

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**215809Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME MEMORANDUM**

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)  
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\*\***

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|---------------------------------------------------------------------|---------------------------------------------------------------|
| <b>Date of This Review:</b>                                         | March 14, 2022                                                |
| <b>Application Type and Number:</b>                                 | NDA 215809                                                    |
| <b>Product Name and Strength:</b>                                   | Ermeza ( (b) (4) ) Oral Solution,<br>150 mcg/5 mL (30 mcg/mL) |
| <b>Product Type:</b>                                                | Combination Product (Drug-Device)                             |
| <b>Rx or OTC:</b>                                                   | Prescription (Rx)                                             |
| <b>Applicant/Sponsor Name:</b>                                      | Mylan Pharmaceuticals Inc. (Mylan)                            |
| <b>PNR ID #:</b>                                                    | 2022-1044724457                                               |
| <b>DMEPA 1 Safety Evaluator:</b>                                    | Corwin D. Howard, PharmD, RPh                                 |
| <b>DMEPA 1 Team Leader:</b>                                         | Sevan H. Kolejian, PharmD, MBA, BCPPS                         |
| <b>DMEPA 1 Associate Director for<br/>Nomenclature and Labeling</b> | Mishale Mistry, PharmD, MPH                                   |

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ermeza, which was found unacceptable under NDA 215809 on September 28, 2021.<sup>a</sup> The proposed proprietary name, Ermeza, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) \*\*\*, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Ermeza, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 215809 is April 29, 2022, whereas the underlying application for (b) (4) \*\*\* remains in complete response status<sup>b</sup>. Therefore, if the proposed proprietary name, Ermeza, is granted approval under NDA 215809 on or before April 29, 2022, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) \*\*\*.

Thus, Mylan resubmitted the proposed proprietary name, Ermeza, for review.

## 2 METHODS AND DISCUSSION

### 2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Ermeza, DMEPA 1 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, DMEPA 1 searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 3, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA 1 evaluated the status of the underlying application of the conflicting name, (b) (4) \*\*\*, and determined that if NDA 215809 for Ermeza is approved on or before the April 29, 2022, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) \*\*\* given the underlying application for (b) (4) \*\*\* remains in complete response status.

Based upon our safety assessment of the proposed proprietary name, Ermeza, the application goal date for NDA 215809, and the status of the underlying application for (b) (4) \*\*\*, we find Ermeza conditionally acceptable.

### 2.2 COMMUNICATION OF DMEPA'S 1 DETERMINATION

DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE) via e-mail on March 14, 2022.

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<sup>a</sup> Kolejian, S. Proprietary Name Review for Ermeza (NDA 215809). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 Sep 28. PNR ID No. 2021-1044724046.

<sup>b</sup> NDA (b) (4) \*\*\* is in complete response status as of (b) (4)

### **3 CONCLUSIONS**

We conclude that the proposed proprietary name, Ermeza, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

#### **3.1 COMMENTS TO MYLAN PHARMACEUTICALS INC.**

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

If any of the proposed product characteristics as stated in your submission, received on February 23, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

## 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.

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/s/  
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**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)  
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\*\*\***

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|--------------------------------------------------------------------------|--------------------------------------------------------------------------|
| <b>Date of This Review:</b>                                              | September 28, 2021                                                       |
| <b>Application Type and Number:</b>                                      | NDA 215809                                                               |
| <b>Product Name and Strength:</b>                                        | Ermeza (levothyroxine sodium) Oral Solution,<br>150 mcg/5 mL (30 mcg/mL) |
| <b>Product Type:</b>                                                     | Combination Product (Drug-Device)                                        |
| <b>Rx or OTC:</b>                                                        | Prescription (Rx)                                                        |
| <b>Applicant/Sponsor Name:</b>                                           | Mylan Pharmaceuticals Inc. (Mylan)                                       |
| <b>PNR ID #:</b>                                                         | 2021-1044724046                                                          |
| <b>DMEPA 1 Team Leader:</b>                                              | Sevan H. Kolejian, PharmD, MBA, BCPPS                                    |
| <b>DMEPA 1 Associate Director<br/>for Nomenclature and<br/>Labeling:</b> | Mishale Mistry, PharmD, MPH                                              |

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## Contents

|     |                                             |   |
|-----|---------------------------------------------|---|
| 1   | INTRODUCTION .....                          | 1 |
| 1.1 | Regulatory History.....                     | 1 |
| 1.2 | Product Information.....                    | 1 |
| 2   | RESULTS.....                                | 3 |
| 2.1 | Misbranding Assessment .....                | 3 |
| 2.2 | Safety Assessment .....                     | 4 |
| 3   | CONCLUSION .....                            | 6 |
| 3.1 | Comments to Mylan Pharmaceuticals Inc. .... | 6 |
|     | REFERENCES .....                            | 8 |
|     | APPENDICES .....                            | 9 |

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Ermeza, 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. Mylan submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

### 1.1 REGULATORY HISTORY

Mylan previously submitted the proposed proprietary name, Ermeza\*\*\* on May 17, 2018 for ANDA 201675, estradiol transdermal system (different product). We found the name, Ermeza\*\*\* acceptable with the proprietary name, Ermeza\*\*\* under ANDA 201675/S-006 on August 8, 2018<sup>a</sup>. However, Mylan submitted the name, Ermeza, for review on June 30, 2021 for levothyroxine sodium Oral Solution under NDA 215809 stating that the proprietary name Ermeza\*\*\* was not marketed under ANDA 201675<sup>b</sup>. Subsequently, Mylan withdrew the name Ermeza for ANDA 201675 for estradiol transdermal system on September 7, 2021<sup>c</sup>.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 30, 2021.

- Intended Pronunciation: er-meh-zah
- Active Ingredient: levothyroxine sodium
- Indication of Use: Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.  
Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer
- Route of Administration: Oral
- Dosage Form: Oral Solution
- Strength: 150 mcg/5 mL (30 mcg/mL)

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<sup>a</sup> Baugh, D. Proprietary Name Review for Ermeza (ANDA 201675/S-006). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 08 08. PNR ID No. 2018-23121870.

<sup>b</sup> Cover letter, Original New Drug Application (NDA 215809 for levothyroxine sodium oral solution). Beltsville (MD): Mylan; 2021 JUN 30. Available from: EDR LINK <file:///cdsesub1/evsprod/NDA215809/0001/m1/us/12-cover-letters/cover-letter-0001-original-nda-20210630.pdf>

<sup>c</sup> Proprietary Name Withdrawal Request (ANDA 201675 for estradiol transdermal system). Beltsville (MD): Mylan; 2021 SEP 7. Available from: EDR LINK <file:///cdsesub1/evsprod/NDA215809/0001/m1/us/12-cover-letters/cover-letter-0001-original-nda-20210630.pdf>

- Dose and Frequency:

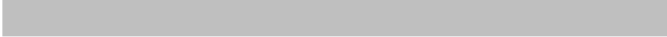
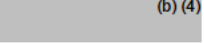
#### **General Principles of Dosing**

- The dose of levothyroxine for hypothyroidism or pituitary TSH suppression depends on a variety of factors including: the patient's age, body weight, cardiovascular status, concomitant medical conditions (including pregnancy), concomitant medications, co-administered food and the specific nature of the condition being treated. Dosing must be individualized to account for these factors and dose adjustments made based on periodic assessment of the patient's clinical response and laboratory parameters
- The peak therapeutic effect of a given dose may not be attained for 4 to 6 weeks.

#### **Primary Hypothyroidism in Adults**

(b) (4)

:

-  he  
average full replacement dose is approximately 1.6 mcg per kg per day   

- Adjust the dose by 12.5 to 25 mcg increments every 4 to 6 weeks  . Doses greater than 200 mcg per day are seldom required. An inadequate response to daily doses of greater than 300 mcg per day is rare and may indicate poor compliance, malabsorption, drug interactions, or a combination of these factors.

(b) (4)

(b) (4)

#### **Pediatric Dosage - Congenital or Acquired Hypothyroidism:**

- The recommended daily dose in pediatric patients with hypothyroidism is based on body weight and changes with age as described in Table 1. (b) (4)

**Table 1**

| <b>AGE</b>                                                                                                                                                                     | <b>Daily Dose Per Kg Body Weight<sup>a</sup></b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| 0-3 months                                                                                                                                                                     | 10-15 mcg/kg/day                                 |
| 3-6 months                                                                                                                                                                     | 8-10 mcg/kg/day                                  |
| 6-12 months                                                                                                                                                                    | 6-8 mcg/kg/day                                   |
| 1-5 years                                                                                                                                                                      | 5-6 mcg/kg/day                                   |
| 6-12 years                                                                                                                                                                     | 4-5 mcg/kg/day                                   |
| Greater than 12 years but growth and puberty incomplete                                                                                                                        | 2-3 mcg/kg/day                                   |
| Growth and puberty complete                                                                                                                                                    | 1.6 mcg/kg/day                                   |
| a. The dose should be adjusted based on clinical response and laboratory parameters [see <i>Dosage and Administration</i> (2.4) and <i>Use in Specific Populations</i> (8.4)]. |                                                  |

- How Supplied:
  - Supplied in a 90 mL or 180 mL amber glass bottle with child resistant closure.
  - A 5 mL or 10 mL oral syringes are provided within the carton to accurately measure the prescribed dose.
- Storage: Store in the original container at 68° to 77°F (20°C to 25°C); [See USP Controlled Room Temperature]. Protect from light. Store and dispense in original bottle. Use within 90 days of opening the bottle.
- Reference Listed Drug/Reference Product: NDA 021402; Synthroid (levothyroxine sodium) Tablets, USP

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

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

## 2.2 SAFETY ASSESSMENT

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

### 2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name<sup>d</sup>.

### 2.2.2 *Components of the Proposed Proprietary Name*

Mylan did not provide a derivation or intended meaning for the proposed proprietary name, Ermeza\*\*\*, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

### 2.2.3 *Comments from Other Review Disciplines at Initial Review*

On July 14, 2021, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Ermeza at the initial phase of the review.

### 2.2.4 *FDA Name Simulation Studies*

One hundred twenty-nine (129) practitioners participated in DMEPA's prescription studies for Ermeza. Forty-six (46) practitioners (26 outpatient and 20 inpatient) interpreted Ermeza\*\*\* as Enmeza and one outpatient practitioner interpreted Ermeza\*\*\* as Enmiza. Enmeza and Enmiza are both similar to the marketed OTC product Enmeez.

#### **Ermeza vs. Enmeez**

We note the marketed product Enmeez was identified in our POCA search. Orthographically, the suffixes look different when scripted (meza vs. meez) as Enmeez contains letters "ee" in suffix and Ermeza\*\*\* ends with letter "a". Additionally, we considered the differences between the products characteristics of this name pair and determined the risk of medication error between **Ermeza vs. Enmeez** is adequately minimized (see Appendix E).

The remaining responses did not overlap with any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

### 2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search<sup>e</sup> identified 90 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.

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<sup>d</sup> USAN stem search conducted on July 10, 2021.

<sup>e</sup> POCA search conducted on August 17, 2021 in version 4.4.

### 2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the 90 names retrieved from our POCA search and 222 names from 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:<br>combined match percentage score $\geq 70\%$                    | 3               |
| Moderately similar name pair:<br>combined match percentage score $\geq 55\%$ to $\leq 69\%$ | 95              |
| Low similarity name pair:<br>combined match percentage score $\leq 54\%$                    | 213             |

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

We determined 311 of the 312 names will not pose a risk for confusion with Ermeza as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4) \*\*\*. The rationale for the risk of confusion is described below.

**Ermeza\*\*\*vs (b) (4) \*\*\***

We have completed our review of the proposed proprietary name, Ermeza, and have concluded that this name is unacceptable for the following reasons:

(b) (4)

<sup>f</sup> Institute for Safe Medication Practices. Safety briefs: New look-alike name pairs. ISMP Med Saf Alert Acute Care. 2004;9(5)21-3.

<sup>g</sup> POCA search conducted on search date in version 4.x.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name which concluded the proposed name, Ermeza<sup>\*\*\*</sup>, is acceptable. However, (b) (4) <sup>(b) (4)</sup>\*\*\* is a pending proposed proprietary name and, thus, was not identified in the (b) (4) study.

Therefore, based on the totality of the information above, we find the proposed proprietary name, Ermeza, vulnerable to medication errors due to name confusion with (b) (4) <sup>(b) (4)</sup>\*\*\*.

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

DMEPA 1 communicated our findings to the Division of General Endocrinology (DGE) on September 28, 2021.

## **3 CONCLUSION**

The proposed proprietary name, Ermeza, is not acceptable from a safety perspective. The proposed proprietary name, Ermeza, is vulnerable to name confusion with the pending name, (b) (4) <sup>(b) (4)</sup>\*\*\*. Therefore, the decision to deny the name will be communicated to Mylan via letter (see Section 3.1).

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

<sup>h</sup> Institute for Safe Medication Practices. 2012 Mar. Safety briefs: Ranexa and Prenexa too similar. ISMP Med Saf Alert Community/Ambulatory Care. 2012;11(3):1-2.

<sup>i</sup> Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

### **3.1 COMMENTS TO MYLAN PHARMACEUTICALS INC.**

We have completed our review of the proposed proprietary name, Ermeza, and have concluded that this name is unacceptable for the following reason:

The proposed proprietary name, Ermeza, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Ermeza, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name, Ermeza, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the [REDACTED] (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and, thus, was not identified by the [REDACTED] (b) (4) [REDACTED] external study.

## 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](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.<sup>j</sup>

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<sup>j</sup> National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

**\*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.                                                 |
| <b>Y/N</b> | <b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>                                                                                                                                                       |
|            | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.                                                                                                   |
| <b>Y/N</b> | <b>Are there inert or inactive ingredients referenced in the proprietary name?</b>                                                                                                                                                                |
|            | 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)). |
| <b>Y/N</b> | <b>Does the proprietary name include combinations of active ingredients?</b>                                                                                                                                                                      |
|            | 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)).                                                                         |
| <b>Y/N</b> | <b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>                                                                                                                                                                 |
|            | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.                                                                                                                                           |
| <b>Y/N</b> | <b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>                                                                                                                               |
|            | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.                                                                                                                          |
| <b>Y/N</b> | <b>Is this a proprietary name of a discontinued product?</b>                                                                                                                                                                                      |
|            | 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 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  $\geq 70$  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<sup>k</sup>. 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

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<sup>k</sup> Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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.

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  $\geq 70\%$ ).**

| 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> |                                                                                                           |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | Do the names begin with different first letters?<br><br><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i> | <b>Y/N</b>                | Do the names have different number of syllables?                                                          |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | Are the lengths of the names dissimilar* when scripted?<br><br><i>*FDA considers the length of names different if the names differ by two or more letters.</i>                              | <b>Y/N</b>                | Do the names have different syllabic stresses?                                                            |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | 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?                        | <b>Y/N</b>                | Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | Is there different number or placement of cross-stroke or dotted letters present in the names?                                                                                              | <b>Y/N</b>                | Across a range of dialects, are the names consistently pronounced differently?                            |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | Do the infixes of the name appear dissimilar when scripted?                                                                                                                                 |                           |                                                                                                           |
| <b>Y/N</b>                                                                                                                                                                                                                                                                                | 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 | <p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul> |
| Step 2 | <p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <b><u>with</u></b> overlapping or similar strengths or doses.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

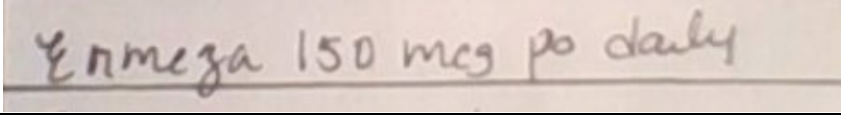
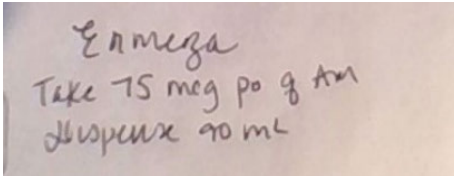
|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>Do the names begin with different first letters?<br/>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</li> <li>Are the lengths of the names dissimilar* when scripted?<br/>*FDA considers the length of names different if the names differ by two or more letters.</li> <li>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?</li> <li>Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>Do the infixes of the name appear dissimilar when scripted?</li> <li>Do the suffixes of the names appear dissimilar when scripted?</li> </ul> | <p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>Do the names have different number of syllables?</li> <li>Do the names have different syllabic stresses?</li> <li>Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li> <li>Across a range of dialects, are the names consistently pronounced differently?</li> </ul> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**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. Ermeza Study (Conducted on July 27, 2021)**

| Handwritten Medication Order/Prescription                                                                            | Verbal Prescription                            |
|----------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <u>Medication Order:</u><br>       | Ermeza<br><br>Take 150 mcg by mouth once daily |
| <u>Outpatient Prescription:</u><br> |                                                |
| <b>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</b><br>Ermeza                                    |                                                |

## FDA Prescription Simulation Responses (Aggregate Report)

|                                                   |            |      |       |           |       |
|---------------------------------------------------|------------|------|-------|-----------|-------|
| Study Name: Ermeza***                             |            |      |       |           |       |
| As of Date 8/9/2021                               |            |      |       |           |       |
| 265 People Received Study<br>129 People Responded |            |      |       |           |       |
| Total                                             | 40         | 29   | 26    | 33        |       |
| INTERPRETATION                                    | OUTPATIENT | CPOE | VOICE | INPATIENT | TOTAL |
| ENMEGA                                            | 0          | 0    | 0     | 1         | 1     |
| ENMERZA                                           | 1          | 0    | 0     | 0         | 1     |
| ENMEZA                                            | 26         | 0    | 0     | 20        | 46    |
| ENMIZA                                            | 1          | 0    | 0     | 0         | 1     |
| ENZEMA                                            | 0          | 0    | 0     | 1         | 1     |
| ERMAVA                                            | 0          | 0    | 1     | 0         | 1     |
| ERMEZA                                            | 11         | 29   | 18    | 11        | 69    |
| ERMEZZA                                           | 0          | 0    | 1     | 0         | 1     |
| EUMEZA                                            | 1          | 0    | 0     | 0         | 1     |
| IRMEZA                                            | 0          | 0    | 2     | 0         | 2     |
| URMEZA                                            | 0          | 0    | 3     | 0         | 3     |
| URMEZZA                                           | 0          | 0    | 1     | 0         | 1     |

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

| No. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg). Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions | POCA Score (%) | <b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b><br><br><b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | Ermeza***                                                                                                                                                                                                                                                                                                                                                                     | 100            | <i>This is the subject of review.</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.  | Omeza                                                                                                                                                                                                                                                                                                                                                                         | 70             | <p>Orthographically, the first letters ("E" vs. "O") of the word pair look differently when written.</p> <p>Phonetically, the first ('Er' vs. 'O') syllables of the name pair have sufficient differences.</p> <p>Additionally, Omeza is the name of a company that manufactures over-the-counter skin care products. There are multiple Omeza products currently marketed including Omeza Lidocaine Lavage, Omeza Skin Protectant, and Omeza Omega-3 Oil; however, Omeza alone does not exist as a proprietary name on the market. A prescription would need to indicate which Omeza product is ordered (e.g., by including the modifier), and if the modifier were not included in an order, a pharmacist would need to verify which product is being ordered. The strength for Omeza Lidocaine Lavage is 0.8 %, but the Omeza Skin Protectant and Omeza Omega-3 oil products do not have a strength. This differs from Ermeza***, which is available as 150 mcg/5 mL (30 mcg/mL) oral solution and there is no numeric overlap in strength or dose. The dose needs to be specified on a prescription order for</p> |

|    |             |    |                                                                                                                                                                |
|----|-------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |             |    | Ermeza***.<br><br>When all the aforementioned mitigations are considered in totality, we find the risk of name confusions is adequately minimized in this case |
| 3. | (b) (4) *** | 70 | (b) (4)                                                                                                                                                        |

**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  | 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. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg).<br>Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions. | POCA Score (%) | <b>Prevention of Failure Mode</b><br><br><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b> |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.  | Pirmella 1/35                                                                                                                                                                                                                                                                                                                                                                     | 64             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 2.  | Pirmella 7/7/7                                                                                                                                                                                                                                                                                                                                                                    |                |                                                                                                                                                                                                |
| 3.  | Pirmella                                                                                                                                                                                                                                                                                                                                                                          |                |                                                                                                                                                                                                |
| 4.  | Xermelo                                                                                                                                                                                                                                                                                                                                                                           | 62             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 5.  | Erelzi                                                                                                                                                                                                                                                                                                                                                                            | 62             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |

| No. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg).<br>Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions. | <b>POCA Score (%)</b> | <b>Prevention of Failure Mode</b><br><br><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6.  | Embeda                                                                                                                                                                                                                                                                                                                                                                            | 62                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 7.  | Erymax                                                                                                                                                                                                                                                                                                                                                                            | 61                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 8.  | Evkeeza                                                                                                                                                                                                                                                                                                                                                                           | 61                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 9.  | Dermazene                                                                                                                                                                                                                                                                                                                                                                         | 59                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 10. | Ervebo                                                                                                                                                                                                                                                                                                                                                                            | 59                    | This name pair has sufficient orthographic and phonetic differences.<br><br>The following differences in product characteristics may also help to mitigate the risk of errors: <ul style="list-style-type: none"> <li>• Ervebo (Ebola Zaire Vaccine, Live) administered intramuscularly by health care provider.</li> <li>• Dose: There is no numerical overlap in dose. The prescription order for Ermeza*** will need to specify the numerical dose.</li> <li>• Dosage Form (<i>oral solution vs sterile suspension for intramuscular injection</i>) and route of administration (<i>oral vs. intramuscular injection</i>) are different and if dosage</li> </ul> |

| No. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg). Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions. | <b>POCA Score (%)</b> | <b>Prevention of Failure Mode</b><br><br><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>                                                                           |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                                                                                                                                                                                                                                                |                       | <p>form and or route is included on the medication order/prescription, there is no overlap between the products.</p> <p>When all the aforementioned mitigations are considered in totality, we find the risk of name confusion is adequately minimized in this case.</p> |
| 11. | Ear-Eze                                                                                                                                                                                                                                                                                                                                                                        | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                     |
| 12. | Dermabet                                                                                                                                                                                                                                                                                                                                                                       | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                     |
| 13. | Dermacin                                                                                                                                                                                                                                                                                                                                                                       | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                     |
| 14. | Dermasil                                                                                                                                                                                                                                                                                                                                                                       | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                     |
| 15. | Emflaza                                                                                                                                                                                                                                                                                                                                                                        | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                     |
| 16. | Enemeez                                                                                                                                                                                                                                                                                                                                                                        | 58                    | <p>Orthographically, Enemeez contains letters “ee” in suffix and Ermeza*** ends with letter “a”, which provide some orthographic differences.</p> <p>Phonetically, the third syllables of this name pair sound different when spoken (‘zah’ vs. ‘meez’).</p>             |

| No. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg). Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions. | <b>POCA Score (%)</b> | <b>Prevention of Failure Mode</b><br><br><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                                                                                                                                                                                                                                                |                       | <p>The following differences in product characteristics may also help to mitigate the risk of errors:</p> <ul style="list-style-type: none"> <li>• Prescription order for Ermeza*** will include the dose, which is based on the patient's weight, and the likelihood for dose to be numerically overlap with 283 mg is very minimal.</li> <li>• Differ in dosage form (oral solution vs rectal enema) and route of administration (oral vs rectal) which if included on the medication order/prescription, there is no overlap between the products.</li> </ul> <p>When all the aforementioned mitigations are considered in totality, we find the risk of name confusions is adequately minimized in this case.</p> |
| 17. | Ertaczo                                                                                                                                                                                                                                                                                                                                                                        | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 18. | Intermezzo                                                                                                                                                                                                                                                                                                                                                                     | 58                    | This name pair has sufficient orthographic and phonetic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 19. | Evomela                                                                                                                                                                                                                                                                                                                                                                        | 58                    | Orthographically, Evomela contains upstroke letters "l" in suffix which provide some orthographic differences.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| No. | <p><b>Proposed name:</b> Ermeza</p> <p><b>Established name:</b> levothyroxine sodium</p> <p><b>Dosage form:</b> Oral Solution</p> <p><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)</p> <p><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg). Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions.</p> | <p><b>POCA Score (%)</b></p> | <p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                                                                                                                                                                                                                                                                                                                                                       |                              | <p>Phonetically, the first ('e' vs 'er') and second ('vo' vs 'mee') third ('mee' vs 'zah') syllables of this name pair sound different. Additionally, Evomela has extra syllables.</p> <p>The following differences in product characteristics may also help to mitigate the risk of errors:</p> <ul style="list-style-type: none"> <li>• Evomela is administered by health care provider and given prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma.</li> <li>• Dosage Form (<i>oral solution vs for injection</i>) and route of administration (<i>oral vs intravenous infusion</i>) are different and if dosage form and route of administration is included on the medication order/prescription, there is no overlap between the products.</li> </ul> <p>When all the aforementioned mitigations are considered in totality, we find the risk of name confusion is adequately minimized in this case.</p> |

| No. | <b>Proposed name:</b> Ermeza<br><b>Established name:</b> levothyroxine sodium<br><b>Dosage form:</b> Oral Solution<br><b>Strength(s):</b> 150 mcg/5 mL (30 mcg/mL)<br><b>Usual Dose:</b> 1.6 mcg/kg/day to 15 mcg/kg/day (12.5 mcg to 300 mcg).<br>Dose depends on a variety of factors including: the patient's age, body weight, indication and concomitant medical conditions. | POCA Score (%) | <b>Prevention of Failure Mode</b><br><br><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b> |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20. | (b) (4) ***                                                                                                                                                                                                                                                                                                                                                                       | 57             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 21. | Ergomar                                                                                                                                                                                                                                                                                                                                                                           | 57             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 22. | Erleada                                                                                                                                                                                                                                                                                                                                                                           | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 23. | Gormel                                                                                                                                                                                                                                                                                                                                                                            | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 24. | Gormel 10                                                                                                                                                                                                                                                                                                                                                                         | 56             |                                                                                                                                                                                                |
| 25. | Dermaphor                                                                                                                                                                                                                                                                                                                                                                         | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 26. | Dermasarra                                                                                                                                                                                                                                                                                                                                                                        | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 27. | Dermazinc                                                                                                                                                                                                                                                                                                                                                                         | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 28. | Permapen                                                                                                                                                                                                                                                                                                                                                                          | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |
| 29. | Rezamid                                                                                                                                                                                                                                                                                                                                                                           | 56             | This name pair has sufficient orthographic and phonetic differences.                                                                                                                           |

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

| No. | Name   | POCA Score (%) |
|-----|--------|----------------|
| 1.  | Kemeya | 53             |

| No. | Name       | POCA<br>Score (%) |
|-----|------------|-------------------|
| 2.  | Trazimera  | 51                |
| 3.  | Gemtesa    | 50                |
| 4.  | Hemady     | 50                |
| 5.  | Inmazeb    | 50                |
| 6.  | Amzeeq     | 48                |
| 7.  | Arazlo     | 48                |
| 8.  | Pemazyre   | 48                |
| 9.  | Abecma     | 47                |
| 10. | Amitiza    | 47                |
| 11. | Xgeva      | 45                |
| 12. | Katerzia   | 44                |
| 13. | Riomet Er  | 44                |
| 14. | Zyprexa    | 43                |
| 15. | Cerianna   | 42                |
| 16. | Fetroja    | 42                |
| 17. | Ibsrela    | 42                |
| 18. | Qelbree    | 42                |
| 19. | Retevmo    | 42                |
| 20. | Danyelza   | 41                |
| 21. | Imcivree   | 41                |
| 22. | Audenz     | 40                |
| 23. | Rybrevant  | 40                |
| 24. | Xenleta    | 40                |
| 25. | Breyanzi   | 38                |
| 26. | Jelmyto    | 38                |
| 27. | Kimyrsa    | 38                |
| 28. | Reblozyl   | 38                |
| 29. | Roszet     | 38                |
| 30. | Tabrecta   | 38                |
| 31. | Verquvo    | 38                |
| 32. | Artesunate | 36                |
| 33. | Barhemsys  | 36                |
| 34. | Gavreto    | 36                |
| 35. | Gemmily    | 36                |
| 36. | Jemperli   | 36                |
| 37. | Mayzent    | 36                |
| 38. | Pemfexy    | 36                |
| 39. | Semglee    | 36                |
| 40. | Tazverik   | 36                |
| 41. | Zepzelca   | 36                |
| 42. | Sarclisa   | 35                |
| 43. | Tralement  | 35                |
| 44. | Abrilada   | 34                |

| No. | Name       | POCA<br>Score (%) |
|-----|------------|-------------------|
| 45. | Brovana    | 34                |
| 46. | Cabenuva   | 34                |
| 47. | Inrebic    | 34                |
| 48. | Kesimpta   | 34                |
| 49. | Milprosa   | 34                |
| 50. | Orladeyo   | 34                |
| 51. | Reyvow     | 34                |
| 52. | Survanta   | 34                |
| 53. | Tepmetko   | 34                |
| 54. | Ubrelvy    | 34                |
| 55. | Wynzora    | 34                |
| 56. | Xeglyze    | 34                |
| 57. | Zeposia    | 34                |
| 58. | Anjeso     | 33                |
| 59. | Palforzia  | 33                |
| 60. | Bafiertam  | 32                |
| 61. | Finzala    | 32                |
| 62. | Impeklo    | 32                |
| 63. | Nouress    | 32                |
| 64. | Onureg     | 32                |
| 65. | Pretomanid | 32                |
| 66. | Reditrex   | 32                |
| 67. | Rybelsus   | 32                |
| 68. | Trodelvy   | 32                |
| 69. | Zynrelef   | 32                |
| 70. | Durysta    | 31                |
| 71. | Isturisa   | 31                |
| 72. | Tecartus   | 31                |
| 73. | Adakveo    | 30                |
| 74. | Biorphen   | 30                |
| 75. | Blenrep    | 30                |
| 76. | Cosela     | 30                |
| 77. | Lyumjev    | 30                |
| 78. | Menquadfi  | 30                |
| 79. | Nayzilam   | 30                |
| 80. | Nourianz   | 30                |
| 81. | Ozobax     | 30                |
| 82. | Riabni     | 30                |
| 83. | Scenesse   | 30                |
| 84. | Victoza    | 30                |
| 85. | Vumerity   | 30                |
| 86. | Ziextenzo  | 30                |
| 87. | Twirla     | 29                |

| No.  | Name               | POCA<br>Score (%) |
|------|--------------------|-------------------|
| 88.  | Avsola             | 28                |
| 89.  | Azstarys           | 28                |
| 90.  | Fintepla           | 28                |
| 91.  | Nyvepria           | 28                |
| 92.  | Oxbryta            | 28                |
| 93.  | Pizensy            | 28                |
| 94.  | Pulmotech Maa      | 28                |
| 95.  | Rinvoq             | 28                |
| 96.  | Rukobia            | 28                |
| 97.  | Sevenfact          | 28                |
| 98.  | Winlevi            | 28                |
| 99.  | Padcev             | 27                |
| 100. | Turalio            | 27                |
| 101. | Beovu              | 26                |
| 102. | Brukinsa           | 26                |
| 103. | Bynfezia Pen       | 26                |
| 104. | Clariscan          | 26                |
| 105. | Mycapssa           | 26                |
| 106. | Nexlizet           | 26                |
| 107. | Rozlytrek          | 26                |
| 108. | Trikafta           | 26                |
| 109. | Xaracoll           | 26                |
| 110. | Amondys 45         | 25                |
| 111. | Breztri Aerosphere | 25                |
| 112. | Pepaxto            | 25                |
| 113. | Triferic Avnu      | 25                |
| 114. | Upneeq             | 25                |
| 115. | Gimoti             | 24                |
| 116. | Kynmobi            | 24                |
| 117. | Lampit             | 24                |
| 118. | Monoferric         | 24                |
| 119. | Nurtec Odt         | 24                |
| 120. | Orgovyx            | 24                |
| 121. | Oriahnn            | 24                |
| 122. | Secuado            | 24                |
| 123. | Sogroya            | 24                |
| 124. | Vesicare Ls        | 24                |
| 125. | Viltepso           | 24                |
| 126. | Zynlonta           | 24                |
| 127. | Chabelina Fe       | 22                |
| 128. | Inqovi             | 22                |
| 129. | Posimir            | 22                |
| 130. | Talicia            | 22                |

| No.  | Name             | POCA<br>Score (%) |
|------|------------------|-------------------|
| 131. | Veklury          | 22                |
| 132. | Zegalogue        | 22                |
| 133. | Zilxi            | 22                |
| 134. | Aklief           | 21                |
| 135. | Fotivda          | 21                |
| 136. | Genosyl          | 21                |
| 137. | Tyblume          | 21                |
| 138. | Ayvakit          | 20                |
| 139. | Byfavo           | 20                |
| 140. | Dayvigo          | 20                |
| 141. | Fensolvi         | 20                |
| 142. | Jynneos          | 20                |
| 143. | Trijardy Xr      | 20                |
| 144. | Detectnet        | 19                |
| 145. | Tauvid           | 19                |
| 146. | Tukysa           | 19                |
| 147. | Vocabria         | 19                |
| 148. | Absorica Ld      | 18                |
| 149. | Caplyta          | 18                |
| 150. | Monjuvi          | 18                |
| 151. | Nexletol         | 18                |
| 152. | Numbrino         | 18                |
| 153. | Valtoco          | 18                |
| 154. | Givlaari         | 17                |
| 155. | Zokinvy          | 17                |
| 156. | Bronchitol       | 16                |
| 157. | Dolishale        | 16                |
| 158. | Hetlioz Lq       | 16                |
| 159. | Ongentys         | 16                |
| 160. | Phesgo           | 16                |
| 161. | Phexxi           | 16                |
| 162. | Tissueblue       | 16                |
| 163. | Nulibry          | 15                |
| 164. | Quzyttir         | 15                |
| 165. | Alkindi Sprinkle | 14                |
| 166. | Bonsity          | 14                |
| 167. | Cystadrops       | 14                |
| 168. | Nextstellis      | 14                |
| 169. | Olinvyk          | 14                |
| 170. | Ponvory          | 14                |
| 171. | Sesquient        | 14                |
| 172. | Tri-lo-lynyah    | 14                |
| 173. | Vyepti           | 14                |

| No.  | Name               | POCA Score (%) |
|------|--------------------|----------------|
| 174. | Xcopri             | 14             |
| 175. | Xywav              | 14             |
| 176. | Conjupri           | 12             |
| 177. | Koselugo           | 12             |
| 178. | Gvoke Hypopen      | 11             |
| 179. | Klisyri            | 11             |
| 180. | Oxlumo             | 11             |
| 181. | Qinlock            | 11             |
| 182. | Wakix              | 11             |
| 183. | Ukoniq             | 10             |
| 184. | Vyondys 53         | 10             |
| 185. | Gvoke Pfs          | 9              |
| 186. | Kloxxado           | 8              |
| 187. | Lupkynis           | 8              |
| 188. | Tivicay Pd         | 8              |
| 189. | Advil Dual Action  | 7              |
| 190. | Dojolvi            | 7              |
| 191. | Qdolo              | 7              |
| 192. | Thyquidity         | 4              |
| 193. | Hulio              | 1              |
| 194. | Qwo                | 0              |
| 195. | Moxeza             | 50             |
| 196. | Emend              | 48             |
| 197. | Giapreza           | 48             |
| 198. | Emerphed           | 46             |
| 199. | Ebanga             | 41             |
| 200. | Erbitux            | 41             |
| 201. | Emergen-C          | 40             |
| 202. | Ergotamine         | 39             |
| 203. | Exservan           | 37             |
| 204. | Exem Foam          | 36             |
| 205. | Evrysdi            | 34             |
| 206. | Enhertu            | 32             |
| 207. | Erythromycin       | 32             |
| 208. | Eysuvis            | 26             |
| 209. | Darzalex Faspro    | 25             |
| 210. | Eluryng            | 25             |
| 211. | Elyxyb             | 24             |
| 212. | Enspryng           | 21             |
| 213. | Sutab (copackaged) | 10             |

**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.  | Permax      | 61             | Brand discontinued with no generic equivalents available. NDA 019385 withdrawn effective 04/08/2009.                                                                                                                                                      |
| 2.  | Atreza      | 68             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 3.  | Berman      | 66             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 4.  | Dermazor    | 64             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 5.  | Derman      | 66             | International product marketed in Mexico and Turkey                                                                                                                                                                                                       |
| 6.  | Derma       | 62             | International product formerly marketed in Greece                                                                                                                                                                                                         |
| 7.  | Dermasav    | 61             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                               |
| 8.  | Dermabon    | 55             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 9.  | Dermasana   | 55             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 10. | Emersal     | 56             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 11. | (b) (4) *** | 60             | Proposed proprietary name for NDA 208612 withdrawn by Applicant (b) (4). Product approved under proprietary name Balcoltra (OSE #2017-19657181).                                                                                                          |
| 12. | Dermazole   | 59             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 13. | (b) (4) *** | 59             | Proposed proprietary name for IND (b) (4) found to be acceptable on (b) (4) (OSE # (b) (4)). The entire application withdrawn by the Applicant on (b) (4).                                                                                                |
| 14. | Ernekumab   | 56             | Name identified in External Name Study. Unable to find product characteristics in commonly used drug databases.                                                                                                                                           |
| 15. | Derma Cas   | 56             | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                               |
| 16. | Enromed     | 58             | Veterinary product.                                                                                                                                                                                                                                       |
| 17. | Erymin      | 58             | Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.                                                                                                                                                    |
| 18. | Respreeza   | 56             | International product marketed in Austria, Germany, France and et al                                                                                                                                                                                      |
| 19. | (b) (4) *** | 56             | Proposed proprietary name for (b) (4) unacceptable under IND (b) (4) in OSE# (b) (4) dated (b) (4). Subsequently, the proposed proprietary name (b) (4) was found conditionally acceptable for NDA (b) (4) (OSE# (b) (4)) and IND (b) (4) (OSE# (b) (4)). |

| No. | Name        | POCA Score (%) | Failure preventions                                                                                                                                                                                                                                    |
|-----|-------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 20. | (b) (4) *** | 55             | Proposed proprietary name for IND 010096 found unacceptable by DMEPA (OSE# 2016-9175271 dated 2/09/2017). Subsequently, the proposed proprietary name Imjudo was found conditionally acceptable for IND 010096 (OSE# 2020-37861196) on August 4, 2020. |
| 21. | Termene     | 56             | Name found 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<sup>1</sup>.

| No. | Name        | POCA Score (%) |
|-----|-------------|----------------|
| 1.  | Arzerra     | 67             |
| 2.  | Afrezza     | 66             |
| 3.  | Ordessa     | 63             |
| 4.  | (b) (4) *** | 63             |
| 5.  | Cyramza     | 62             |
| 6.  | Verbena     | 62             |
| 7.  | Arm-A-Med   | 61             |
| 8.  | Remedy      | 60             |
| 9.  | Rynesa      | 60             |
| 10. | Ortez       | 59             |
| 11. | Rezira      | 59             |
| 12. | Abreva      | 58             |
| 13. | (b) (4) *** | 58             |
| 14. | Herzuma     | 58             |
| 15. | Ingrezza    | 58             |
| 16. | Iressa      | 58             |
| 17. | Margenza    | 58             |
| 18. | Orbexa      | 58             |
| 19. | Renova      | 58             |
| 20. | Rynessa     | 58             |
| 21. | Tepezza     | 58             |
| 22. | Theromega   | 58             |
| 23. | Xerava      | 58             |
| 24. | Prometa     | 57             |

<sup>1</sup> 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<br>Score (%) |
|-----|----------|-------------------|
| 25. | Zerbaxa  | 57                |
| 26. | Albenza  | 56                |
| 27. | Aredia   | 56                |
| 28. | Berdoz   | 56                |
| 29. | Certiva  | 56                |
| 30. | Femara   | 56                |
| 31. | Gemzar   | 56                |
| 32. | Merzee   | 56                |
| 33. | Ormazine | 56                |
| 34. | Pharmaf  | 56                |
| 35. | Relenza  | 56                |
| 36. | Reme-T   | 56                |
| 37. | Remeven  | 56                |
| 38. | Rymed    | 56                |
| 39. | Temaz    | 56                |
| 40. | Zimeta   | 56                |
| 41. | Zometa   | 56                |
| 42. | Amerge   | 55                |
| 43. | Ca-Rezz  | 55                |
| 44. | Mirena   | 55                |
| 45. | Verdad   | 55                |

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/s/  
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SEVAN H KOLEJIAN  
09/28/2021 11:03:58 AM

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