

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

211970Orig1s000

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:	December 5, 2019
Application Type and Number:	NDA 211970
Product Name and Strength:	Vyondys 53 (golodirsen) 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.
Panorama #:	2019-36125575
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Briana Rider, PharmD, CPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vyondys 53, which was found conditionally acceptable under NDA 211970 on May 17, 2019.^a However, NDA 211970 received a Complete Response on August 19, 2019. On November 22, 2019, the Agency issued a Dispute Appeal Granted Letter. Thus, Sarepta re-submitted the name, Vyondys 53, for review with their Class I Resubmission of NDA 211970 on November 27, 2019. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT^b

The Office of Prescription Drug Promotion (OPDP) determined that Vyondys 53 would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Vyondys 53.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 proposed proprietary name. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 27, 2019 search of USAN stem list did not identify any USAN stems in the proposed proprietary name, Vyondys 53.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Neurology 1 (DN 1) via e-mail on December 4, 2019. 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 December 5, 2019, they stated no additional concerns with the proposed proprietary name, Vyondys 53.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Vyondys 53, is acceptable.

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

^a Morris, C. Proprietary Name Review for Vyondys 53 (golodirsen) NDA 211970. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 MAY 17. Panorama No.: 2019-30317423.

^b Misbranding assessment was conducted during the previous review cycle. OPDP determined that Vyondys 53 would not misbrand the proposed product and DN1 concurred with OPDP's assessment on April 2, 2019 and April 12, 2019, respectively.

3.1 COMMENTS TO SAREPTA THERAPEUTICS, INC.

We have completed our review of the proposed proprietary name, Vyondys 53, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on November 27, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

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/

JOHN C MORRIS
12/05/2019 09:04:00 AM

BRIANA B RIDER
12/05/2019 09:09:29 AM

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:	May 17, 2019
Application Type and Number:	NDA 211970
Product Name and Strength:	Vyondys 53 (golodirsen) 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 #:	2019-30317423
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader (Acting):	Briana Rider, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyondys 53, 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 REGULATORY HISTORY

Sarepta previously submitted the proposed proprietary name, (b) (4) *** and the alternate proposed name, Vyondys 53***, on December 19, 2018. However, we found the name, (b) (4) *** unacceptable due to concerns that it will be confused with the proprietary name, (b) (4), under NDA (b) (4) on March 19, 2019.^a

Thus, Sarepta submitted a request for review of their proposed alternative proprietary name, Vyondys 53, on March 26, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 26, 2019.

- Intended Pronunciation: vy-ON-dys
- Active Ingredient: golodirsen
- Indication of Use: treatment for the subset of DMD patients who have a mutation of the DMD gene that is amenable to exon 53 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: Carton containing 1 single-dose vial (2 mL)
- Storage: 2 °C to 8 °C (36 °F to 46 °F) in its original carton until ready for use to protect from light.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Vyondys 53.

2.1 MISBRANDING ASSESSMENT

^a Morris, C. Proprietary Name Review for (b) (4) (golodirsen) (NDA 211970). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 MAR 19. Panorama No. 2018-28117624.

The Office of Prescription Drug Promotion (OPDP) determined that Vyondys 53 would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment for Vyondys 53.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Vyondys 53.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name is comprised of a root name, Vyondys, and a numeric modifier, 53. Sarepta indicated in their submission that the root name, Vyondys, is somewhat evocative of “exon” and “dystrophin” or “dystrophy,” and the modifier “53” is intended to identify the exon number in the dystrophin gene that is targeted to be skipped by Vyondys 53, and thus identify the Duchenne Muscular Dystrophy (DMD) patient subset, which is amenable to treatment by Vyondys 53. We assess the proposed modifier “53” in Section 2.2.3 below.

2.2.3 Assessment of the Modifier, 53

The strategy to use a numeric modifier to convey the exon to be skipped was previously evaluated in two reviews of Exondys 51^{cd} and in our review of (b) (4) ***a; 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 20/88 participants (22.7%) in the FDA Prescription Simulation Study (18 in the inpatient written prescription study and 2 in the outpatient written prescription study) dropped the modifier '53' (see Appendix B). However, since there are no other products marketed with the root name, Vyondys, 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, 53, in this case.

^b USAN stem search conducted on April 8, 2019.

^c 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.

^d Harris, J. Proprietary Name Review MEMO for Exondys 51 (eteplirsen) (NDA 206488). 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 SEP 30. Panorama No. 2015-1341038.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 5, 2019 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to Vyondys 53 at the initial phase of the review.

2.2.5 FDA Name Simulation Studies

Eighty-eight practitioners participated in DMEPA's prescription studies for Vyondys 53. The responses did not directly overlap with any currently marketed products or any products in the pipeline. Two participants in the verbal prescription study misinterpreted the first syllable 'vy' as 'my' and provided the responses, Myondis 53 and Myondiss 53. We find the root names for these responses to be similar to the marketed product, Mydayis. We considered the risk for name confusion between Vyondys 53 and Mydayis, and determine the name pair has sufficient orthographic, phonetic, and product characteristic differences. See our assessment of the name pair, Vyondys 53 and Mydayis, in Appendix E. Appendix B contains the results from the verbal and written prescription studies.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^e identified 30 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. 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, FDA Prescription Study, 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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	28
Low similarity name pair: combined match percentage score $\leq 54\%$	10

^e POCA search conducted on April 8, 2019 in version 4.3.

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

Our analysis of the 39 names contained in Table 1 determined none of the names would pose a risk for confusion with Vyondys 53 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 Products (DNP) via e-mail on May 10, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on May 17, 2019, they stated no additional concerns with the proposed proprietary name, Vyondys 53.

3 CONCLUSION

The proposed proprietary name, Vyondys 53, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO SAREPTA THERAPEUTICS, INC.

We have completed our review of the proposed proprietary name, Vyondys 53, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on March 26, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the checklist (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 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.

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

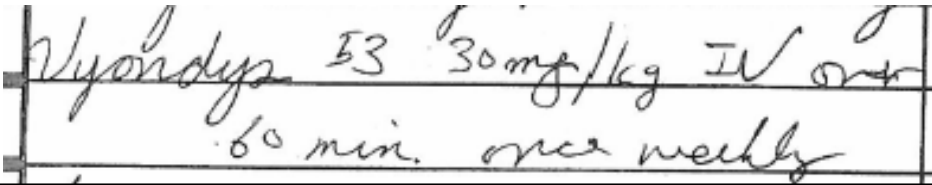
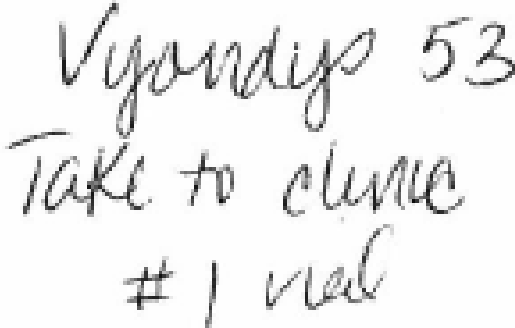
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Vyondys 53 Study (Conducted on April 5, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u>  <u>Outpatient Prescription:</u> 	Vyondys 53 Take to clinic #1 vial

FDA Prescription Simulation Responses (Aggregate Report)

221 People Received Study
88 People Responded

Study Name: Vyondys 53

Total	18	17	53	88
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
MYONDIS 53	0	1	0	1
MYONDISS 53	0	1	0	1
VIONDESS 53	0	1	0	1
VIONDIS 53	0	6	0	6
VIONDYS	0	0	1	1
VIONDYS 53	0	5	0	5
VYANDYS	1	0	0	1
VYANDYS 53	6	0	0	6
VYNDYS 53	0	0	1	1
VYONDES 53	0	1	1	2
VYONDIS 53	0	1	0	1
VYONDIS-53	0	1	0	1
VYONDYS	1	0	17	18
VYONDYS 53	10	0	31	41
VYONDYX 53	0	0	1	1
VYONDYZ 53	0	0	1	1

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

No.	Proposed name: Vyondys 53 Established name: golodirsen 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.	Vyondys 53***	100	This is the name under review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
N/A		

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

No.	Proposed name: Vyondys 53 Established name: golodirsen 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
2.	Exondys	68	This is the root name for the product, Exondys 51. See below for prevention of failure mode for Exondys 51.

No.	Proposed name: Vyondys 53 Established name: golodirsen 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
3.	Exondys 51	68	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes ('Vy' vs 'Ex') provide some orthographic differences. Vyondys contains the downstroke letter 'y' in the prefix whereas, Exondys does not contain any downstroke letters in the prefix, which gives the names different shapes when scripted. Phonetically, the 1st syllables ('vy' vs 'ex') provide sufficient phonetic differences. Additionally, the modifiers ('53' vs '51') provide further orthographic and phonetic differences, if used.

No.	Proposed name: Vyondys 53 Established name: golodirsen 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
4.	Syndros	68	This name pair has sufficient orthographic and phonetic differences. Orthographically, the first letters ('V' vs 'S') of this name pair are different. The suffixes ('ys' vs 'ros') of this name pair also provide some orthographic differences. Vyondys contains the downstroke letter 'y' in the suffix whereas, Syndros does not contain any downstroke letters in the suffix, which gives the names different shapes when scripted. Phonetically, the 1st ('vy' vs 'sin') and 2nd syllables ('on' vs 'dros') of this name pair provide some phonetic differences. Additionally, the root name Vyondys contains an extra syllable. Additionally, the modifier, 53, for the proposed name, Vyondys 53, will provide further orthographic and phonetic differences, if used.
5.	Yondelis	62	This name pair has sufficient orthographic and phonetic differences.
6.	Bron-Tuss	58	This name pair has sufficient orthographic and phonetic differences.
7.	Brontuss	58	This name pair has sufficient orthographic and phonetic differences.
8.	Vantas	58	This name pair has sufficient orthographic and phonetic differences.
9.	Vyxeos	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Vyondys 53 Established name: golodirsen 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
10.	Vionex	57	This name pair has sufficient orthographic and phonetic differences. Orthographically, the second letters ('y' vs 'i') and suffixes ('dys' vs 'ex') provide some differences. Phonetically, the 3rd syllables ('dys' vs 'ex') sound different. Furthermore, Vionex is a nonprescription antiseptic handwash; there is no direct overlap in the following product characteristics: dosage form (injection vs gel), route of administration (intravenous infusion vs topical), dose (30 mg/kg vs 5 mL), or frequency (weekly vs as needed).
11.	Vyvanse	57	This name pair has sufficient orthographic and phonetic differences.
12.	Cyonanz	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Vyondys 53 Established name: golodirsen 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
13.	Mydayis	48	This name pair has sufficient orthographic and phonetic differences. Orthographically, the first letters ('V' vs 'M') of this name pair are different, and the infixes and beginning of the suffixes are sufficiently different. Phonetically, the 2nd syllable ('on' vs 'day') and onset of the 3rd syllable ('dys' vs 'is') sound different. Additionally, the modifier, 53, for the proposed name, Vyondys 53, will provide further orthographic and phonetic differences, if used. Furthermore, there is no direct overlap in the following product characteristics: dosage form (injection vs ER capsule), route of administration (intravenous infusion vs oral), dose (30 mg/kg vs 12.5 mg, 25 mg 37.5 mg, or 50 mg), or frequency (weekly vs daily in the morning).

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

No.	Name	POCA Score (%)
14.	Yonsa	52
15.	Vytorin	48
16.	Bion tears	46
17.	Bionect	42
18.	Byvalson	40
19.	Indocin	39
20.	Bydureon	36
21.	Ionamin	36
22.	Vyzulta	36

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
23.	Brondil	55	International product marketed in the Philippines and formerly marketed in Thailand.
24.	(b) (4) ***	68	Proposed proprietary name for NDA 211970 found unacceptable by DMEPA (OSE# 2018-28117624). The proposed proprietary name, Vyondys 53, has been submitted for NDA 211970, and is the name currently under evaluation in this review.
25.	Ionsys	66	Brand discontinued with no generic equivalents available. Sponsor requested withdrawal of NDA 021338 approval on 09/17/2018, which was acknowledged by the agency on 09/27/2018. Pending FR notice.
26.	Savlon Dry	56	International product marketed in UK and formerly marketed in Australia and Ireland.
27.	Vendone	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
28.	(b) (4) ***	56	Proposed proprietary name for NDA 208743 found unacceptable by DMEPA (OSE# 2016-8278936). NDA 208743 approved under proprietary name Tymlos.
29.	Ventuss	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
30.	Vicodin Es	56	ANDA 89736 was withdrawn, FR effective 07/17/2014.
31.	(b) (4) ***	57	Proposed proprietary name for IND (b) (4) found conditionally acceptable by DMEPA (OSE # (b) (4), dated (b) (4)). IND (b) (4) is inactive since (b) (4).

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 (%)
32.	Bonsity***	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

No.	Name	POCA Score (%)
33.	Bronkids	56
34.	Dytan-Cs	56
35.	Omontys	64
36.	Sronyx	56
37.	Syntest	57
38.	Synvisc	60
39.	Xyosted	58

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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 19, 2019
Application Type and Number:	NDA 211970
Product Name and Strength:	(b) (4) (golodirsen) Injection, 50 mg/mL (100 mg/2 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 #:	2018-28117624
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD
DMEPA Deputy Director	Danielle Harris, PharmD, BCPS

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