	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes (‘Am’ vs ’Ex’) provide some orthographic differences. The name pair begin with different first letters (A vs. E) and Exondys contains the crossed letter ‘x’ in the prefix whereas, Amondys does not contain any crossed letters in the prefix. Phonetically, the 1st syllables (‘ah’ vs ‘ex’) and second syllables (‘MAHN’ vs ‘ON’) provide sufficient phonetic differences. Additionally, the modifiers (‘45’ vs ‘51’) provide further orthographic and phonetic differences, if used.
16.	Aminess	63	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, the onset of the 3rd syllables (dis vs ess) sound different. Additionally, the name Amondys contains the modifier '45' which provides further orthographic and phonetic differences, if used. Furthermore, there is no direct overlap in strength (100 mg/2 mL [50 mg/mL]) vs. 5.2%), which may provide additional differentiation if included.
17.	Aminess 5.2	63	This name pair has sufficient orthographic and phonetic differences. Phonetically, the onset of the 3rd syllables (dis vs ess) sound different. Additionally, the modifiers ('45' vs '5.2') provide further orthographic and phonetic differences, if used. Furthermore, there is no direct overlap in strength (100 mg/2 mL [50 mg/mL]) vs. 5.2%), which may provide additional differentiation if included.
18.	Mononessa	62	This name pair has sufficient orthographic and phonetic differences.
19.	Aminosyn	62	This name pair has sufficient orthographic and phonetic differences.
20.	Aminosyn 10	62	This name pair has sufficient orthographic and phonetic differences.
21.	Aminosyn 10%	62	This name pair has sufficient orthographic and phonetic differences.
22.	Aminosyn 3.5	62	This name pair has sufficient orthographic and phonetic differences.
23.	Aminosyn 3.5%	62	This name pair has sufficient orthographic and phonetic differences.
24.	Aminosyn 5	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	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**
25.	Aminosyn 5%	62	This name pair has sufficient orthographic and phonetic differences.
26.	Aminosyn 7	62	This name pair has sufficient orthographic and phonetic differences.
27.	Aminosyn 7%	62	This name pair has sufficient orthographic and phonetic differences.
28.	Aminosyn 8.5	62	This name pair has sufficient orthographic and phonetic differences.
29.	Aminosyn 8.5%	62	This name pair has sufficient orthographic and phonetic differences.
30.	Monodox	61	This name pair has sufficient orthographic and phonetic differences.
31.	Adempas	60	This name pair has sufficient orthographic and phonetic differences.
32.	Cosamin Ds	60	This name pair has sufficient orthographic and phonetic differences.
33.	Amoxil	58	This name pair has sufficient orthographic and phonetic differences. Orthographically the suffixes (‘dys’ vs ‘il’) provide some differentiation. Amondys contains the upstroke letter ‘d’ and downstroke letter ‘y’ in the suffix, whereas Amoxil contains the dotted letter “i” and upstroke letter “l” in the suffix, which gives the names different shapes when scripted. Additionally, the name Amondys contains the modifier ‘45’, which provides further orthographic and phonetic differences, if used.
34.	Aminosyn 10% (Ph6)	58	This name pair has sufficient orthographic and phonetic differences.
35.	Aminosyn 7% (Ph6)	58	This name pair has sufficient orthographic and phonetic differences.
36.	Aminosyn 8.5% (Ph6)	58	This name pair has sufficient orthographic and phonetic differences.
37.	Monovisc	57	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	**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**
38.	(b) (4) ***	56	(b) (4)
39.	Ammonul	56	This name pair has sufficient orthographic and phonetic differences. Orthographically the suffixes ('dys' vs 'nul') provide some differentiation. Amondys contains the upstroke letter 'd' and downstroke letter 'y' in the suffix, whereas Ammonul ends with the upstroke letter "l", which gives the names different shapes when scripted. Additionally, the name Amondys contains the modifier '45', which provides further orthographic and phonetic differences, if used.
40.	Amino Acids	56	This name pair has sufficient orthographic and phonetic differences.
41.	Amino Acids 11.4%	56	This name pair has sufficient orthographic and phonetic differences.
42.	Amino Acids 15%	56	This name pair has sufficient orthographic and phonetic differences.
43.	Amino Acids 20%	56	This name pair has sufficient orthographic and phonetic differences.
44.	Amino Acids 4%	56	This name pair has sufficient orthographic and phonetic differences.
45.	Amino Acids 5%	56	This name pair has sufficient orthographic and phonetic differences.
46.	Amino Acids 5.4%	56	This name pair has sufficient orthographic and phonetic differences.
47.	Amino Acids 6%	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Amondys 45 **Established name:** casimersen **Dosage form:** injection **Strength(s):** 50 mg/mL **Usual Dose:** 30 mg/kg once weekly	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**
48.	Amino Acids 6.5%	56	This name pair has sufficient orthographic and phonetic differences.
49.	Amino Acids 6.9%	56	This name pair has sufficient orthographic and phonetic differences.
50.	Amino Acids 8%	56	This name pair has sufficient orthographic and phonetic differences.
51.	Aminosyn 3.5% M	56	This name pair has sufficient orthographic and phonetic differences.
52.	Antimony	55	This name pair has sufficient orthographic and phonetic differences.
53.	Asendin	55	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes ('dys' vs 'din') provide some differences. Amondys contains the downstroke letter "y" in the suffix, whereas Asendin contains the dotter letter "i", which gives the names different shapes when scripted. Additionally, the name Amondys contains the modifier '45', which provides further orthographic and phonetic differences, if used.

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

No.	Name	POCA Score (%)
54.	Amino Acid	52
55.	Amoclan	52
56.	Amlobenz	51
57.	Imodium	45
58.	Omnipred	44
59.	Amoxicillin	40

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
60.	(b) (4) ***	67	Proposed proprietary name for NDA 211970 found unacceptable by DMEPA (OSE# 2018-28117624). NDA 211970 approved under the proprietary name Vyondys 53.
61.	Diamond	63	International product marketed in Turkey.
62.	Ionsys	63	Brand discontinued with no generic equivalents available, withdrawn FR effective 08/02/2019.
63.	Amend	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
64.	Monit Ls	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	(b) (4) ***	60	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (OSE# 2017-17475436 dated December 4, 2017). (b) (4) *** found conditionally acceptable for NDA (b) (4), application is currently in CR status.
66.	Monocid	59	Brand discontinued with no generic equivalents available. NDA 050579 and ANDA 063295 withdrawn FR effective 03/13/2002 and 11/12/2002, respectively.
67.	Ambodryl	58	Brand discontinued with no generic equivalents available. NDA 007984 withdrawn FR effective 12/07/1992.
68.	Almodan	58	International product formerly marketed in the United Kingdom and Ireland.
69.	Ammoniac	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
70.	Monodur	58	International product marketed in Turkey and Australia.
71.	Amnest	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	Monit Sr	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Amidox	56	International product formerly marketed in the United Kingdom.
74.	Amonafide	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
75.	Amoxidin	56	International product formerly marketed in United Kingdom.
76.	Atromid-S	56	Brand discontinued with no generic equivalents. NDA 016099 withdrawn FR Effective 06/16/2006.
77.	Numonyl	56	International product formerly marketed and Mexico.
78.	Amoxi	55	International product marketed in Thailand and formerly marketed in multiple other countries outside of the US.
79.	Harmonyl	55	Brand discontinued with no generic equivalent available. NDA 010796 withdrawn FR effective 03/13/2009.
80.	Damason-P	52	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
81.	Samson 8	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
82.	Minodyl	61
83.	Namenda	61
84.	Urban Ds	60
85.	(b) (4)***	58
86.	Mandol	58
87.	Ongentys***	58
88.	Eminase	56
89.	Mannose	56
90.	M-End Wc	56
91.	Mindal	56
92.	(b) (4)***	56
93.	Omnaris	56
94.	Mydayis	55

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

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