

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**022458Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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

**Proprietary Name Review--Final**

Date:	February 8, 2012
Reviewer:	Manizheh Siahpoushan, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Zachary Oleszczuk, PharmD Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Elelyso (Taliglucerase Alfa) for Injection 200 units/vial
Application Type/Number:	NDA 022458
Applicant/sponsor:	Protalix Ltd.
OSE RCM #:	2011-4199

\*\*\* This document contains proprietary and confidential information that should not be released to the public.\*\*\*

## CONTENTS

1	INTRODUCTION.....	3
2	METHODS AND RESULTS.....	3
3	CONCLUSIONS AND RECOMMENDATIONS.....	3
4	REFERENCES.....	4

## **1 INTRODUCTION**

This re-assessment of the proposed proprietary name, Elelyso is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Elelyso, acceptable in OSE Reviews RCM #2010-2627 and 2011-4199, dated January 21, 2011, and November 28, 2011.

## **2 METHODS AND RESULTS**

For re-assessment of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2010-2627 and 2011-4199 for the proposed proprietary name, Elelyso. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names thought to look similar to Elelyso and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Elelyso, as of January 19, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on November 10, 2011 and had no concerns regarding the proposed name from a promotional perspective. The Division of Gastroenterology and Inborn Errors Products (DGIEP) and DMEPA concurred with the findings of OPDP's promotional assessment of the proposed name.

## **3 CONCLUSIONS**

The re-evaluation of the proposed proprietary name, Elelyso, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Elelyso, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Errors Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

#### 4 REFERENCES

1. OSE Review #2011-2627 Elelyso (Taliglucerase Alfa) Proprietary Name Review; Oleszczuk, Z. January 21, 2011.
2. OSE Review #2011-4199, Elelyso (Taliglucerase Alfa) Proprietary Name Review; Siahpoushan, M. November 28, 2011.
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)  
Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)  
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis proprietary name 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.

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/s/  
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MANIZHEH SIAHPOUSHAN  
02/08/2012

ZACHARY A OLESZCZUK  
02/09/2012

CAROL A HOLQUIST  
02/09/2012

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

**Proprietary Name Review**

Date: November 28, 2011

Reviewer(s): Manizheh Siahpoushan, Pharm.D., Safety Evaluator  
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, Pharm.D.  
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, RP.h.  
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Elelyso (Taliglucerase Alfa) for Injection  
200 units/vial

Application Type/Number: NDA 022458

Applicant/sponsor: Protalix Ltd.

OSE RCM #: 2011-4199

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3	CONCLUSIONS AND RECOMMENDATIONS.....	3
4	REFERENCES.....	4

## **1 INTRODUCTION**

This re-assessment of the proposed proprietary name, Elelyso is written in response to the anticipated approval of this NDA within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Elelyso, acceptable in OSE Review #2010-2627, dated January 21, 2011.

## **2 METHODS AND RESULTS**

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2010-2627 for the proposed proprietary name, Elelyso. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names thought to look similar to Elelyso and represent a potential source of drug name confusion. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. We did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Elelyso, as of November 8, 2011.

Additionally, OPDP re-reviewed the proposed name on November 10, 2011 and had no concerns regarding the proposed name from a promotional perspective. The Division of Gastroenterology and Inborn Errors Products (DGIEP) and DMEPA concurred with the findings of OPDP's promotional assessment of the proposed name.

## **3 CONCLUSIONS AND RECOMMENDATIONS**

The proposed proprietary name, Elelyso is acceptable from a safety and promotional perspective.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Errors Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

#### 4 REFERENCES

1. **OSE review #2011-4199 Elelyso (Taliglucerase Alfa) Proprietary Name Review; Oleszczuk, Z.**
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)  
Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)  
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11/28/2011

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11/28/2011

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11/28/2011



**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology**

Date: January 21, 2011

Through: Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention and Analysis (DMEPA)

From: Zachary Oleszczuk, PharmD, Team Leader  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Elelyso (Taliglucerase Alfa) for Injection  
200 units/vial

Application Type/Number: NDA 022458

Sponsor: Protalix Ltd.

OSE RCM #: 2010-2627

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## CONTENTS

EXECUTIVE SUMMARY .....	3
1 BACKGROUND .....	3
1.1 Introduction .....	3
1.2 Regulatory History .....	3
1.3 Product Information .....	4
2 METHODS AND MATERIALS.....	4
2.1 Search Criteria.....	4
2.2 FDA Prescription Analysis Studies.....	5
2.3 External Proprietary Name Risk Assessment .....	6
3 RESULTS.....	6
3.1 Database and Information Sources.....	6
3.2 CDER Expert Panel Discussion .....	6
3.3 FDA Prescription Analysis Studies.....	7
3.4 External Proprietary Name Risk Assessment .....	7
3.5 Comments from the Division of Gastroenterology Products (DGP) .....	7
3.6 Safety Evaluator Risk Assessment.....	7
4 DISCUSSION.....	7
4.1 Promotional Assessment .....	8
4.2 Safety Assessment.....	8
4.3 External Name Study .....	8
5 CONCLUSIONS AND RECOMMENDATIONS .....	8
5.1 Comments to the Applicant.....	8
6 REFERENCES .....	9
APPENDICES .....	11

## EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Elelyso for Taliglucerase Alfa for Injection. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Elelyso, acceptable for this product.

If approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products (DGP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 1 BACKGROUND

### 1.1 INTRODUCTION

The Applicant, Protalix, Ltd., requested an assessment of the proposed proprietary name in a submission dated December 10, 2010. The Division of Medication Error Prevention and Analysis (DMEPA) assesses a proposed proprietary name regarding its potential for name confusion with other proprietary or established drug names in the usual practice settings. Additionally, DMEPA considers the Division of Drug Marketing, Advertising and Communications' (DDMAC's) promotional assessment of the name.

### 1.2 REGULATORY HISTORY

DMEPA initially reviewed (b) (4) in the IND phase and found the name acceptable (OSE Review #2009-891, dated July 23, 2009) based upon the product characteristics submitted with the IND. At that time, the Applicant proposed (b) (4) for the product (200 units/vial (b) (4)).

On April 30, 2010, the Applicant submitted a request for review of the proposed proprietary (b) (4) because the NDA (024458) was submitted for this product. However, at that time the Applicant proposed only one product strength (200 units/vial), and as such all of the names previously identified as having potential confusion with (b) (4) were re-evaluated in this review.

DMEPA found the proposed name (b) (4) unacceptable on June 3, 2010 (OSE Review #2009-2471), because the name (b) (4).

On September 27, 2010, The Applicant submitted a request for reconsideration for the proposed proprietary name (b) (4). On November 16, 2010, DMEPA and the Applicant held a teleconference to discuss that the DMEPA concerns were not mitigated by the information submitted. On December 3, 2010, the Applicant withdrew the reconsideration for (b) (4) and submitted the name Elelyso.

### 1.3 PRODUCT INFORMATION

Elelyso (Taliglucerase Alfa) for injection is being developed for the indication of long-term enzyme replacement therapy in patients diagnosed with Gaucher's Disease that results in one or more of the following conditions: a) anemia, b) thrombocytopenia, b) bone disease, or d) hepatomegaly or splenomegaly. Elelyso will be supplied as a lyophilized powder in 200 units per vial. Elelyso dosing should be individualized to each patient with initial dosage (b) (4) 60 units/kg once every two weeks.

On the day of use, after the dose of Elelyso to be administered to the patient is determined, the appropriate number of vials is each reconstituted with Sterile Water for Injection, USP. The final concentrations and administration volumes are provided in the table below:

	200 unit vial
Sterile water for reconstitution	5.1 mL
Final volume of reconstituted product	5.3 mL
Concentration after reconstitution	40 unit/mL
Withdrawal volume	5 mL
Units of enzyme within final volume	200 units

5 mL of reconstituted enzyme is withdrawn from each vial. The drug must be further diluted with 0.9 % Sodium Chloride Injection, USP, to a final volume of 100 mL to 200 mL. Elelyso is administered by intravenous infusion over 1 to 2 hours. Since Elelyso does not contain any preservative, after reconstitution, the vials should be promptly diluted and not stored for subsequent use. Elelyso, after reconstitution, has been shown to be stable for up to (b) (4) when stored at room temperature (25°C) and at 2-8°C. Elelyso, when diluted, has been shown to be stable for up to 24 hours when stored at 2-8°C. (b) (4)

## 2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify information associated with the methodology for the proposed proprietary name, Elelyso.

### 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'E' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>1,2</sup>

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<sup>1</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

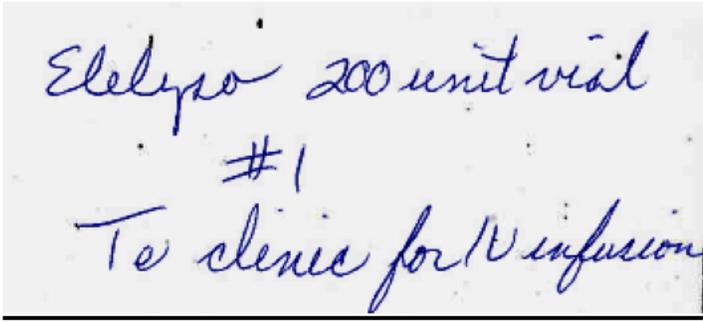
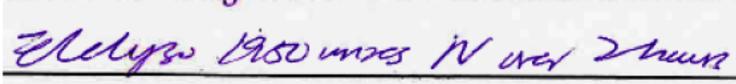
To identify drug names that may look similar to Elelyso, the DMEPA safety evaluators also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (Three, capital letter E and two lowercase l's), down strokes (one, lowercase y), cross strokes (none), and dotted letters (none). Additionally, several letters in Elelyso may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Elelyso.

When searching to identify potential names that may sound similar to Elelyso, the DMEPA safety evaluators search for names with similar number of syllables (four), stresses (E-le-lye'-soe, e-LE-lye'-soe, e-le-LYE'-soe, or e-le-lye'-SOE), and placement of vowel and consonant sounds. The Sponsor's intended pronunciation (*e el lye' soe*) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following outpatient medication order, inpatient medication order and verbal prescription were communicated during the FDA prescription studies.

**Figure 1. Elelyso Prescription Study (conducted on January 2, 2011)**

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Medication Order:</u></p> 	<p>Elelyso infuse 1950 units IV over 2 hours</p>
<p><u>Inpatient Medication Order:</u></p> 	

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

### **2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT**

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether DMEPA's risk assessment concurs or differs with the findings of the external risk assessment. When the proprietary name risk assessment differs, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

## **3 RESULTS**

The names identified from DMEPA's methods as potential sources for name confusion with Eleyso are listed below.

### **3.1 DATABASE AND INFORMATION SOURCES**

Our searches of database and DMEPA' information sources yielded a total of 23 names as having some similarity to the name Eleyso.

Twenty-two of the names were thought to look like Eleyso. These include: (b) (4), Astepro, Celebrex, Delmycin, Delsym, Elaprase, Eldepryl, Eldoquin, Elecure, (b) (4), Elestat, Elestrin, Eleton, (b) (4), Eliphos, Elspar, (b) (4), Estrogel, Ethyol, Eutonyl, Eylea, and Ilotycin. The remaining name, Eleyso was thought to look and sound similar to Eleyso.

Additionally, DMEPA safety evaluators did not identify any United States Adopted Names stems in the proposed proprietary name, as of December 20, 2010.

### **3.2 CDER EXPERT PANEL DISCUSSION**

The Expert Panel reviewed the pool of names identified by DMEPA safety evaluators (see Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Eleyso.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

### **3.3 FDA PRESCRIPTION ANALYSIS STUDIES**

A total of 37 practitioners responded to the prescription analysis study. None of the responses overlapped with a currently marketed product. Nine participants responded correctly with all correct responses occurring in the outpatient study. The most common misinterpretation in the written prescription studies were misinterpretations of the last letter 'o' as the letter 'a'. The most common misinterpretation in the verbal prescription studies was misinterpretation of the first syllable "El" as "Ill". See Appendix C for complete results.

### **3.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT**

The proposed proprietary name risk assessment submitted by the Applicant, (b) (4) found Elelyso acceptable. (b) (4) evaluated a total of 11 names (Arcalyst, Elavil, Elecare, Elestat, Elestrin, Eleton, Elidel, Elocon, Estradiol, Exelon, and Lysodren) thought to have some potential for confusion with the name Elelyso.

Four of the names (Elecare, Elestat, Elestrin, and Eleton) were also identified by DMEPA during the database searches. Thus, the remaining seven names (Arcalyst, Elavil, Elidel, Elocon, Estradiol, Exelon, and Lysodren) were evaluated as part of the Safety Evaluator Risk Assessment. (b) (4) did not specify whether the names were thought to look or sound like, Elelyso, thus DMEPA assumed the names were similar in both aspects (look and sound).

### **3.5 COMMENTS FROM THE DIVISION OF GASTROENTEROLOGY PRODUCTS (DGP)**

#### ***3.5.1 Initial Phase of Review***

In response to an December 28, 2010, OSE e-mail, the Division of Gastroenterology Products (DGP) indicated they had no issues at the initial phase of the name review.

#### ***3.5.2 Midpoint of Review***

DMEPA notified DGP via e-mail that we found the proposed proprietary name, Elelyso, acceptable on January 12, 2011. Per e-mail correspondence from DGP on January 18, 2011, they indicated they had no additional comments regarding this decision.

### **3.6 SAFETY EVALUATOR RISK ASSESSMENT**

Independent searches by the primary DMEPA safety evaluator did not result in the identification of any additional names which were thought to look or sound similar to Elelyso and represent a potential source of drug name confusion. Thus, we identified a total of 30 names (23 from the database searches and seven names from the external study) as having similarity to the proposed name.

## **4 DISCUSSION**

This proposed name, Elelyso, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

#### **4.1 PROMOTIONAL ASSESSMENT**

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the DGP concurred with the findings of DDMAC's promotional assessment of the proposed proprietary name.

#### **4.2 SAFETY ASSESSMENT**

DMEPA identified 30 names for their potential similarity to the proposed name, Elelyso. No other aspects of the name were determined to pose a different source for potential confusion with the name.

Ten of the 30 names were eliminated for the following reasons (see Appendices D through G): Four proprietary names lack sufficient orthographic similarity with Elelyso to result in confusion, one name is for a product that has been withdrawn from the market and has no generic equivalents, four names were never marketed and are not currently associated with a pending applicant, and one name, Elelyso, was identified in our is the trademark name for this product.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 20 names and lead to medication errors. This analysis determined that the name similarity between Elelyso the remaining names was unlikely to result in medication error for the reasons presented in Appendix H.

#### **4.3 EXTERNAL NAME STUDY**

We note that our findings are in agreement with the conclusion of the (b) (4) name assessment provided by the Applicant that the proposed name Elelyso is not vulnerable to confusion that could result in a medication error.

### **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Elelyso, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proposed proprietary name, Elelyso, for this product at this time.

#### **5.1 COMMENTS TO THE APPLICANT**

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

If approval of this NDA is delayed more than 90 from the date of this review, Elelyso will have to be re-reviewed. If we find the name unacceptable following the re-review, we will notify you.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 6 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***  
(<http://factsandcomparisons.com> )

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Applicant submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

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7. ***Electronic online version of the FDA Orange Book***  
(<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

**9. Clinical Pharmacology Online ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))**

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

**10. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://www.thomson-thomson.com))**

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

**11. Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://www.naturaldatabase.com))**

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

**12. Stat!Ref ([www.statref.com](http://www.statref.com))**

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

**13. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)**

USAN Stems List contains all the recognized USAN stems.

**14. Red Book Pharmacy's Fundamental Reference**

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

**15. Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

**16. Medical Abbreviations Book**

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, NDA, and ANDA products currently under review by the Center. 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>3</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>4</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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<sup>3</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>4</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>5</sup> DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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<sup>5</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

**Table 1.** Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

<b>Type of similarity</b>	<b>Considerations when searching the databases</b>		
	<i>Potential causes of drug name similarity</i>	<i>Attributes examined to identify similar drug names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

## **1. Database and Information Sources**

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

## **2. CDER Expert Panel Discussion**

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

## **3. FDA Prescription Analysis Studies**

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

#### **4. Comments from the OND review Division or Generic drugs**

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

#### **5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

***“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”***

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<sup>6</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

***“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”***

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the

currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

**Appendix B:** Letters with possible orthographic or phonetic misinterpretation for Elelyso

Letters in Name, Elelyso	Scripted may appear as	Spoken may be interpreted as
Capital 'E'	C	A, E, or I
Combination 'El'	A	L
lower case 'l'	h, t, c, i, e or b	el
lower case 'e'	l or i	Any vowel
Combination 'el'	d	L
lower case 'y'	ij, u, g or z	any vowel
lower case 's'	r, n, a, or x	Z
lower case 'o'	a, v or u	a, ol

**Appendix C: FDA Prescription Study Responses**

Inpatient Prescription	Outpatient Prescription	Verbal Prescription
?? 1950 units intravenous over 2 hours	Elelipa 200 unit vial	Eliliso infuse 1950 U iv over 2 hours
Eldyso 1950 units intravenously over 2 hours	Elelipo 200 unit vial	Ililico infuse 1,950 units IV over 2 hours
Elelysa 1950 mcg IV over 2 hours	Elelysa 200 unit	ililyso infuse 1950 units IV over 2 hours
Elelysis 1950 units IV over 2 hours	Elelysa 200 unit vial	Ililyso
Z? 1950 units IV over 2 hours	Elelysa 200 unit vial	Ililyso
Zeleyso 1950 units N over 2 hours	Elelysa 200 unit vial To clinic for IV infusion	Illilyso infuse 1950 units IV over 2 hours
Zeleyso - 1950 ... (units not clear)	Elelysa 200 unit vial, to clinic for IV infusion	Illilyso infuse 1950 units IV over 2 hours
	elelysa, 200 unit vial, quantity	Illilysol infuse
	Elelyso	Illyliso Infuse 1950 units IV over 2 hours
	Elelyso	Illyliso Infuse 1950 units iv over 2 hours
	Elelyso 200 unit vial, To clinic for intravenous infusion. Dispense 1.	Unable to determine the drug name, infuse 1950 units, IV over 2 hours
	Elelyso 200 unit vial, to clinic for IV infusion, dispense 1	
	Elelyso 200 unit vial; #1; to clinic for IV infusion	
	Elelyso 200 units	
	Elelyso 200 units	
	Elelyso 200 units.	
	Elelyso? 200 unit vail #1 to clinic for IV infusion	
	Elelyza 200unit vial #1	
	Elepro 200 unit vial #1 to clinic for IV infusion	

**Appendix D:** Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name
Elestat
Arcalyst
Estradiol
Lysodren

**Appendix E:** Proprietary name that is the subject of this review

Proprietary Name	Similarity to Elelyso	Source
Elelyso	Look/Sound	USPTO

**Appendix F:** Names for products that have been withdrawn from the market with no generic equivalents available.

Proprietary Name	Similarity to Elelyso	Status
Eutonyl (Paragylene)	Look	NDA 13448 withdrawn per DARRTS effective November 5, 1992

**Appendix G:** Proprietary names that were never marketed and are not currently associated with a pending application

Proprietary Name	Similarity to Eleyso	Source	Status
(b) (4)			

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\*\*\*This is proprietary and confidential information that should not be released to the public.\*\*\*

**Appendix H:** Names with orthographic or different product characteristics that minimize the risk of medication error

Product name with potential for confusion	Similarity to Eleyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Astepro (azelastine hydrochloride)	Look	Nasal Spray 0.1% and 0.15%	<u>Seasonal rhinitis:</u> 0.1% or 0.15%: 1 or 2 sprays per nostril twice daily in adults and adolescents 12 years of age and older  0.15%: 2 sprays per nostril once daily in adults and adolescents 12 years of age and older  <u>Perennial allergic rhinitis:</u> 0.15%: 2 sprays per nostril twice daily in adults and adolescents 12 years of age and older (2.2)	<b>Dose:</b> (b) (4) 60 units/kg vs. 1 to 2 sprays  <b>Dosage form:</b> lyophilized powder for injection vs. nasal spray  <b>Route of administration:</b> intravenous vs. intranasally  <b>Frequency of Administration:</b> every 2 weeks vs. once or twice daily
Celebrex (celecoxib)	Look	Capsule 50 mg, 100 mg, 200 mg and 400 mg	50 mg to 200 mg orally once or twice daily or 400 mg orally one daily	<b>Orthographic Differences:</b> Eleyso contains a downstroke (lowercase 'y') and no crosstrokes vs. Celebrex that contains no downstrokes and one crosstroke (lowercase 'x')  <b>Dosage form:</b> lyophilized powder for injection vs. capsule  <b>Route of administration:</b> intravenous vs. oral  <b>Frequency of Administration:</b> every 2 weeks vs. once or twice daily

Product name with potential for confusion	Similarity to Eleylyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleylyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Delmycin (erythromycin)	Look	Topical solution 2%	Apply a thin layer topically to affected area once or twice daily	<p><b>Orthographic Differences:</b> Although both names contain a similar number of letters (7 vs. 8) Delmycin appears longer than Eleylyso when scripted because the letter ‘m’ elongates the name Delmycin</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. Topical Solution</p> <p><b>Route of administration:</b> intravenous vs. Topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. once or twice daily</p>
Delsym (dextromethorphan)	Look	Extended-release oral suspension 30 mg/5 mL	2.5 mL (15 mg) to 10 mL (60 mg) every 12 hours	<p><b>Dosage form:</b> lyophilized powder for injection vs. Extended-release oral suspension</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. 2.5 mL (15 mg) to 10 mL (60 mg)</p> <p><b>Route of administration:</b> intravenous vs. oral</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. twice daily</p>

Product name with potential for confusion	Similarity to Eleyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Elaprase (idursulfase)	Look	Solution for intravenous infusion 6 mg/0.3 mL	0.5 mg/kg of body weight administered every week as an intravenous infusion, and initially infused over a period of one to three hours	<p><b>Orthographic Differences:</b> Eleyso contains three upstrokes (capital 'E', and 2 lowercase 'l's) vs. Elaprase contains two upstrokes (capital 'E' and one lower case 'l').</p> <p><b>Dose:</b> Although the dose are both weight bases (b) (4) 60 units/kg vs. 0.5 mg/kg) the calculated doses for a patient would not overlap. For example a 40 kg patient would receive (b) (4) 1800 units of Eleyso each dose while they would only receive 20 mg of Elaprase for each dose.</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. once every week</p>
Eldepryl (selegiline hydrochloride)	Look	Capsule and Tablet 5 mg	5 mg orally twice daily	<p><b>Orthographic Differences:</b> The ending of each name ('-so' vs. '-ryl') appears different when scripted</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. tablet or capsule</p> <p><b>Route of administration:</b> intravenous vs. oral</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. twice daily</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. 5 mg</p>
Eldoquin (Hydroquinone)	Look	Cream 2%	Apply to affected areas twice daily	<p><b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. cream</p> <p><b>Route of administration:</b> intravenous vs. Topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. twice daily</p>

Product name with potential for confusion	Similarity to Eleylyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleylyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
<p>Elecare (b) (4) Corn Syrup Solids*, (b) (4) High Oleic Safflower Oil*, (b) (4) Medium-Chain Triglycerides*, (b) (4) % Soy Oil*, (b) (4) L-Glutamine*.</p> <p>Less than 2% of the Following: L-Asparagine, L-Leucine, DATEM†, L-Lysine Acetate, Calcium Phosphate, L-Valine, Potassium Phosphate, L-Isoleucine, L-Arginine, L-Phenylalanine, L-Tyrosine, L-Threonine, Potassium Citrate, Sodium Citrate, L-Proline, L-Serine, L-Alanine, Glycine, L-Histidine, L-Methionine, Ascorbic Acid, Magnesium Chloride, L-Cystine Dihydrochloride, L-Tryptophan, Calcium Carbonate, Salt (Sodium Chloride), Choline Chloride, m-Inositol, Ferrous Sulfate, Taurine, Ascorbyl Palmitate, Zinc Sulfate, L-Carnitine, Niacinamide, dl-Alpha-Tocopheryl Acetate, Calcium Pantothenate, Thiamine Chloride Hydrochloride, Cupric Sulfate, Manganese Sulfate, Vitamin A Palmitate, Riboflavin, Pyridoxine Hydrochloride, Folic Acid, Beta-Carotene, Biotin, Phylloquinone, Chromium Chloride, Potassium Iodide, Sodium Selenate, Sodium Molybdate, Vitamin D3, and Cyanocobalamin.)</p>	Look	Powder for oral infant formula	Mix 2 ounces of water with each scoop of powder formula to obtain a concentration of 20 calories/ounce for each feeding	<p><b>Orthographic Differences:</b> Eleylyso contains a downstroke (lowercase ‘y’) and an additionally upstroke (a second lower case ‘l’) vs. Elecare contains no downstrokes and one less pstroke</p> <p><b>Route of administration:</b> intravenous vs. oral</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. every feeding</p>

Product name with potential for confusion	Similarity to Elelyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Elelyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) to 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Elestrin (Estradiol)	Look	Topical gel 0.06%	Apply one pump to upper arm once daily	<b>Orthographic Differences:</b> The ending of each name ('-yso' vs. '-rin') appears different when scripted <b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application <b>Dosage form:</b> lyophilized powder for injection vs. Topical gel <b>Route of administration:</b> intravenous vs. Topical <b>Frequency of Administration:</b> every 2 weeks vs. once daily
Eletone (petrolatum, purified water, mineral oil, cetostearyl alcohol, ceteth-20, citric acid, sodium citrate, propylparaben, and butylparaben)	Look	Topical Cream single strength	Apply liberally 2 to three times per day.	<b>Orthographic Differences:</b> The ending of each name ('-yso' vs. '-one') appears different when scripted <b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application <b>Dosage form:</b> lyophilized powder for injection vs. Topical cream <b>Route of administration:</b> intravenous vs. Topical <b>Frequency of Administration:</b> every 2 weeks vs. twice to three times daily
Eliphos (calcium acetate)	Look	Tablets 667 mg	2 to 4 tablets orally with each meal	<b>Dosage form:</b> lyophilized powder for injection vs. tablet <b>Route of administration:</b> intravenous vs. oral <b>Frequency of Administration:</b> every 2 weeks vs. with each meal <b>Dose:</b> (b) (4) 60 units/kg vs. 2 to 4 tablets

Product name with potential for confusion	Similarity to Elelyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Elelyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Elspar (asparaginase)	Look	Injection 10,000 units/vial	6,000 International Units/m <sup>2</sup> intramuscularly or intravenously three times a week	<b>Orthographic Differences:</b> Elelyso contains three upstrokes (capital 'E', and 2 lowercase 'l's) vs. Elspar contains two upstrokes (capital 'E' and one lower case 'l'). <b>Frequency of Administration:</b> every 2 weeks vs. three times per week
EstroGel (estradiol)	Look	Topical gel 0.06%	Apply one pump to upper arm once daily	<b>Orthographic Differences:</b> Although each name contains the same number of upstroke (3), the upstrokes are located in different positions (1 <sup>st</sup> , 2 <sup>nd</sup> , and 4 <sup>th</sup> letters vs. 1 <sup>st</sup> , 3 <sup>rd</sup> , and 8 <sup>th</sup> letter). <b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application <b>Dosage form:</b> lyophilized powder for injection vs. Topical gel <b>Route of administration:</b> intravenous vs. Topical <b>Frequency of Administration:</b> every 2 weeks vs. once daily
Ethiol (amifostine)	Look	Injection 500 mg/10 mL	200 mg to 910 mg/m <sup>2</sup> given by intravenous infusion once daily beginning 30 minutes prior to the first dose of chemotherapy.	<b>Orthographic Differences:</b> Elelyso contains three upstrokes (capital 'E', and 2 lowercase 'l's) vs. Ethiol contains four upstrokes (capital 'E', lower case 't', 'h', and 'l'). <b>Frequency of Administration:</b> every 2 weeks vs. daily

Product name with potential for confusion	Similarity to Eleyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Eylea*** (aflibercept)	Look	Aqueous solution for intravitreal injection  40 mg/mL	2 mg by intravitreal injection every month for 3 months, then every 2 months	<p><b>Orthographic Differences:</b> Eleyso (7 letters) appears longer than Eylea*** (6 letters), Eleyso has more upstrokes (3, capital 'E', and 2 lowercase 'l's) vs. Eylea*** (2, capital 'E' and one lower case 'l'), and although both names contain 1 downstroke (lower case letter 'y'), the downstroke is located in different positions (5<sup>th</sup> letter vs. 2<sup>nd</sup> letter)</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. 2 mg</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. once every 1 to 2 months</p>
Ilotycin (erythromycin)	Look	Ophthalmic Ointment 5 mg/g	1 cm in length of Ophthalmic Ointment should be applied directly to the infected structure up to 6 times daily	<p><b>Orthographic Differences:</b> The ending of each name ('-so' vs. '-cin') appears different when scripted</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 cm application</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. ophthalmic ointment</p> <p><b>Route of administration:</b> intravenous vs. Topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. up to six times daily</p>

Product name with potential for confusion	Similarity to Eleyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Eleyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Elavil (amitriptyline) Discontinued, but generic equivalents available for the tablets only. There are no generic equivalents for the injection per Drugs@FDA, the Orange Book, or the RedBook.	Look and Sound	Tablets 10 mg, 25 mg, 75 mg, 100 mg, and 150 mg  Injection 10 mg/mL	30 mg to 300 mg orally daily in divided doses (1 to 4 times daily)	<p><b>Orthographic Differences:</b> The ending of each name ('-lyso' vs. '-vil') appears different when scripted and sounds different when spoken</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. tablet (there are no injections on the market for this product)</p> <p><b>Route of administration:</b> intravenous vs. oral</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. one to 4 times daily</p>
Elidel (pimecrolimus)	Look and Sound	Topical Cream 1%	Apply a thin layer of cream the affected skin twice daily	<p><b>Orthographic Differences:</b> The ending of each name ('-yso' vs. '-el') appears different when scripted and sounds different when spoken</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. topical cream</p> <p><b>Route of administration:</b> intravenous vs. topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. twice daily</p>

Product name with potential for confusion	Similarity to Elelyso	Strength, Dosage Form	Usual Dose	Differing product characteristics that minimize the risk of medication error
Elelyso (Taliglucerase Alfa)		Lyophilized powder for Injection 200 units per vial	(b) (4) 60 units/kg body weight intravenous infusion over one to two hours given every two weeks.	
Elocon (mometasone furoate)	Look and Sound	Ointment, Cream, and Lotion  0.1%	Apply a thin film to the affected skin areas once daily	<p><b>Orthographic Differences:</b> The ending of each name ('-lyso' vs. '-con') appears different when scripted and sounds different when spoken</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. apply thin layer or 1 application</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. topical ointment, cream, or lotion</p> <p><b>Route of administration:</b> intravenous vs. topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. once daily</p>
Exelon (rivastigmine)	Look and Sound	Capsules 1.5 mg, 3 mg, 4.5 mg and 6 mg  Oral Solution 2 mg/mL  Topical Patch, Extended-release  4.6 mg/24 hours and 9.5 mg/24 hours	Capsules and Oral solution 3 mg to 6 mg orally twice daily  Topical Extended-release Patch Replace the 4.6 mg/24 hours or 9.5 mg/24 hours patch once daily	<p><b>Orthographic Differences:</b> The ending of each name ('-yso' vs. '-on') appears different when scripted and sounds different when spoken</p> <p><b>Dose:</b> (b) (4) 60 units/kg vs. 3 mg to 6 mg, 4.6 mg, or 9.5 mg</p> <p><b>Dosage form:</b> lyophilized powder for injection vs. capsule, oral solution, or Topical path</p> <p><b>Route of administration:</b> intravenous vs. oral or topical</p> <p><b>Frequency of Administration:</b> every 2 weeks vs. once or twice daily</p>

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/s/  
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02/01/2011

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