

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208264Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME RECONSIDERATION REVIEW
Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	October 12, 2016
Application Type and Number:	NDA 208264
Product Name and Strength:	Tepadina (thiotepa) for Injection, 15 mg, 100 mg
Product Type:	Single-Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Adienne
Panorama #:	2016- 10028734
DMEPA Primary Reviewer:	Leeza Rahimi, Pharm.D.
DMEPA Acting Team Leader:	Hina Mehta, Pharm.D.
DMEPA Deputy Director:	Lubna Merchant, PharmD, MS

Contents

1	INTRODUCTION.....	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment.....	1
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	5
4	REFERENCES.....	6
	APPENDICES.....	7

1 INTRODUCTION

This review responds to a September 6, 2016 request from Adienne, to reconsider the proposed proprietary name, Tepadina. We evaluated the proposed proprietary name, Tepadina, from a safety and misbranding perspective. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

DMEPA had previously reviewed the proposed proprietary name, Tepadina, when it was submitted on May 12, 2016. DMEPA determined that the proposed name Tepadina was unacceptable due to orthographic and phonetic similarities with the pending name, (b) (4) *** which is a proposed proprietary name within the Agency for (b) (4) previously reviewed by DMEPA^a. After our review of the name, Tepadina in July of 2016, we notified both Applicants of our decision to deny both of the names.

On September 6, 2016, the Applicant requested a reconsideration of the proposed proprietary name, Tepadina.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 6, 2016 proprietary name submission.

- Intended Pronunciation: tĕ-pă-dĕ-nă
- Active Ingredient: thiotepa
- Indication of Use: Used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogenic hematopoietic progenitor cell transplantation for patients with class 3 β -thalassemia
- Route of Administration: Intravenous infusion
- Dosage Form: Lyophilized Powder for Injection
- Strengths: 15 mg, 100 mg
- Dose and Frequency: (b) (4)
(b) (4)
- How Supplied: Single-dose vial
- Storage: Tepadina vials must be stored and transport refrigerated at 2°C-8°C (36° to 46°F). DO NOT FREEZE.

^a Whales, E. Proprietary Name Review for Tepadina NDA 208264 Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Jul 20. RCM No.: OSE (b) (4)

2 RECONSIDERATION OF THE NAME TEPADINA

In our initial review of the proposed name, Tepadina, we noted that Tepadina was similar in pronunciation and spelling to (b) (4)*** which was a pending name for (b) (4) (b) (4) within the Agency. Thus, we found the proposed proprietary name, Tepadina unacceptable based on 21 CFR 201.10(c)(5), which states "The labeling of a drug may be misleading by reason of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient."

Adienne submitted a request for reconsideration dated September 6, 2016, to the agency outlining their rationale for finding the name acceptable (see appendix A)

Since our initial review, we note that the conflict with (b) (4)*** is no longer applicable as the Applicant has proposed an alternate name for (b) (4) product for review by the agency. The applicant submitted this request on October 12, 2016. We did not identify any other safety or misbranding concerns with the proposed proprietary name, Tepadina. Based on the above, we find the proposed proprietary name, Teapdina, acceptable.

Given this conclusion, we did not evaluate the rationale provided by the Applicant in support of the reconsideration of the proposed proprietary name.

4.1 CONCLUSIONS

The proposed proprietary name, Tepadina, is acceptable. If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

4.1 COMMENTS TO THE APPLICANT

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

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

APPENDIX A: APPLICANT’S RATIONALE FOR NAME RECONSIDERATION

“ADIENNE SA believes that the proprietary name TEPADINA® has been widely recognized by US healthcare professionals and therefore the risk of medication error due to confusion of TEPADINA® with another product is improbable. In fact, during the critical shortage of Thiotepa for Injection in the United States market in the past years, ADIENNE SA agreed with FDA the temporary importation into the US market of the drug product TEPADINA® 15 mg and 100 mg (thiotepa) already authorized in EU.

The drug use in shortage started on April, 05th 2011 and ended on July, 01st 2016, as given in the TEPADINA® FDA listings (Attachment 2a and 2b). During this period the drug product labelled with the proprietary name TEPADINA® was widely distributed in the hematologic centers in the United States and recognized by American physicians, nurses and pharmacists. Therefore, the US healthcare professionals have extensively used the drug product thiotepa identified with trademark TEPADINA® for 5 years. This trademark is well-known since 2007 when it was registered in USA, EU and other countries worldwide. Furthermore, among international physicians in the therapeutic field of hematology/blood and marrow transplantation, the trademark TEPADINA® is well-established and identifies the same medicinal product marketed in 42 countries worldwide listed hereafter: Italy, Spain, Portugal, Germany, France, UK, Belgium, Netherlands, Sweden, Norway, Denmark, Finland, Austria, Switzerland, Ireland, Belarus, Czech Republic, Serbia, Jordan, Lebanon, Israel, Turkey, Oman, Iran, Argentina, Brazil, Colombia, Chile, Perú, Japan, China, India, Hong Kong, South Korea, Estonia, Malaysia, Poland, Singapore, Russia, Taiwan, Canada, Australia”.

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

/s/

LEEZA RAHIMI
10/12/2016

HINA S MEHTA
10/13/2016

LUBNA A MERCHANT
10/13/2016

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	July 20, 2016
Application Type and Number:	NDA 208264
Product Name and Strength:	Tepadina (thiotepa) for Injection, 15 mg, 100 mg
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Adienne
Panorama #:	2016-7994779
DMEPA Primary Reviewer:	Ebony Whaley, PharmD, BCPPS
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Deputy Director:	Lubna Merchant, PharmD, MS
DMEPA Division Director:	Todd Bridges, RPh

Contents

1	INTRODUCTION.....	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment.....	1
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	5
4	REFERENCES.....	6
	APPENDICES.....	7

1 INTRODUCTION

This review evaluates the proposed proprietary name, Tepadina, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name

1.1 PRODUCT INFORMATION

The following product information is provided in the May 12, 2016 proprietary name submission.

- Intended Pronunciation: tē-pā-dē-nā
- Active Ingredient: thiotepa
- Indication of Use: Used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor cell transplantation for patients with class 3 β -thalassemia
- Route of Administration: Intravenous infusion
- Dosage Form: Lyophilized Powder for Injection
- Strengths: 15 mg, 100 mg
- Dose and Frequency: (b) (4)
(b) (4)
- How Supplied: Single-dose vial
- Storage: Tepadina vials must be stored and transport refrigerated at 2°C-8°C (36° to 46°F). DO NOT FREEZE.
- Reference Listed Drug: Thioplex, 020058

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Tepadina, is derived from the suffix of the nonproprietary name thiotepa combined with name ‘-dina, which was not derived from any particular concept. 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 FDA Name Simulation Studies

114 practitioners participated in DMEPA’s prescription studies. The responses did not overlap with any currently marketed products. However, one response to the voice study did look similar to the product Depade. Depade is discontinued but generic equivalents are available. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 31, 2016 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search² organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	393
Low similarity name pair: combined match percentage score $\leq 49\%$	0

¹USAN stem search conducted on May 25, 2016.

² POCA search conducted on May 25, 2016.

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

We determined 395 of the 396 of names will not pose a risk for confusion as described in Appendix C through H. However, the proposed name could be confused with (b) (4)***. The rationale for the risk of confusion is described below and in Section 3.1.



2.2.7 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Tepadina that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	June 7, 2016
Drug Name	Tepadina [product name]
Event (MedDRA Terms)	DMEPA Official PNR Name Confusion Search Terms Event List: Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF

³ Lingua Manca. Linguistics Session 2 – An Introduction to Linguistics. 2.1 Phonetics. Accessed 2016 Jul 18 at http://www.linguamanca.net/linguistics/linguistics_2/linguistics2_page1/index.htm.

	LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	FDA Rcvd Dates To: 20160607

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

The search yielded zero relevant cases.

2.2.8 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on July 12, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on July 18, 2016, they stated no additional concerns with the proposed proprietary name, Tepadina.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the name will be communicated to the Sponsor via letter (See ***Section 3.1***).

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

3.1 COMMENTS TO THE APPLICANT

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

This name 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, Tepadina, 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 of Tepadina, you will be requested to submit another name.

4 REFERENCES

1. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>)

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

3. Electronic Drug Registration and Listing System (eDRLS) database

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁴

⁴ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there medical and/or coined abbreviations in the proprietary name?
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 49\%$.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).

- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical

issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP’s decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator’s assessment.

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?

	in the names?		
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ 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"> 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
--------	--

	<p>versa.</p> <ul style="list-style-type: none"> • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg 	
<p>Step 2</p>	<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 with overlapping or similar strengths or doses.</p>	
	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

	scripted?	
--	-----------	--

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

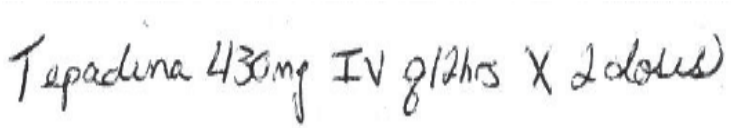
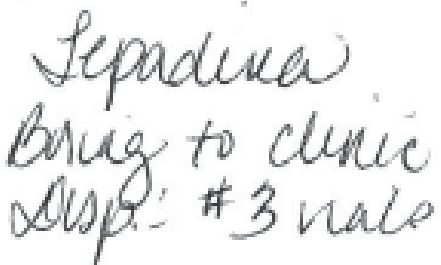
Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database

adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Tepadina Study (Conducted on June 1, 2016)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> 	<p>Tepadina Bring to clinic Dispense: 3 vials</p>
<p>Outpatient Prescription:</p> 	

FDA Prescription Simulation Responses

Study Name: Tepadina					311 People Received Study 114 People Responded
Total	38	31	45		
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
Cepadana	0	1	0	1	
Cepadina	0	1	0	1	
Cepadna	0	1	0	1	
Cipadena	0	2	0	2	
Decabinoff	0	1	0	1	
Depaddina	0	1	0	1	
Depadena	0	1	0	1	
Depadina	0	1	0	1	
Depadina?	0	1	0	1	
Depado	0	1	0	1	
Depagana	0	1	0	1	

Depondinon	0	1	0	1
Dipadena	0	1	0	1
Dipagona	0	1	0	1
Ipadia	0	1	0	1
Ipadina	0	1	0	1
Lepadina	22	0	0	22
Lepadira	1	0	0	1
Lepadiua	1	0	0	1
Lepadiva	9	0	0	9
Sepadal	0	1	0	1
Sepadena	0	1	0	1
Sepadina	1	0	0	1
Sepadiva	1	0	0	1
Sepodina	0	1	0	1
Sipadana	0	1	0	1
Tepadien	0	0	1	1
Tepadiina	0	1	0	1
Tepadina	2	1	38	41
Tepadina ?	0	0	1	1
Tepadine	0	0	5	5
Tepadiva	1	0	0	1
Tipadana	0	1	0	1
Tipadena	0	1	0	1
Tipadina	0	1	0	1
Tipagana	0	1	0	1
Tipana	0	1	0	1
Tpadenia	0	1	0	1
Zepaderna	0	1	0	1
Zipodina	0	1	0	1

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

No.	<p>Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)</p>	POCA Score (%)	<p>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</p> <p>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</p>
1.	<p>Bepadin (Orthographic score 71, Phonetic score 80)</p>	76	<p>Bepadin is discontinued and there are no available generic equivalents.</p> <p>Orthographic: Tepadina contains the prefix “Tep-” which has a cross-stroke, and Bepadin contains the prefix “Bep-” which contains a rounded letter without a cross-stroke.</p> <p>Phonetic: Tepadina has an extra syllable.</p>
2.	<p>Pepsin A (Phonetic score 74)</p>	71	<p>Pepsin A was identified in RxNorm. Unable to find product characteristics in internal drug databases.</p> <p>Orthographic: Tepadina contains the prefix “Tep-” which has a cross-stroke on the 1st letter, and Pepsin A contains the prefix “Pep-” which has a rounded portion and a downstroke on the 1st letter.</p> <p>Phonetic: Tepadina has an extra syllable.</p>

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

No.	Name	POCA Score (%)
1.	Tripedia	68

No.	Name	POCA Score (%)
2.	Vitamin A (Phonetic score 76)	67
3.	Betadine	62
4.	Vitadil 2A	61
5.	Vitadil 5A	61
6.	Nepafenac	60
7.	(b) (4) ***	60
8.	Tinactin	60
9.	Otolidin	58
10.	Banadyne (Phonetic score 70)	56
11.	Kerydin	56
12.	Pyocidin	56
13.	Tetrasine	56
14.	Tinaderm	56
15.	Triadine	56
16.	(b) (4) ***	55
17.	(b) (4) ***	55
18.	Tri-Statin	55
19.	Extina	54
20.	Neocidin	54
21.	Tetcaine	54
22.	Tetterine	54
23.	Triseptin	54
24.	Emadine	53
25.	Testim	53
26.	Vitacilina	53
27.	Cetaderm (Phonetic score 70)	52
28.	Povidine	52

No.	Name	POCA Score (%)
29.	Teargen	52
30.	Tears Again	52
31.	Terocin	52
32.	(b) (4) ***	52
33.	Tetrasine Ex	52
34.	Topicaine	52
35.	Azatadine	51
36.	Cepastat	51
37.	Teladar	51
38.	Travatan	51
39.	Dexacidin	50
40.	Falmina	50
41.	Fucidin	50
42.	Keepan	50
43.	Temovate E	50
44.	Tenivac	50
45.	Terminator	50
46.	Testomar	50
47.	Tokisan	50
48.	Trametinib	50

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

No.	<p>Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: _____ (b) (4) _____ (b) (4)</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	Tasigna	65	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second syllables of this name pair sound different. Tepadina has an extra syllable.</p>
2.	Cephadyn (Phonetic score 74)	64	<p>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.</p>
3.	Tactinal	64	<p>Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.</p>
4.	Tepanil	64	<p>Orthographic: The suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.</p>
5.	Tetracyn (Phonetic score 70)	63	<p>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.</p>

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Tekturna	61	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different. Tepadina has an extra syllable.
7.	Betadren (Phonetic score 70)	60	Orthographic: The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
8.	Cytadren (Phonetic score 72)	60	Orthographic: The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
9.	Depacon	60	Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.
10.	Depakene	60	Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.
11.	Teveten	60	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.

No.	<p>Proposed name: Tepadina</p> <p>Established name: thiotepa</p> <p>Dosage form: Lyophilized Powder for Injection</p> <p>Strength(s): 15 mg, 100 mg</p> <p>Usual Dose: _____ (b) (4)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
12.	Tusscidin (Phonetic score 70)	60	<p>Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.</p>
13.	Cefdinir	58	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first syllables of this name pair sound different. Tepadina has an extra syllable.</p>
14.	Fetzima (Phonetic score 70)	58	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first, second, and third syllable of this name pair sound different. Tepadina has an extra syllable.</p>
15.	Taladine	58	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second syllables of this name pair sound different. Tepadina has an extra syllable.</p>
16.	Tetracon	58	<p>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.</p>

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
17.	Tecfidera	57	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different.
18.	Heparin	56	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first and third syllables of this name pair sound different. Tepadina has an extra syllable.
19.	Tanabid	56	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first and third syllables of this name pair sound different. Tepadina has an extra syllable.
20.	Teramine	56	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable
21.	Teramine ER	56	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.
22.	T-Painol	56	Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
23.	Tussafin	56	Orthographic: The prefixes and infixes of this name have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.
24.	Tusscidin Pe	56	Orthographic: The prefixes and infixes of this name have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
25.	Testolin	55	Orthographic: The infixes and suffixes of this name have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
26.	Tolmetin	55	Orthographic: The infixes and suffixes of this name have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.
27.	Tradjenta	55	Orthographic: The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
28.	Coumadin	54	Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
29.	Epanova	54	Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The third and fourth syllables of this name pair sound different.
30.	Neo-Fradin	54	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, third, and fourth syllables of this name pair sound different.
31.	Tanamine	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
32.	Teldrin	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different. Tepadina has two extra syllables.
33.	Tessalon	54	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
34.	Tiopronin	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different.
35.	(b) (4)***	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.
36.	Tusana D	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different.
37.	Two-Dyne	54	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second third syllables of this name pair sound different. Tepadina has two extra syllables.
38.	Depandro 100	53	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
39.	Rifadin	53	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
40.	Tenormin	53	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
41.	Topamax	53	Orthographic: The suffixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.
42.	Cerubidin	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, third, and fourth syllables of this name pair sound different.
43.	Dalteparin	52	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, third, and fourth syllables of this name pair sound different.
44.	Depade	52	Orthographic: The prefixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: Tepadina has two extra syllables.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: _____ (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
45.	Medcodin	52	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
46.	Nesina	52	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
47.	Symadine	52	Orthographic: The prefixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
48.	Temazepam	52	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second, third, and fourth syllables of this name pair sound different.
49.	Terazosin	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second, third, and fourth syllables of this name pair sound different.
50.	Testa Span	52	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
51.	Tetracaine	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
52.	Tetracap	52	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
53.	Tinzaparin	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The first, second, third, and fourth of this name pair sound different.
54.	Tizanidine	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The second, third, and fourth syllables of this name pair sound different.
55.	Topiragen	52	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The third and fourth syllables of this name pair sound different.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
56.	Totacillin	52	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar.</p> <p>Phonetic: The second, third, and fourth syllables of this name pair sound different.</p>
57.	Tretinoin	52	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second, third, and fourth syllables of this name pair sound different.</p>
58.	Triacin	52	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.</p>
59.	Triposed	52	<p>Orthographic: The suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and third syllables of this name pair sound different. Tepadina has an extra syllable.</p>
60.	Tussiden C	52	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and second syllables of this name pair sound different.</p>

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
61.	(b) (4)***	52	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first and third syllables of this name pair sound different. Tepadina has an extra syllable.
62.	Zykadia	52	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
63.	Telavancin	51	Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The second, third, and fourth syllables of this name pair sound different.
64.	(b) (4) (b) (4)***	51	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
65.	Thiotepa	51	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first, third, and fourth syllables of this name pair sound different. Established name of subject of review

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
66.	Zepatier	51	Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences. Phonetic: The first, third, and fourth syllables of this name pair sound different.
67.	Asendin	50	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.
68.	Desirudin	50	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second and third syllables of this name pair sound different.
69.	Epaned	50	Orthographic: The suffixes of this name pair have sufficient orthographic differences. The lengths of the name pair are dissimilar. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.
70.	Karbinal	50	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.

No.	<p>Proposed name: Tepadina</p> <p>Established name: thiotepa</p> <p>Dosage form: Lyophilized Powder for Injection</p> <p>Strength(s): 15 mg, 100 mg</p> <p>Usual Dose: _____ (b) (4) _____ (b) (4)</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
71.	Prandin	50	<p>Orthographic: The prefixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The first and second syllables of this name pair sound different. Tepadina has two extra syllables.</p>
72.	Tafinlar	50	<p>Orthographic: The suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.</p>
73.	Tapazole	50	<p>Orthographic: The suffixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.</p>
74.	Tapentadol	50	<p>Orthographic: The suffixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar.</p> <p>Phonetic: The third and fourth syllables of this name pair sound different.</p>
75.	Tazidime	50	<p>Orthographic: The infixes of this name pair have sufficient orthographic differences.</p> <p>Phonetic: The second syllables of this name pair sound different. Tepadina has an extra syllable.</p>

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
76.	Temodar	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The third syllables of this name pair sound different. Tepadina has an extra syllable.
77.	Terbinex	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second and third syllables of this name pair sound different. Tepadina has an extra syllable.
78.	Tiagabine	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The third and fourth syllables of this name pair sound different.
79.	Ticlopidine	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The second syllables of this name pair sound different.
80.	Tipranavir	50	Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The third and fourth syllables of this name pair sound different.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg Usual Dose: (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
81.	Tolectin Tolectin 600	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different.
82.	Totacillin N	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. The lengths of this name pair are dissimilar. Phonetic: The second, third, and fourth syllables of this name pair sound different.
83.	Trepoxen-250	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
84.	Triaprin	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first, second, and third syllables of this name pair sound different. Tepadina has an extra syllable.
85.	Tricodene	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.

No.	Proposed name: Tepadina Established name: thiotepa Dosage form: Lyophilized Powder for Injection Strength(s): 15 mg, 100 mg (b) (4) (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
86.	Triptone	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The second syllables of this name pair sound different. Tepadina has two extra syllables.
87.	Tussidin Dm	50	Orthographic: The infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different.
88.	Vicodin	50	Orthographic: The prefixes and infixes of this name pair have sufficient orthographic differences. Phonetic: The first and second syllables of this name pair sound different. Tepadina has an extra syllable.

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.	Kefadim (Phonetic score 74)	68	International product marketed in Europe and Asia.
2.	Tanabid Da (Phonetic score 76)	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
3.	Teebacin (Phonetic score 71)	68	Brand discontinued with no generic equivalent available.
4.	Tadenan	66	International product marketed in Europe and Asia.
5.	Prepadine	63	International product marketed in the United Kingdom.
6.	Prepodyne (Phonetic score 73)	62	Veterinary product
7.	Depakota	60	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
8.	Kappadione	60	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
9.	Tiadenol	60	International product marketed in Europe.
10.	Trexima	59	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
11.	Disadine	59	International product marketed in Europe.
12.	(b) (4)***	59	Proposed proprietary name withdrawn by the Applicant. IND (b) (4) was withdrawn 11/10/2015.
13.	Ketacine	58	Veterinary product
14.	Papa-Deine #3	58	Product was withdrawn FR effective 3/13/1991.
15.	Papa-Deine #4	58	Product was withdrawn FR effective 3/13/1991.
16.	(b) (4)***	58	Proposed proprietary name found unacceptable by DMEPA (b) (4). Application is pending and an alternative proprietary name, Upravi***, was found acceptable.
17.	(b) (4)***	58	Proposed proprietary name withdrawn by the Applicant. Product approved under without a proprietary name.

No.	Name	POCA Score (%)	Failure preventions
18.	Predenema	57	Name identified in RxNorm database. Unable to find product characteristics in internal databases.
19.	Titanium (Phonetic score 70)	57	Product is not a drug. It is an excipient used in pharmaceutical compounding.
20.	Dermacin	56	Brand discontinued with no generic equivalent available.
21.	Fentazin	56	International product marketed in United Kingdom and Ireland.
22.	Antepsin	56	International product marketed in the United Kingdom, Italy, and Argentina.
23.	Jeridin	56	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
24.	1,9-Decadiene	56	This product is not a drug. It is chemical compound used in manufacturing.
25.	Depinar	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Padimate A	56	This product is not a drug. It is compound found in sunscreen products.
27.	Tavist Da	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Taxadone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Tebamide	56	Product withdrawn from the market due to safety concerns.
30.	(b) (4) ***	56	This is a secondary proposed proprietary name and the product was approved under proprietary name Tecfidera.
31.	Tedrigen	56	Brand discontinued with no generic equivalent available.
32.	Temopen	56	International product marketed in Europe.

No.	Name	POCA Score (%)	Failure preventions
33.	Tenathan	56	Brand discontinued with no generic equivalent available.
34.	Tetramed	56	Brand discontinued with no generic equivalent available.
35.	Tiadilon	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	Timentin	56	Brand discontinued with no generic equivalent available.
37.	(b) (4)***	56	ANDA (b) (4) was withdrawn FR effective 8/5/2011.
38.	Trapidil	56	International product marketed in Europe and Asia.
39.	Vetmedin	56	Veterinary product
40.	Sandrena	55	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
41.	Tenkicin	55	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases.
42.	Cephradine	55	Brand discontinued with no generic equivalent available.
43.	Tegopen	55	Brand discontinued with no generic equivalent available.
44.	Catechin	54	This product is not a drug. It is a flavonoid found in green tea.
45.	Propaderm A	54	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
46.	(b) (4)***	54	The proposed name found unacceptable in OSE reviews (b) (4) and (b) (4). ANDA 091209 approved with the established name Norethindrone.
47.	Epanutin	54	International product marketed in Europe and South Africa.

No.	Name	POCA Score (%)	Failure preventions
48.	Kenocidin	54	Veterinary product
49.	Metrodin	54	Brand discontinued with no generic equivalent available.
50.	Tafamidis	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	(b) (4) ***	54	Proposed proprietary name was withdrawn by the Applicant. Product approved under new proprietary name Tagrisso.
52.	Terfenadine	54	Brand discontinued with no generic equivalent available.
53.	Testamone-100	54	Brand discontinued with no generic equivalent available.
54.	(b) (4) ***	54	Proposed proprietary name found unacceptable by OPDP (b) (4). Application is pending and the proprietary name (b) (4) *** has been found conditionally acceptable.
55.	Tetradure	54	Veterinary product
56.	Tetra-Mag	54	Brand discontinued with no generic equivalent available.
57.	(b) (4) ***	54	Proposed proprietary name was withdrawn by the Applicant. Product approved under new proprietary name, Ibrance.
58.	(b) (4) ***	54	This is a secondary proposed proprietary name and the product was approved under proprietary name Tri-Estarylla.
59.	Trypsin	54	This product is not a drug. It is substance used for pharmaceutical compounding.
60.	Peroxin A	53	Name identified in POCA in RxNorm. Unable to find product characteristics in internal databases and commonly used drug databases.
61.	(b) (4) ***	53	This is a secondary proposed proprietary name and the application was withdrawn FR effective 2/7/11.

No.	Name	POCA Score (%)	Failure preventions
62.	Tilidine	53	International product marketed in Europe.
63.	Tussaminic	53	Product withdrawn from the market due to safety concerns.
64.	Beta-Escin	52	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases.
65.	Peptones	52	Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases.
66.	Tilarin	52	International product marketed in Czech Republic, Finland, New Zealand, Switzerland, United Kingdom, Austria, and Italy.
67.	Ardeparin	52	Brand discontinued with no generic equivalent available.
68.	Padimate-O	52	This product is not a drug. It is a compound use in sunscreen products.
69.	Palladia	52	Veterinary product
70.	Picaridin	52	This product is not a drug. It is a substance found in insect repellent.
71.	Tab Tussin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	Tequin	52	Brand discontinued with no generic equivalent available.
73.	Terfinax	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
74.	Tetradecene	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Tiamulin	52	Veterinary product
76.	Triacetin	52	This product is not a drug. It is an excipient.
77.	Triactin	52	Product withdrawn from the market due to safety concerns.

No.	Name	POCA Score (%)	Failure preventions
78.	(b) (4) ***	52	Proposed proprietary name found unacceptable by DMEPA (OSE (b) (4)). Product approved under the established name cephalexin.
79.	Tricaprin	52	This product is not a drug. It is an excipient.
80.	(b) (4) ***	52	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)). Product approved under the established name norgestimate and ethinyl estradiol.
81.	Trinalin	52	Brand discontinued with no generic equivalent available.
82.	Rt Capsin	51	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
83.	Tegison	51	Brand discontinued with no generic equivalent available.
84.	Synadrin	51	Identified by RxNorm. Unable to find product characteristics in commonly used drug databases.
85.	Tepanil Ten-Tab	51	Brand discontinued with no generic equivalent available.
86.	Terramycin	51	Veterinary product
87.	Thaumatococin	51	International product marketed in the United Kingdom.
88.	Zetamine	51	Veterinary product
89.	Bovadine	50	Veterinary product
90.	Diucardin	50	Brand discontinued with no generic equivalent available. ANDA 083383 was withdrawn FR effective 11/18/2004.
91.	Hepacon	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
92.	Lepirudin	50	Brand discontinued with no generic equivalent available.

No.	Name	POCA Score (%)	Failure preventions
93.	Mantadine	50	International product marketed in United Kingdom.
94.	Oxeladin	50	International product marketed Europe, Asia, and Mexico.
95.	Tannate 12D S	50	Brand discontinued with no generic equivalent available.
96.	Terazoosin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
97.	Terpineol	50	This product is not a drug. It is a chemical found in detergent and cleaning products.
98.	Testradial	50	Brand discontinued with no generic equivalent available.
99.	Tetrazepam	50	International product marketed in Europe.
100.	Theaflavin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
101.	Thiphenamil	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
102.	Thymidine	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
103.	Thypinone	50	Brand discontinued with no generic equivalent available.
104.	Tildiem La	50	International product marketed in Europe and Asia.
105.	Tiletamine	50	Veterinary product
106.	Tipiracil	50	This ingredient is only available in combination with trifluridine in the product Lonsurf.
107.	Tolazine	50	Veterinary product
108.	Acemannan	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
109.	Actacin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
110.	Tresaderm	50	Veterinary product
111.	Platinum	50	Name found in RxNorm. Unable to find product characteristics in commonly used databases.
112.	Platosin	50	This is an international product marketed in Europe, Asia, and South Africa.
113.	Tripalmitin	50	This product is not a drug. It is an excipient.
114.	(b) (4) ***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). Product approved under established name ethinyl estradiol and levonorgestrel.
115.	(b) (4) ***	50	Proposed proprietary name was withdrawn by the Applicant. Application is pending and the proprietary name (b) (4) *** has been found conditionally acceptable.
116.	(b) (4) ***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). Application is pending and the proposed proprietary name Ingrezza*** is under review.
117.	(b) (4) ***	50	IND (b) (4) was withdrawn by the Applicant effective 6/6/2016.
118.	(b) (4) ***	50	Proposed proprietary name was withdrawn by the Applicant. Product approved under established name ethinyl estradiol and norgestimate.
119.	Zaditen	50	International product marketed in Europe, Asia, South America, Canada, and Mexico.
120.	Zotepine	50	International product marketed in Europe and Asia.

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

No.	Name	POCA Score (%)
1.	Kemadrin	64
2.	Demazin	59
3.	Dermatin	58
4.	Epidrin	58
5.	Evadyne	58
6.	Ketamine	58
7.	Ketodan (Phonetic score 70)	58
8.	Paradyne	58
9.	Pepcid Ac	58
10.	Jevtana	57
11.	Stopain	57
12.	Ceprotin	56
13.	Cresatin	56
14.	Decadron	56
15.	Decadron-La	56
16.	Dermasana	56
17.	Kepivance	56
18.	Prefrin-A	56
19.	Papain	55
20.	Pepsodent	55
21.	Betalin 12	54
22.	(b) (4) ***	54
23.	Decabid	54
24.	Deltalin	54
25.	Deplin	54
26.	Diprivan	54
27.	Ketaved	54

No.	Name	POCA Score (%)
28.	Kinetin	54
29.	Papacon	54
30.	Pediatan	54
31.	Peptimax 200	54
32.	Peptimax 400	54
33.	Peptimax 800	54
34.	Septtrin	54
35.	Setlakin	54
36.	Staticin	54
37.	Stendra	54
38.	Fleet Enema	53
39.	Kepvance	53
40.	(b) (4) ***	53
41.	Pavagen	53
42.	Peroxin A 10	53
43.	Barbidonna	52
44.	Betagan	52
45.	Cetafen	52
46.	Cetazone	52
47.	Cortenema	52
48.	Cytamen	52
49.	Definity	52
50.	(b) (4) ***	52
51.	Deponit	52
52.	Desitin	52
53.	Diapedic	52
54.	Dopamine	52
55.	Genamin	52
56.	Kafocin	52
57.	Lapatinib	52

No.	Name	POCA Score (%)
58.	Medipain 5	52
59.	Nystatin	52
60.	P.A.S. Sodium	52
61.	Panretin	52
62.	(b) (4) ***	52
63.	Pataday	52
64.	Percodan	52
65.	Phimetin	52
66.	Pitocin	52
67.	Podactin	52
68.	Prepidil	52
69.	Secretin	52
70.	Sensodyne	52
71.	Suphedrin	52
72.	Vitapirena	52
73.	Betavent	51
74.	Ceradon	51
75.	Cetapred	51
76.	Cystadane	51
77.	Depodur	51
78.	Detussin	51
79.	Dexacen-4	51
80.	Efasin	51
81.	Gitalin	51
82.	Kedbumin	51
83.	Ketanodur	51
84.	Permapen	51
85.	(b) (4) ***	51
86.	Sodium Na-22	51
87.	Uniparin	51

No.	Name	POCA Score (%)
88.	(b) (4)***	50
89.	Acetadrink	50
90.	Betaderm	50
91.	Betalin S	50
92.	Biperiden	50
93.	Capoten	50
94.	Capsin	50
95.	Cefazolin	50
96.	Ceftin	50
97.	Cetazone T	50
98.	Cidacin	50
99.	Decaderm	50
100.	Diperodon	50
101.	Epoetin Beta	50
102.	Etrafon-A	50
103.	Kanamycin A	50
104.	Ketofen	50
105.	Meptazinol	50
106.	Mexsana	50
107.	Mitoxana	50
108.	Natacyn	50
109.	Natazia	50
110.	Neoplatin	50
111.	Pacifene	50
112.	Patanase	50
113.	Pectin	50
114.	Pediaphen	50
115.	Pentazine	50
116.	Pepcid	50
117.	Pitressin	50

No.	Name	POCA Score (%)
118.	Retin-A	50
119.	Senna-Gen	50
120.	Serpalan	50
121.	Spastrin	50
122.	(b) (4)***	50
123.	Vitamin B 12	50
124.	Vitamin B6	50
125.	Vitamin B9	50
126.	Vitamin D	50
127.	Vitamin D3	50
128.	Vitamin K	50
129.	Vitamin K 1 Vitamin K1	50
130.	Vitamin K 2	50
131.	Vitamin K 3	50
132.	Vitaped	50
133.	Zevalin	50

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

/s/

EBONY A WHALEY
07/20/2016

HINA S MEHTA
07/20/2016

LUBNA A MERCHANT
07/20/2016

TODD D BRIDGES
07/20/2016