CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

7610886Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	August 7, 2018
Application Type and Number:	BLA 761088
Product Name and Strength:	Truxima ("CT-P10"*) Injection 10 mg/mL
Total Product Strength:	100 mg/10 mL and 500 mg/50 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celltrion, Inc.
Panorama #:	2018-23371427
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* In this document, we refer to the proposed biosimilar product by the descriptor "CT-P10", which was the name Celltrion used to refer to this product during development. FDA has not yet designated a nonproprietary name for Celltrion's proposed biosimilar that includes a distinguishing suffix (see Draft Guidance on Nonproprietary Naming of Biological Products).

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Truxima, which was found conditionally acceptable under BLA 761088 on July 25, 2017.[a] We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

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

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 25, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 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 19, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on August 3, 2018, they stated no additional concerns with the proposed proprietary name, Truxima.

3 CONCLUSIONS

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

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on May 29, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Garrison, N. Proprietary Name Review for Truxima (BLA 761088)]. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); [Insert Date as 2017 JUL 25]. Panorama No. 2017-14747170.

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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NICOLE B GARRISON
08/07/2018

MISHALE P MISTRY on behalf of HINA S MEHTA
08/07/2018

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 25, 2017
Application Type and Number:	BLA 761088
Product Name and Strength:	Truxima ("CT-P10"*) Injection 10 mg/mL
Total Product Strength:	100 mg/10 mL and 500 mg/50 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celltrion
Panorama #:	2017-14747170
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* Truxima has been developed as a proposed biosimilar to US-licensed Rituxan (rituximab). Since the proper name for Truxima has not yet been determined, "CT-P10" is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the May 1, 2017 proprietary name submission.

- Intended Pronunciation: trux ee' mah
- Active Ingredient: "CT-P10"*
- Indication of Use: For the treatment of Non-Hodgkin's Lymphoma (NHL), (b) (4)
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 100 mg/10 mL and 500 mg/50 mL (10 mg/mL)
- Dose and Frequency:
  - ***NHL***: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses.

(b) (4)

- How Supplied: 100 mg/10 mL and 500 mg/50 mL single-dose vials
- Storage: Truxima vials are stable at 2°C-8°C(36°F-46°F). Truxima vials should be protected from direct sunlight. Do not freeze or shake.
- Reference Product: Rituxan, BLA 103705

* Truxima has been developed as a proposed biosimilar to US-licensed Rituxan (rituximab). Since the proper name for Truxima has not yet been determined, "CT-P10" is used throughout this review as the nonproprietary name for this product.

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 name[a].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Truxima, is derived from rituximab. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 12, 2017 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.

2.2.4 FDA Name Simulation Studies

Sixty-nine (n=69) practitioners participated in DMEPA's prescription studies. In the inpatient study, two participants misinterpreted Truxima for the proposed name (b) (4)***, which was found unacceptable by DMETS in OSE# 05-0296 and OSE# 2007-610 for NDA 021926 (sumatriptan succinate and naproxen sodium tablets). NDA 021926 is approved under the proprietary name, Treximet. Given the similarity between Truxima and Treximet, we considered the risk of confusion between Truxima and Treximet. We determined that the name pair Truxima and Treximet has minimal potential for confusion for the following reasons:

Orthographically, Treximet has an upstroke letter 't' at the end of the name, which is absent in Truxima. The third syllables ('met' vs. 'ma') of this name pair have notable phonetic differences when spoken. Truxima and Treximet differ in terms of dose ((b) (4) *375 mg/m^2,* (b) (4) vs.*1 tab or 500 mg/85 mg and 60 mg/10 mg*), strength (*100 mg/10 mL and 500 mg/50 mL [10 mg/mL]* vs. *500 mg/85 mg and 60 mg/10 mg*), dosage form (*injection* vs. *oral*), and route of administration (*intravenous* vs. *oral*). Therefore, in the absence of overlapping

[a] USAN stem search conducted on June 23, 2017.

product characteristics, we do not think that the name pair is vulnerable to name confusion (see Appendix C for evaluation of the name pair).

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 149 names with a combined phonetic and orthographic score of ≥55percentage or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	9
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	121
Low similarity name pair: combined match percentage score ≤54%	19

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

Our analysis of the 149 names contained in Table 1 determined 149 names will not pose a risk for confusion as described in Appendices C through H.

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 19, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on July 23, 2017, they stated no additional concerns with the proposed proprietary name, Truxima.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

[b] POCA search conducted on May 9, 2017 in version 4.0.

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

If any of the proposed product characteristics as stated in your May 1, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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 supports 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. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

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

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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 ≥ 70%).

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg

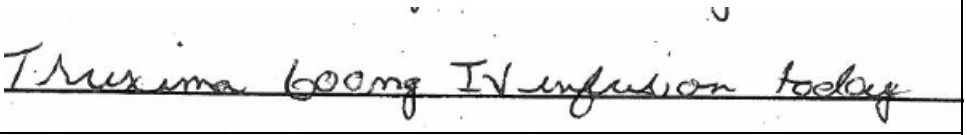
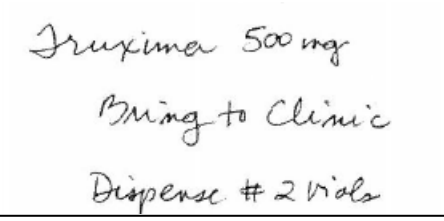
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Truxima Study (Conducted on May 15, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Truxima 500 mg Bring to clinic Dispense# 2 vials
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

296 People Received Study

69 People Responded

Study Name: Truxima

Total	22	18	29	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
IRUXIMA	1	0	0	1
TRAXEMA	0	1	0	1
TRAXIMA	0	1	0	1
TREKCIMA	0	1	0	1
TREXIMA	0	0	2	2
TRIXIMA	0	0	1	1
TROXEMA	0	5	0	5

TRUCKSEMIA	0	1	0	1
TRUCSEMA	0	1	0	1
TRUKSEMA	0	1	0	1
TRUSIMA	0	0	1	1
TRUXEMA	0	3	0	3
TRUXIMA	21	4	25	50

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

No.	**Proposed name:Truxima** **Established name: CT-P10*** **Strength(s):** 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Truxima***	100	Subject of this review
2.	(b) (4)***	90	The proposed name, (b) (4)*** was found unacceptable by DMETS in OSE# 05-0296 dated April 4, 2006 OSE# 2007-610, dated May 3, 2007. NDA 021926 was approved under the name Treximet on April 15, 2008.
3.	Traxam	76	This is an international product marketed in the UK.

No.	Proposed name:Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (b) (4)	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
4.	Treximet	74	Treximet has an upstroke letter in the eighth position. The last sound of the third syllable of this name pair has notable differences when spoken ('met' vs. 'ma'). Dose: (b) (4) 375 mg/m^2 (b) (4) vs.1 tab or 500 mg/85 mg or 60 mg/10 mg Strength: 100 mg/10 mL, 500 mg/50 mL (10 mg/mL) vs. 500 mg/85 mg or 60 mg/10 mg Dosage Form: injection vs. tablets Route of Administration: intravenous vs. oral
5.	(b) (4) ***	73	The proposed name, (b) (4) *** was withdrawn by the Applicant on (b) (4). The Applicant subsequently submitted the proposed name, (b) (4) ***, which was found acceptable by DMEPA in OSE# (b) (4).

No.	**Proposed name:Truxima** **Established name: CT-P10*** **Strength(s):** 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (b) (4)	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
6.	Truxade	73	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.
7.	Trioxin	71	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.

No.	Proposed name:Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (b) (4)	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
8.	Troxyca	71	The name pair has different suffixes ('yca' vs. 'ima'). The second syllables of this name pair have notable differences when spoken ('yc' vs. 'im'). Dose: (b) (4) 375 mg/m^2 (b) (4) vs. 1.2 mg/10 mg or 1 capsule PO every 12 hours Strength: 10 mg/mL vs. 1.2 mg/10 mg or 2.4 mg/20 mg or 3.6 mg/30 mg or 4.8 mg/40 mg or 7.2 mg/60mg or 9.6 mg/80 mg Route of administration: intravenous vs. oral

No.	Proposed name:Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (b) (4)	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
9.	Trexan	70	Truxima has the letter 'a' (vs. 'i') in the fifth position and an additional letter 'a' at the end of the name, which provides some orthographic differences. The second and third syllables of this name pair have notable differences when spoken ('i') and ('an' vs. 'ma'). Trexan has 2 syllables and Truxima has 3 syllables. Dose: (b) (4) 375 mg/m^2 (b) (4) vs.1 tab or 50 mg Route of Administration: intravenous vs. oral

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

No.	Name	POCA Score (%)
1.	Tri-Luma	68
2.	Triam-A	66
3.	Peroxin A	66
4.	tru-Micin	64
5.	Tuxarin	64
6.	trumenba	63
7.	Trimo San	62
8.	truvada	62
9.	Tricalm Hydrogel	60
10.	Trexbrom	59
11.	Tarsum	58
12.	Trexall	58
13.	Triam	58
14.	Triaprin	58
15.	Tri-Statin	58
16.	Trixaicin	58
17.	Tuxarin Er***	58
18.	Dinutuximab	56
19.	Fluxid	56
20.	Triclosan	56
21.	Tripedia	56
22.	Triderm	55
23.	Troxyca Er	55
24.	Urimar-T	46
25.	Irrimax	44

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

No.	**Proposed name: Truxima** **Established name: CT-P10*** **Strength(s):** 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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**
1.	Rituximab	68	This name pair has sufficient orthographic and phonetic differences.
2.	Droxia	68	The first letters (‘D’ vs. ‘T’) and the additional letter ‘m’ in the suffix of Truxima provide some orthographic differences. The first syllables of this name pair have notable differences when spoken (‘Drox’ vs. ‘Trux’). Strength: 100 mg/10 mL, 500 mg/50 mL vs. 200 mg or 300 mg or 400 mg Route of Administration: intravenous vs. oral Dosage form: injection vs. capsule

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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
3.	Tracrium	67	This name pair has different infixes (‘cri’ vs. ‘i’) and ends with suffixes (‘um’ vs. ‘ma’). Truxima contains a crossed letter ‘x’ in the fourth position, which is absent from Tracrium. The second and third syllables of this name pair have notable differences when spoken (‘cri’ vs. ‘i’) and (‘um’ vs. ‘ma’). Dose: (b) (4) 375 mg/m^2 (b) (4) vs. 0.3 to 0.4 mg/kg.
4.	Peroxin A 10	66	This name pair has sufficient orthographic and phonetic differences.
5.	Cetuximab	64	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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.	Farxiga	64	This name pair has different prefixes (‘Far’ vs. ‘Trux’). The first syllables of this name pair have notable differences when spoken (‘Far’ vs. ‘Trux’). Additionally, Farxiga has a downstroke in the sixth position, which is absent from Truxima. Dose: (b) (4) 375 mg/m^2 (b) (4) vs. 5 mg or 10 mg Route of Administration: intravenous vs. oral
7.	Siltuximab	63	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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
8.	Tresiba	63	This name pair has different prefixes ('Tre' vs. 'Trux'). Tresiba contains an upstroke letter 'b' in the sixth position, which is absent from Truxima. Additionally, Truxima contains a crossed letter 'x' in the fourth position, which is absent from Tresiba. The first syllables of this name pair have notable differences when spoken ('Tre' vs. 'Trix'). Dose: (b) (4) 375 mg/m^2 (b) (4) vs. 0.2 to 0.4 units/kg initially Route of Administration: intravenous vs. subcutaneous How supplied: single-dose vial vs. prefilled pen
9.	Trospium	63	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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
10.	Truxadryl	63	This name pair has different infixes (‘a’ vs. ‘i’) and suffixes (‘dryl’ vs. ‘ma’). Truxadryl contains an upstroke letter ‘d’ in the sixth position, which is absent from Truxima. Additionally, Truxadryl contains a downstroke letter ‘y’ in the seventh position, which is absent from Truxima. The second and third syllables of this name pair have notable differences when spoken (‘a’ vs. ‘i’) and suffixes (‘dryl’ vs. ‘ma’).
11.	Primaxin	62	This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***	61	This name pair has sufficient orthographic and phonetic differences.
13.	truxacaine	60	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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
14.	Fetzima	58	The first letter ('F' vs. 'T') provides some orthographic differences. Additionally, Fetzima has an upstroke in the third position, which is absent from Truxima. The first syllables ('Fet' vs. 'Tru') of this name pair sound different. Route of Administration: oral vs. intravenous Dosage form: extended-release capsule vs. injection
15.	Trepoxen-250	58	This name pair has sufficient orthographic and phonetic differences.
16.	Triacin	58	This name pair has sufficient orthographic and phonetic differences.
17.	Trimox	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* Strength(s): 100 mg/10 mL, 500 mg/50 mL Usual Dose: NHL: the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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
18.	Tri-Pseudo	58	This name pair has sufficient orthographic and phonetic differences.
19.	Triostat	57	This name pair has sufficient orthographic and phonetic differences.
20.	Primaxin Iv	56	This name pair has sufficient orthographic and phonetic differences.
21.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
22.	(b) (4)***	56	This name pair has sufficient orthographic and phonetic differences.
23.	Trastuzumab	56	This name pair has sufficient orthographic and phonetic differences.
24.	Triptone	56	This name pair has sufficient orthographic and phonetic differences.
25.	Tranxene T-tabs	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Truxima Established name: CT-P10* **Strength(s):** 100 mg/10 mL, 500 mg/50 mL **Usual Dose:** **NHL:** the dose is 375 mg/m^2. Depending on severity and/or stage of disease, administration can range from 4 to 16 doses. (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**
26.	Tremfya***	55	This name pair has different infixes ('fy' vs. 'i'). Tremfya contains an upstroke letter 'f' in the fifth position, which is absent from Truxima. Additionally, Tremfya contains a downstroke letter 'y' in the sixth position, which is absent from Truxima. The first syllables of this name pair have notable differences when spoken ('Trem' vs. 'Trux'). Route of Administration: intravenous vs. subcutaneous How supplied: single-dose vial vs. prefilled syringe

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

No.	Name	POCA Score (%)
1.	Arixtra	54
2.	Praxbind	54
3.	Triumeq	54
4.	Nexium	52
5.	Propecia	52
6.	Robaxin	52
7.	Robaxin 750	52
8.	Trulicity	52
9.	Trizivir	51
10.	Pradaxa	50
11.	Prometrium	50
12.	Retin-A	50
13.	Rotarix	50
14.	Tinactin	50
15.	Toradol IM	50
16.	Trisenox	50
17.	Trusopt	50
18.	Ruxolitinib	45
19.	Lenvima	44

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.	Triactin	66	This name was identified in Redbook. However, this product is listed as discontinued with no generic equivalents.
2.	truxcillin	65	This name was identified in RxNorm. However, this product is listed as discontinued with generic equivalents available.
3.	(b) (4)***	64	This ANDA (090836) product has been marketed since December 20, 2010 under the established name, Cephalexin. The Applicant submitted a proprietary name review request for the proposed name, (b) (4)*** on December 22, 2015. DMEPA found the proposed name, (b) (4)*** unacceptable in OSE# 2016-2441508 dated April 12, 2016.

No.	Name	POCA Score (%)	Failure preventions
4.	(b) (4) ***	64	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) IND (b) (4) is active and no new names have been submitted.
5.	truxazole	61	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.
6.	Tropium	60	This is an international product marketed in the UK and Greece.
7.	Taractan	59	This product was identified in Drugs at FDA, however is discontinued withdrawn FR effective 1/9/97 (tablet), 6/25/97 (injection), 10/31/95 (oral concentrate). There are no generic equivalents available.
8.	Primaxin Im	58	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.
9.	Triacting	58	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.
10.	Trypsin	58	This product is a bulk powder used for compounding.
11.	(b) (4) ***	57	This was secondary name submitted for IND 051292. The product was approved under the name, Orbactiv on August 6, 2014.
12.	Tricaprin	57	This product is not a drug. It is a medium chain fatty acid.
13.	truxicillin	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Triactin Dm	56	This name was identified in RxNorm. However, this product is listed as discontinued with no generic equivalents available.
15.	(b) (4) ***	56	The proposed name, (b) (4) was withdrawn by the Applicant on 5/21/12. The Applicant submitted the proposed name, (b) (4), which was found acceptable in OSE# 2012-1245. The application was approved on 6/25/12.
16.	Trobicin	56	This product was identified in Drugs at FDA, however is discontinued with no generic equivalents available.
17.	truprofen	56	This product is for veterinary use.
18.	Tucoprim	56	This product is for veterinary use.

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

No.	Name	POCA Score (%)
1.	Duraxin	64
2.	Purixan	64
3.	Brexin L.A.	62
4.	Crixivan	62
5.	Droxicam	62
6.	Puroxcin	62
7.	Rituxan	62
8.	(b) (4)***	61
9.	Eltroxin	60
10.	Miraxid	60
11.	Neutrexin	60
12.	Prudoxin	60
13.	(b) (4)***	60
14.	Atracurium	59
15.	Carisoma	58
16.	Drixomed	58
17.	M-R-Vax Ii	58
18.	Mytrex A	58
19.	Otrexup	58
20.	Piroxicam	58
21.	Succimer	58
22.	Noroxin	57
23.	Zeroxin	57
24.	82 Strontium	56
25.	85 Strontium	56
26.	Atrac-Tain	56
27.	Auryxia	56
28.	(b) (4)***	56
29.	Curatrem	56
30.	Draxxin	56
31.	Droxidopa	56
32.	Matrix	56
33.	Metvixia	56
34.	Mitoxana	56
35.	Paxipam	56
36.	Rixubis	56

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

No.	Name	POCA Score (%)
37.	Serostim	56
38.	Seroxat	56
39.	Strontium	56
40.	Strontium-89	56
41.	Surfaxin	56
42.	(b) (4)***	56
43.	(b) (4)***	55
44.	Bactrim	55
45.	Cardoxin	55
46.	Diurex Max	55
47.	Dristan	55
48.	Frumax	55
49.	Quixin	55
50.	Nutrimix	52
51.	Pripsen	50
52.	Procto-Med	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
	N/A

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

/s/

NICOLE B GARRISON
07/25/2017

HINA S MEHTA
07/25/2017