

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761034Orig1s000

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 Memorandum: March 4, 2016

OND Review Office or Division: Division of Oncology Products 1 (DOP1)

Application Type and Number: BLA 761034 (b) (4)

Product Name and Strength: Tecentriq (atezolizumab) Injection, 60 mg/mL

Total Product Strength: 1,200 mg/20 mL

Product Type: Single Ingredient Product

Rx or OTC: Rx

Submission Date: December 18, 2015 (BLA 761034) (b) (4)

Applicant/Sponsor Name: Genentech, Inc.

Panorama #: 2015-2312188 (b) (4)

DMEPA Primary Reviewer: Otto L. Townsend, PharmD

DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

The proposed proprietary name, Tecentriq, was reviewed by DMEPA on June 17, 2015 under IND 120827 (b) (4) and found conditionally acceptable.¹ (b) (4)

¹ Mathew, D. Proprietary Name Review for Tecentriq (IND 120827 (b) (4) Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 JUN 17. OSE RCM No.: 2015-79245 (b) (4)

2 METHODS AND DISCUSSION

To reassess the proposed proprietary name, we searched the POCA database^{2,3} to identify names with orthographic and phonetic similarities that were not identified in the previous OSE proprietary name review. Our POCA search yielded six names with POCA scores of 50% or above that were not identified in our previous review. We determined that none of the names would pose a risk for confusion as described in the table below.

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

³ **POCA Search Criteria:** Date searched: January 22, 2016; Databases searched: Drugs@FDA and Names Entered by Safety Evaluators

No.	Proposed name: Tecentriq Established name: atezolizumab Dosage form: Injection Strength(s): 1,200 mg/20 mL (60 mg/mL) Usual Dose: 1,200 mg administered by intravenous infusion every three weeks	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.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2015-574846). The Sponsor has not submitted an alternative Proposed Proprietary Name for review.
2.	(b) (4) ***	60	No overlap or numerical similarity in Strength and/or Dose.
3.	(b) (4) ***	60	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2015-453678). The Sponsor has withdrawn the name and submitted an alternative Proposed Proprietary Name for review.
5.	(b) (4) ***	50	No overlap or numerical similarity in Strength and/or Dose.
6.	(b) (4) ***	52	No overlap or numerical similarity in Strength and/or Dose.

⁴The USAN stem list is available at the web page: <http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page>

Additionally, we searched the USAN stem list⁴ to determine if the name contains any USAN stems as of the last USAN update.

Our re-assessment did not identify any new names that represent a potential source of drug name confusion. Our January 29, 2016 search of USAN stems did not yield any USAN stems that are present in the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name, Tecentriq, is acceptable from both a misbranding and safety perspective under BLA 761034 (b)(4).

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager at 301-796-0942.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 18, 2015 (BLA 761034) (b)(4) submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

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

/s/

OTTO L TOWNSEND
03/04/2016

CHI-MING TU
03/04/2016

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: June 17, 2015

Application Type and Number: IND 120827 (b) (4)

Product Name and Strength: Tecentriq (Atezolizumab) Injection, 1200 mg/20 mL (60 mg/mL)

Product Type: Single Ingredient

Rx or OTC: Rx

Applicant/Sponsor Name: Genentech Inc.

Submission Date: March 20, 2015 (IND 120827) (b) (4)
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Panorama #: 2015-79245 (b) (4)

DMEPA Primary Reviewer: Davis Mathew, PharmD

DMEPA Team Leader: Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Tecentriq, 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 [REDACTED] (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant submitted the proposed proprietary name, Tecentriq, on March 20, 2015 under IND 120827. [REDACTED] (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the March 20, 2015 [REDACTED] (b) (4)

- Intended Pronunciation: te sen' trik
- Active Ingredient: Atezolizumab
- Indication of Use:
 - (IND 120827) Treatment of adult patients with [REDACTED] (b) (4) locally advanced or metastatic PD-L1 selected Urothelial Bladder Carcinoma (UBC).

- [REDACTED] (b) (4)
- Route of Administration: Intravenous
 - Dosage Form: Injection
 - Strength: 1200 mg/20 mL (60 mg/mL)
 - Dose and Frequency: 1200 mg administered by intravenous infusion every three weeks.
 - How Supplied: Single-use 20 mL glass vial.
 - Storage: Refrigerated at 2°C- 8°C (36°F – 46°F)

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 Oncology Products 1 (DOP1) 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 did not provide a derivation or intended meaning for the proposed name, Tecentriq, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety one practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. In the voice study, common misinterpretations included the letters "i" for "e" in the prefix (n=7), "a" for "e" in the prefix (n=3), "s" for "c" in the infix (n=16) and "c" for "q" in the suffix (n=26). In the inpatient written study common misinterpretations included the letter "i" for "e" in the infix (n=4). There were fifty participants who correctly interpreted the name. 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 April 3, 2015 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review. (b) (4)

¹USAN stem search conducted on March 25, 2015.

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 also includes names identified from the FDA Prescription Simulation or by Drug Safety Institute, inc.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	101
Low similarity name pair: combined match percentage score $\leq 49\%$	10

2.2.6 *Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength*

The proposed product, Tecentriq will be available in strength of 1200 mg/20 mL. Since this is not a typical strength/ is an unusual strength/ not commonly marketed strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR^oPLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Tecentriq that were not identified in POCA, and found to have an overlap in strength with Tecentriq. Our search did not identify any additional names with potential orthographic, spelling, and phonetic similarities with Tecentriq.

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

Our analysis of the 112 names contained in Table 1 determined none of the names will 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 Oncology Products 1(DOP1) via e-mail on May 15, 2015 (b) (4)

(b) (4) At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on May 26, 2015 (b) (4) (b) (4) they stated no additional concerns with the proposed proprietary name, Tecentriq.

² POCA search conducted on April 21, 2015.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Tecentriq should be submitted once the NDA is submitted.

If any of the proposed product characteristics as stated in your March 20, 2015 and May 15, 2015 submissions 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.

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 DNCE. OPDP or DNCE 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 DNCE 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.³

³ 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 $\geq 70\%$).

<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 <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<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 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
<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 <u>with</u> 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? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<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?
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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 B: Prescription Simulation Samples and Results

Figure 1. Tecentriq Study (Conducted on April 7, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p>Tecentriq 1200 mg intravenous infusion x1. over 60 min</p>	<p>Tecentriq 1200 mg vial Bring to Infusion Center Dispense #1</p>
<p><u>Outpatient Prescription:</u></p> <p>Tecentriq 1200mg vial Bring to infusion center #1</p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

247 People Received Study

91 People Responded

Study Name: Tecentriq

	Total	32	29	30	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
TACENTRIC	0	3	0	3	
TACENTRIK	0	1	0	1	
TASENTRIC	0	1	0	1	
TASETRIC	0	1	0	1	
TASINTRIC	0	1	0	1	
TECCENTRIC	0	1	0	1	
TECENRIQ	0	0	2	2	
TECENTRIC	0	2	0	2	
TECENTRIQ	30	0	20	50	
TECEPTRIC	0	1	0	1	
TECHINTRIQ	0	0	1	1	
TECINTRIQ	0	0	4	4	
TERSEPTRIC	0	1	0	1	
TESENTRIC	0	2	0	2	
TESENTRICK	0	1	0	1	
TESENTRIG	0	0	1	1	
TESENTRIK	0	1	0	1	
TESENTRIQ	0	0	2	2	
TESETRIC	0	1	0	1	

TICENTRIC	0	3	0	3
TISENTRIC	0	4	0	4
TOCENTIC	0	1	0	1
TOCENTRIQ	1	0	0	1
TOSENTRIC	0	1	0	1
TRECENTRIQ	1	0	0	1
TRESCENTRIC	0	1	0	1
TUCENTRIC	0	1	0	1
TUSENTRIC	0	1	0	1

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

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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.	Tecentriq	100	Subject of Review

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.	Proposed Name	POCA Score (%)
1.	Centrax	62
2.	(b) (4) ***	50
3.	Cogentin	50
4.	Isentress	59
5.	K-Vescent	52
6.	Lucentis	52
7.	Pentrax	56
8.	Phentride	52
9.	(b) (4) ***	50 (P 70)
10.	Serentil	50
11.	Take Control	54
12.	Targiniq	52
13.	(b) (4) ***	52
14.	Tenkorex	55
15.	Testolin	50
16.	Tetrex	52
17.	Timentin	56

No.	Proposed Name	POCA Score (%)
18.	Tri Vent HC	51

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.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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.	Adcetris	54	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic difference.
2.	Beegentle	50	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have sufficient phonetic differences.
3.	Cometriq	60	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic difference.
4.	Concentraid	58	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic difference.
5.	Cosentyx	54	The prefix and suffix of this name pair have sufficient orthographic differences. The first syllable of this name pair has sufficient phonetic difference.
6.	Cosyntropin	51	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences and Cosyntropin contains an extra syllable when compared to Tecentriq.

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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
7.	Dexatrim	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The first, second and third syllables of this name pair has sufficient phonetic difference.</p>
8.	Ecotrin	51	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second and third syllable of this name pair has sufficient phonetic difference.</p>
9.	Elestrin	51	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second and third syllables of this name pair have sufficient phonetic differences.</p>
10.	Femintrol	50	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair have sufficient phonetic difference.</p>
11.	Gestrin	50	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair have sufficient phonetic difference and Tecentriq contain an extra syllable when compared to Gestrin.</p>
12.	Hizentra	52	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair have sufficient phonetic difference.</p>

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	Kantrex	54	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair have sufficient phonetic differences and Tecentriq contains an extra syllable when compared to Kantrex.</p>
14.	Kcentra	66	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllable of this name pair has sufficient phonetic difference.</p>
15.	Medent C	50	<p>The prefix, infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair have sufficient phonetic difference and Tecentriq contains an extra syllable when compared to the root name Medent.</p>
16.	Myrbetriq	54	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair have sufficient phonetic difference.</p>
17.	Pegintron	56	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first, second and third syllables of this name pair have sufficient phonetic differences.</p>
18.	Procentra	62	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair have sufficient phonetic differences.</p>

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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
19.	Selzentry	60	<p>The prefix of this name pair has sufficient orthographic differences.</p> <p>The first and third syllables of this name pair have sufficient phonetic difference.</p>
20.	Tecfidera	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic difference and Tecfidera contains an extra syllable when compared to Tecentriq.</p>
21.	Tencet	51	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference and Tecentriq contains an extra syllable when compared to Tencet.</p>
22.	Tenoretic	51	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic difference and Tenoretic contains an extra syllable when compared to Tecentriq.</p>
23.	Terfenor	53	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic difference.</p>
24.	Testred	60	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference and Tecentriq contains an extra syllable when compared to Testred.</p>

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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
25.	Testro	54	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference and Tecentriq contains an extra syllable when compared to Testro.</p>
26.	Testro Aq	66	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference and Tecentriq contains an extra syllable when compared to the root name Testro.</p>
27.	Tev Tropin	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic differences.</p>
28.	Teveten	52	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic differences.</p>
29.	Tev-tropin	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic differences.</p>
30.	Texacort	51	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The third syllable of this name pair has sufficient phonetic difference.</p>

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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
31.	Tice BCG	50	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>Tecentriq contains an extra syllable when compared to the root name Tice. Tice BCG contains extra syllables that sound phonetically different when compared to the name Tecentriq.</p>
32.	Triferic	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference.</p>
33.	Tri-Nefrin	52	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic differences.</p>
34.	Triseptin	50	<p>The infix and suffix of this name pair have sufficient orthographic differences.</p> <p>The third syllable of this name pair has sufficient phonetic difference.</p>
35.	Twinrix	50	<p>The suffix of this name pair has sufficient orthographic differences.</p> <p>The second syllable of this name pair has sufficient phonetic difference and Tecentriq contains an extra syllable when compared to the name Twinrix.</p>
36.	(b) (4) ***	61	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair have sufficient phonetic difference.</p>

No.	Proposed name: Tecentriq Established name: Atezolizumab Dosage form: Injection Strength(s): 1200 mg/20 mL (60 mg/mL) Usual Dose: 1200 mg via Intravenous Infusion every three weeks.	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
37.	Zentrip	59	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair have sufficient phonetic differences and Tecentriq contains an extra syllable when compared to the name Zentrip.</p>

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 49\%$)

No.	Name	POCA Score (%)
1.	Actiq	36
2.	Pristiq	42
3.	Tazorac	44
4.	Tegretol	38
5.	Teicoplanin	40
6.	Tekturna	41
7.	Temazepam	36
8.	Tiazac	34
9.	Tri-Sprintec	44
10.	Zyrtec	34

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.	(b) (4)***	64	Proposed proprietary name was found acceptable by DMEPA (OSE# 2012-222). However, application received a complete response (b) (4)
2.	(b) (4)***	50	Proposed Proprietary Name was found unacceptable by DMEPA (OSE# 2011-3369). Product was found acceptable under new proprietary name Aptensio XR***.
3.	Centrine	58	Veterinary product.
4.	Combantrin	54	International Product marketed in Asia, South America, Europe, Australia, New Zealand, Mexico and Canada.
5.	(b) (4)***	58	Proposed Proprietary Name was found unacceptable by DMEPA (OSE# 2012-302). Product is currently under review with new proposed proprietary name (b) (4)***.
6.	Econtra	56	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
7.	Fematrix 40	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
8.	Fematrix 80	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
9.	Pentran	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
10.	Pigment Red 48	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

No.	Name	POCA Score (%)	Failure preventions
11.	Pigment Red 5	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
12.	(b) (4)***	54	This is the second alternate proposed proprietary name and the product was approved under the alternate proposed proprietary name Fulyzaq.
13.	Saventrine	54	International product marketed in Europe.
14.	Solvent Red 27	53	Product is not a drug but a dye.
15.	Solvent Red 4	53	Product is not a drug but a dye.
16.	Technetium 99M	50	Product is not a drug but a medical radioisotope used as a diagnostic agent.
17.	(b) (4)***	54	Proposed Proprietary Name was found unacceptable by DMEPA (b) (4) which was communicated to the applicant via telephone call and the name was withdrawn.
18.	(b) (4)***	54	Proposed Proprietary Name was found unacceptable by DMEPA (OSE# 2012-1019). Product was found acceptable under new proprietary name Aptensio XR***.
19.	Tenoret	50	International product marketed in Europe, Asia, South Africa and New Zealand.
20.	Tensopril	54	International product marketed in Portugal, Argentina, Ireland and Israel.
21.	Tequin Teqpaq	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
22.	Tiratricol	50	International product marketed in Europe.

No.	Name	POCA Score (%)	Failure preventions
23.	(b) (4) ***	52	Proposed Proprietary name was found acceptable by DMEPA (OSE# 2011-2634). However, the name was withdrawn by the applicant on August 6, 2013.
24.	Tricaprin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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

No.	Name	POCA Score (%)
1.	Betatrex	52
2.	Cafetrate	50
3.	Defencin CP	50
4.	Defend II	54
5.	Dendrid	54
6.	Depandrate	52
7.	Depandro 100	52
8.	Depestrate	54
9.	Diphendryl	54
10.	Econopred	50
11.	Estra AQ	52
12.	(b) (4) ***	54
13.	Jevantique	52
14.	Ketanserin	56
15.	Mesantoin	52
16.	Metandren	54
17.	Oxandrin	51
18.	Pacitron	51
19.	Penetrex	54
20.	(b) (4) ***	51
21.	Stendra	54
22.	Strensiq***	58

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/s/

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06/17/2015

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