# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761061Orig1s000

# 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:** | April 19, 2017 |
| **Application Type and Number:** | BLA 761061 |
| **Product Name and Strength:** | Tremfya<br>(guselkumab)<br>Injection<br>100 mg/mL |
| **Product Type:** | Single Ingredient Combination Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Janssen Biotech, Inc. |
| **Panorama #:** | 2017-14295075 |
| **DMEPA Primary Reviewer:** | Carlos M Mena-Grillasca, RPh |
| **DMEPA Acting Team Leader:** | Sarah K. Vee, PharmD |

# 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tremfya, which was found unacceptable under BLA 761061 on February 06, 2017.[a] The proposed proprietary name, Tremfya, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) ***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Tremfya, was dependent upon which underlying application was approved first.

We note that the goal date for BLA 761061 is July 16, 2017, whereas the underlying application for (b) (4) *** remains in IND status. Thus, the applicant resubmitted the proposed proprietary name, Tremfya, for review.

# 2 METHODS AND DISCUSSION

## 2.1 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 April 18, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, DMEPA evaluated the status of the underlying application of the conflicting name, (b) (4) ***. We determined the underlying application for (b) (4) *** remains in IND status. Therefore, if the proposed proprietary name, Tremfya, is granted approval under BLA 761061 on or before the July 16, 2017 PDUFA goal date for the application, this application approval will precede approval of the application with the conflicting proposed name, (b) (4) ***.

Based upon our safety assessment of the proposed proprietary name, Tremfya, the application goal date for BLA 761061, and the status of the underlying application for (b) (4) ***, we find Tremfya conditionally acceptable.

## *2.2 Communication of DMEPA's Analysis*

DMEPA communicated our findings to the Division of Dermatology and Dental Product (DDDP) via e-mail on April 17, 2017.

# 3 CONCLUSIONS

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

If you have any questions or need clarifications, please contact Tri Bui-Nguyen, OSE project manager, at 240-402-3726.

## 3.1 COMMENTS TO THE APPLICANT

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

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[a] Mena-Grillasca, C. Proprietary Name Review for Tremfya (BLA 761061). 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); 2017 Feb 06. Panorama No. 2016-11472075.

If any of the proposed product characteristics as stated in your April 7, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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

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## 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.

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CARLOS M MENA-GRILLASCA
04/19/2017

SARAH K VEE
04/19/2017

**PROPRIETARY NAME REVIEW**

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

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Center for Drug Evaluation and Research (CDER)

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| | |
|---|---|
| **Date of This Review:** | April 5, 2017 |
| **Application Type and Number:** | BLA 761061 |
| **Product Name and Strength:** | (b) (4)<br>(guselkumab)<br>Injection<br>100 mg/mL |
| **Product Type:** | Single Ingredient Combination Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Janssen Biotech, Inc. |
| **Panorama #:** | 2017- 13165377 |
| **DMEPA Primary Reviewer:** | Carlos M Mena-Grillasca, RPh |
| **DMEPA Acting Team Leader:** | Sarah K. Vee, PharmD |
| **DMEPA Acting Associate Director:** | Mishale Mistry, PharmD, MPH |
| **DMEPA Division Director:** | Todd Bridges, RPh |

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CARLOS M MENA-GRILLASCA
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04/06/2017

TODD D BRIDGES
04/06/2017

**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)

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|---|---|
| **Date of This Review:** | February 6, 2017 |
| **Application Type and Number:** | BLA 761061 |
| **Product Name and Strength:** | Tremfya<br>(guselkumab)<br>Injection<br>100 mg/mL |
| **Product Type:** | Single Ingredient Combination Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Janssen Biotech, Inc. |
| **Panorama #:** | 2016-11472075 |
| **DMEPA Primary Reviewer:** | Carlos M Mena-Grillasca, RPh |
| **DMEPA Acting Associate Director:** | Mishale Mistry, PharmD, MPH |
| **DMEPA Division Director:** | Todd Bridges, RPh |

Contents

# 1 INTRODUCTION

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

## 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** on May 5, 2016. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name (b) (4) *** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) in OSE Review #2016-7853541, dated September 29, 2016.

Thus, the Applicant submitted the name, Tremfya, for review on November 21, 2016.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the November 21, 2016 proprietary name submission.

- Intended Pronunciation: trem fye' ah
- Active Ingredient: Guselkumab
- Indication of Use: Adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 100 mg/mL
- Dose and Frequency: 100 mg at Week 0, Week 4 and every 8 weeks thereafter
- How Supplied: 100 mg/mL single-dose pre-filled syringe
- Storage: Store refrigerated (2-8°C), protect from light
- Container and Closure Systems: 1mL glass syringe with a 27G, half inch fixed needle assembled in (b) (4) Passive Needle Guard
- Reference Listed Drug: n/a

# 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 Dermatology and Dental Products (DDDP) 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 did not provide a derivation or intended meaning for the proposed name, Tremfya 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-eight 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. 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, December 16, 2016 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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

Table 1 lists the number of names retrieved from our POCA search[b]. These names are organized as highly similar, moderately similar or low similarity for further evaluation.

| **Table 1. Similarity Category** | **Number of Names** |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 2 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 51 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 0 |

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

We determined 52 of the 53 names will not pose a risk for confusion as described in Appendices C through H. However, the proposed name could be confused with (b) (4)***.

The proposed proprietary name, Tremfya, may be confused with the proposed name, (b) (4)*** (b) (4) due to orthographic similarity and overlapping product characteristics. Tremfya and (b) (4)*** have a similar (b) (4) in

[a] USAN stem search conducted on January 19, 2017.

[b] POCA search conducted on December 20, 2016 in version 4.0

(b) (4)

The similarity of this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates a combined orthographic and phonetic score of 74% for this name pair. This further suggests that the names Tremfya and (b) (4)*** have high similarity and pose a risk for confusion. Additionally, (b) (4) we are concerned (b) (4)

In addition to the orthographic similarity of this name pair, the products share overlapping product characteristics, which increase the potential for error. (b) (4) (b) (4)

Therefore, based on orthographic similarities and overlapping product characteristics we find the proposed name Tremfya unacceptable. The proposed proprietary names Tremfya and (b) (4)*** are vulnerable to medication errors due to name confusion.

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

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on February 1, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DDDP on February 3, 2017, they stated no additional concerns with the proposed proprietary name, Tremfya.

## 3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

### 3.1 COMMENTS TO THE APPLICANT

[a] Institute for Safe Medication Practices. Safety briefs: Similar drug names confused. ISMP Med Saf Alert Acute Care. 2014;19(12):1-3.

[b] "FDA Alerts Pharmacists and Health Care Professionals to the Potential for Injury when Dispensing the Similar-Sounding Drugs Durezol and Durasal". FDA Safety Alert. December 28, 2011. http://www.fda.gov/Drugs/DrugSafety/ucm285235.htm

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

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

## 4 REFERENCES


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

   USAN Stems List contains all the recognized USAN stems.

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

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

***Drugs@FDA***

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

***RxNorm***

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

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

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

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

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

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

The electronic Drug Registration and Listing System (eDRLS) was established to 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. [a]

***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

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

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[a]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign 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

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

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?<br>*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?<br>**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.<br>For single strength products, also consider circumstances where the strength may not be expressed.<br>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. |

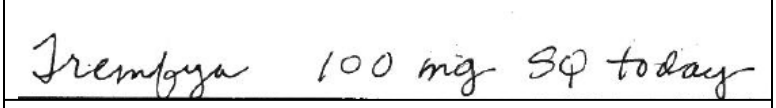
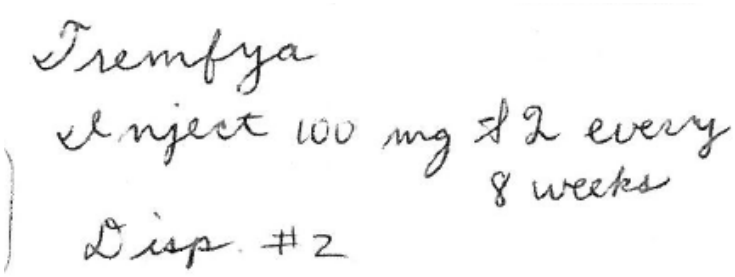
<table>
<tr><td></td><td colspan="2">To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<ul><li>Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.</li><li>Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li><li>Similar sounding doses: 15 mg is similar in sound to 50 mg</li></ul></td></tr>
<tr><td>Step 2</td><td colspan="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 <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)<ul><li>Do the names begin with different first letters?<br><br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</li><li>Are the lengths of the names dissimilar* when scripted?<br><br>*FDA considers the length of names different if the names differ by two or more letters.</li><li>Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?</li><li>Is there different number or placement of cross-stroke or dotted letters present in the names?</li><li>Do the infixes of the name appear dissimilar when scripted?</li><li>Do the suffixes of the names appear dissimilar when scripted?</li></ul></td><td>Phonetic Checklist (Y/N to each question)<ul><li>Do the names have different number of syllables?</li><li>Do the names have different syllabic stresses?</li><li>Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?</li><li>Across a range of dialects, are the names consistently pronounced differently?</li></ul></td></tr>
</table>

**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. Tremfya Study (Conducted on December 23, 2016)**

| Handwritten Medication Order/Prescription | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br><br>Outpatient Prescription:<br>  <br> | Tremfya<br>Inject 100 mg subcutaneously every 8 weeks<br>Disp. #2 |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

As of Date 1/20/2017

306 People Received Study
98 People Responded

## Study Name: Tremfya

| Total | 38 | 31 | 29 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| FREMBYA | 0 | 0 | 2 | 2 |
| FREMFYA | 0 | 0 | 1 | 1 |
| JREMFRA | 1 | 0 | 0 | 1 |
| TRAMPHIA | 0 | 1 | 0 | 1 |
| TRAMVAYA | 0 | 2 | 0 | 2 |
| TREMBAYA | 0 | 1 | 0 | 1 |
| TREMBIA | 0 | 1 | 0 | 1 |
| TREMBYA | 2 | 0 | 7 | 9 |
| TREMFAYA | 0 | 1 | 0 | 1 |
| TREMFIA | 0 | 3 | 0 | 3 |
| TREMFIYA | 0 | 2 | 0 | 2 |
| TREMFYA | 35 | 3 | 18 | 56 |
| TREMPHIA | 0 | 1 | 0 | 1 |
| TREMPVIA | 0 | 1 | 0 | 1 |
| TREMPVYA | 0 | 1 | 0 | 1 |
| TREMPYA | 0 | 0 | 1 | 1 |
| TREMVAYA | 0 | 2 | 0 | 2 |
| TREMVAYA INJECTION | 0 | 1 | 0 | 1 |
| TREMVIA | 0 | 6 | 0 | 6 |
| TREMVYA | 0 | 2 | 0 | 2 |
| TREPHIYA | 0 | 1 | 0 | 1 |
| TRIMVIA | 0 | 1 | 0 | 1 |
| TRUMPVAYA | 0 | 1 | 0 | 1 |

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

| No. | **Proposed name:** Tremfya<br>**Established name:** Guselkumab<br>**Dosage form:** Injection<br>**Strength:** 100 mg/mL<br>**Usual Dose:** 100 mg at Week 0, 4 and every 8 weeks thereafter | POCA Score (%) | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Tremfya | 100 | Proposed name subject of this review. |

**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 (%) |
|---|---|---|
| 2. | Trinza<br>(Name retrieved from "Name entered by safety evaluator database"; however, NDA 207946 approved under the name Invega Trinza) | 66<br>(Phonetic 74) |
| 3. | Prempro | 62<br>(Phonetic 77) |
| 4. | Tremin<br>(Note: Discontinued trihexphenidyl hydrochloride product with generic equivalents available) | 60 |
| 5. | Trymex<br>(Note: Discontinued triamcinolone acetonide cream and ointment product with branded and generic equivalents available) | 59 |
| 6. | Troxyca | 58 |
| 7. | Tranmep<br>(Note: Discontinued meprobamate product with branded and generic equivalents available) | 56 |
| 8. | (b) (4) *** | 55 |

**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:** Tremfya<br>**Established name:** Guselkumab<br>**Dosage form:** Injection<br>**Strength:** 100 mg/mL<br>**Usual Dose:** 100 mg at Week 0, 4 and every 8 weeks thereafter | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 9. | Trental<br>(Note: Discontinued pentoxifylline product with generic equivalents available) | 66<br>(Phonetic 70) | Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tremfya contains an extra syllable. The second/third syllables of this name pair sound different. |
| 10. | Treanda | 66 | Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second syllables of this name pair sound different. |
| 11. | Tempra | 66 | Dose: 100 mg vs. xx mL<br>Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tremfya contains an extra syllable. The second/third syllables of this name pair sound different. |
| 12. | Trinessa | 64<br>(Phonetic 74) | Dose: 100 mg vs. 1 tablet<br>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second and third syllables of this name pair sound different. |
| 13. | Premphase 14/14 | 62<br>(Phonetic 70) | Dose: 100 mg vs. 1 tablet<br>Orthographic: The length of the root names (7 vs. 9 letters), infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tremfya contains an extra syllable. The second/third syllables of this name pair sound different. |
| 14. | Tresiba | 62 | Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second and third syllables of this name pair sound different. |

| No. | **Proposed name:** Tremfya<br>**Established name:** Guselkumab<br>**Dosage form:** Injection<br>**Strength:** 100 mg/mL<br>**Usual Dose:** 100 mg at Week 0, 4 and every 8 weeks thereafter | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 15. | Triam-A<br>(Note: Discontinued triamcinolone acetonide injection product with branded and generic equivalents available) | 60 | Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second syllables of this name pair sound different.. |
| 16. | Pimtrea | 59 | Dose: 100 mg vs. 1 tablet<br>Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The first syllables of this name pair sound different. |
| 17. | Trimo San | 58 | Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second and third syllables of this name pair sound different. |
| 18. | Trexall | 58 | Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tremfya contains an extra syllable. The second/third syllables of this name pair sound different. |
| 19. | (b) (4) *** | 58 | Orthographic: (b) (4) .<br>Phonetic: (b) (4) |
| 20. | Toremifene | 58 | Dose: 100 mg vs. 60 mg or 1 tablet<br>Orthographic: The length of the names (7 vs. 10 letters), infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Toremifene contains an extra syllable. The first, second, third/fourth syllables of this name pair sound different. |
| 21. | Tripedia<br>(Note: Discontinued diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed available as generic DTaP) | 56 | Dose: 100 mg vs. 0.5 mL<br>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tripedia contains an extra syllable. The first, second, and third syllables of this name pair sound different. |

| No. | **Proposed name:** Tremfya<br>**Established name:** Guselkumab<br>**Dosage form:** Injection<br>**Strength:** 100 mg/mL<br>**Usual Dose:** 100 mg at Week 0, 4 and every 8 weeks thereafter | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 22. | Trumenba | 56 | Dose: 100 mg vs. 0.5 mL<br>Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second and third syllables of this name pair sound different. |
| 23. | (b) (4) *** | 56 | Dose: 100 mg vs. (b) (4)<br>Orthographic: (b) (4) .<br>Phonetic: (b) (4) |
| 24. | (b) (4) *** | 56 | Orthographic: (b) (4)<br>Phonetic: (b) (4) |
| 25. | Paremyd | 56 | Orthographic: The prefixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The first, second, and third syllables of this name pair sound different. |
| 26. | Premasol | 55 | Orthographic: The infixes and suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: The second and third syllables of this name pair sound different. |
| 27. | Trandate | 55 | Orthographic: The suffixes of this name pair have sufficient orthographic differences.<br>Phonetic: Tremfya contains an extra syllable. The second/third syllables of this name pair sound. |
| 28. | (b) (4) *** | 55 | Orthographic: (b) (4) .<br>Phonetic: (b) (4) |
| 29. | (b) (4) *** | 55 | Orthographic: (b) (4) .<br>Phonetic: (b) (4) . |

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

N/A

**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 |
|---|---|---|---|
| 30. | (b) (4) *** | 66 (Phonetic 71) | Proposed name for NDA 021926 found unacceptable by DMEPA in OSE RCM 2007-610. The NDA was approved under the name Treximet. |
| 31. | Tramake | 62 | International name for tramadol hydrochloride in Ireland and the UK. |
| 32. | (b) (4) *** | 62 | Proposed name for CBER IND (b) (4) found unacceptable by CBER's Advertising and Promotional Labeling Branch (APLB) |
| 33. | Trynate | 60 | Name identified in Rx Norm database. No product characteristics available in common drug databases. |
| 34. | Mytrex A | 59 (Ortho 71) | Discontinued neomycin sulfate and triamcinolone acetonide product with no generic equivalents available. |
| 35. | (b) (4) *** | 58 | Proposed name for ANDA 205588 withdrawn by the Applicant. The ANDA was approved under the established name norgestimate and ethinyl estradiol. |
| 36. | Traxam | 58 | International name for felbinac in Ireland and the UK. |
| 37. | Triam-Forte | 58 | Discontinued triamcinolone diacetate product with no generic equivalents available. |
| 38. | Atreza | 57 | Discontinued atropine sulfate product with no generic equivalents available. |
| 39. | Triumph | 56 | Not a human prescription drug, but an animal drug. |
| 40. | Tymtran | 56 | Discontinued ceruletide diethylamine product with no generic equivalents available. |
| 41. | Terramycin | 56 | Discontinued oxytetracycline product with no generic equivalents available. |
| 42. | (b) (4) *** | 56 | Alternate name submitted to IND 051292. NDA 206334 as approved under the name Orbactiv. |
| 43. | Tri-Nefrin | 55 | Discontinued chlorpheniramine and phenylpropanolamine product with no generic equivalents available. |
| 44. | Torem | 55 | International name for torasemide in marketed in various countries. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 45. | Predfoam | 62 |
| 46. | Prometa | 61 |
| 47. | (b) (4) *** | 60 |
| 48. | Cyramza | 60 |
| 49. | (b) (4) *** | 59 |
| 50. | Bromfed | 57 |
| 51. | Bromfenac | 56 |
| 52. | (b) (4) *** | 56 |

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

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/s/

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02/07/2017

MISHALE P MISTRY
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02/08/2017