CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210745Orig1s000
210745Orig2s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	January 29, 2025
Application Type and Number:	NDA 210745
Product Name, Dosage Form, and Strength:	Otezla XR (apremilast) extended-release tablets, 75 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant Name:	Amgen (Amgen)
PNR ID #:	2024-1044726111 2024-1044726110
DMEPA 1 Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREM
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Otezla XR, which was found conditionally acceptable under NDA 210745 on March 28, 2018.[a] Thus, Amgen submitted the proposed proprietary name, Otezla XR, under NDA 210745 for re-review on November 15, 2024.[b] We note that NDA 210745 is being reviewed by two different divisions as follows:

- NDA 210745/Original 1 is being managed by the Division of Rheumatology and Transplant Medicine (DRTM) for the treatment of adult patients with active psoriatic arthritis.
- NDA 210745/Original 2 is being managed by the Division of Dermatology and Dentistry (DDD) for the treatment of: adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy; pediatric patients 6 years of age and older and weighing at least 50 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic; and adult patients with oral ulcers associated with Behçet's disease.

We note that there is a slight change in indication [treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy and treatment of pediatric patients 6 years of age and older and weighing at least 50 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy] to include pediatric patients; all other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Otezla XR would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Otezla XR. The Division of Rheumatology and Transplant Medicine (DRTM) and Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Otezla XR.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Otezla XR, we considered our previous analysis of the use of the same root name, Otezla, whether the use of a modifier is sufficient to differentiate the products, and whether the use of the proposed modifier, XR, is appropriate. We considered any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name.

---

[a] Mena-Grillasca, C. Proprietary Name Review for Otezla XR (NDA 210745). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAR 28. PNR ID No. 2018-20203646; 2018-20203722.

[b] Request for Proprietary Name Review. Thousand Oaks (CA): Amgen; 2024 NOV 15. Available from: \\CDSESUB1\EVSPROD\nda210745\0018\m1\us\118-proprietary-names\proprietary-name.pdf

Our reassessment has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Otezla XR.

Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 3, 2025 search of USAN stems did not find any USAN stems in the proposed proprietary name, Otezla XR.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On January 29, 2025, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

3 CONCLUSION

Our re-assessment did not alter our previous conclusion regarding the acceptability of the proposed proprietary name, Otezla XR as noted above. Therefore, we maintain that the proposed proprietary name, Otezla XR, is conditionally acceptable.

3.1 COMMENTS TO AMGEN

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

If any of the proposed product characteristics as stated in your submission, received on November 15, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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/

SARAH K VEE
01/29/2025 03:21:14 PM

DAMON A BIRKEMEIER
01/29/2025 03:56:34 PM

IDALIA E RYCHLIK
01/30/2025 09:27:04 AM

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:	March 28, 2018
Application Type and Number:	NDA 210745
Product Name and Strength:	Otezla XR (apremilast) extended release tablets, 75 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Celgene Corp.
Panorama #:	2018-20203646 2018-20203722
DMEPA Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Associate Director (acting):	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Otezla XR, 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

Otezla was originally approved under NDA 205437 for the treatment of adult patients with active psoriatic arthritis on March 21, 2014, and for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy on September 23, 2014 under NDA 206088. Otezla is currently available in 10 mg, 20 mg, and 30 mg tablets. The recommended dose for both indications include a dose titration up to 30 mg to reduce the risk of gastrointestinal symptoms, followed by a maintenance dose of 30 mg twice daily.

On December 14, 2017, the applicant submitted NDA 210745, which proposes apremilast 75 mg extended release tablet to provide the convenience of once daily dosing during maintenance therapy. Thus, the Applicant submitted the proposed proprietary name, Otezla XR on January 8, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 14, 2017.

	Otezla XR (proposed product) **NDA 210745**	**Otezla (initial approval March 21, 2014)** **NDA 205437 and NDA 206088**
Intended Pronunciation	oh-TEZ-luh X-R	oh-TEZ-luh
Active Ingredient	Apremilast	
Indication of Use	Treatment of adult patients with active psoriatic arthritis and treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	
Route of Administration	Oral	
Dosage Form	Tablets (extended-release)	Tablets (immediate-release)
Strength	75 mg	10 mg, 20 mg, 30 mg

	Otezla XR (proposed product) **NDA 210745**	**Otezla (initial approval March 21, 2014)** **NDA 205437 and NDA 206088**
Dose and Frequency	Maintenance dose following titration with immediate-release formulation: 75 mg once daily	To reduce the risk of gastrointestinal symptoms, titrate to recommended dose per the following schedule: • Day 1: 10 mg in morning • Day 2: 10 mg in morning and 10 mg in evening • Day 3: 10 mg in morning and 20 mg in evening • Day 4: 20 mg in morning and 20 mg in evening • Day 5: 20 mg in morning and 30 mg in evening Day 6 and thereafter (maintenance dose): 30 mg twice daily Severe Renal impairment (Creatinine clearance of less than 30 mL per minute): maintenance dose should be reduced to 30 mg once daily. Otezla should be titrated using only the morning schedule listed above.
How Supplied	Bottes of 30; 14count carton; 28-day starter pack	Bottles of 60; 2-week starter pack; 28-count carton; 28-day starter pack
Storage	Store at 20°C-25°C (68°F-77°F)	Store below 30°C (86°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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) 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, Otezla XR, in their submission. However, the applicant noted that the use of the modifier 'XR' is to denote the once-daily extended release formulation. This proprietary name is comprised of a root name, Otezla, and the modifier 'XR'. The use of the root name, Otezla, and the modifier, XR, is evaluated in Section 2.2.6.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 17, 2018 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) 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

Eighty-five (n=85) 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.

2.2.5 Medication Error Data Selection of Cases

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

Table 2. FAERS Search Strategy	
Search Date	March 5, 2018
Drug Name	Otezla [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR

[a] USAN stem search conducted on March 5, 2018.

Table 2. FAERS Search Strategy	
	PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	none

This search did not retrieve any cases relevant to drug name confusion.

2.2.6 Safety Assessment of the Proposed Name Otezla XR

In this section, we provide a safety analysis of the proposed name Otezla XR. The Applicant currently markets Otezla (apremilast) immediate-release tablets. The Applicant proposes to differentiate the proposed extended-release tablets from the currently marketed formulation using the modifier 'XR'.

Safety Assessment of the root name Otezla

Otezla (apremilast) was approved on March 21, 2014. Our search of the FDA Adverse Event Reporting System (FAERS) database did not identify any cases of name confusion related to the root name Otezla (see Section 2.2.5 Medication Error Data Selection of Cases). Moreover, Otezla and Otezla XR have the same active ingredient, indication of use, and route of administration. Therefore, we have determined that the use of the root name 'Otezla' is acceptable for this product.

Safety Assessment of the Modifier XR

The modifier XR is currently utilized in the marketplace. The modifier XR is typically used to convey the meaning "extended-release" for products with modified-release formulations. Provided that the Office of Pharmaceutical Quality (OPQ) determines that the product meets the criteria for this dosage form, the modifier may serve as a signal to health care practitioners that this product differs from the currently marketed immediate-release apremilast tablet product, which may reduce the potential for wrong frequency errors.

Although we acknowledge that modifiers may be omitted or overlooked, we believe a modifier signaling the extended-release properties of this drug provides an incremental level of safety. Therefore, the modifier XR is appropriate for conveying this characteristic of the product formulation.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on March 23, 2018. At that time we also requested additional information or concerns

that could inform our review. Per e-mail correspondence from the DPARP on March 23, 2018, they stated no additional concerns with the proposed proprietary name, Otezla XR.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Saharat Patanavanich, OSE project manager, at 240-402-0139.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on January, 8, 2018, 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.

APPEARS THIS WAY ON ORIGINAL

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

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

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[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.

---

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

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%).

<table>
<tr><td>Step 1</td><td colspan="2">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</td></tr>
<tr><td rowspan="2">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>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?</td><td>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?</td></tr>
</table>

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

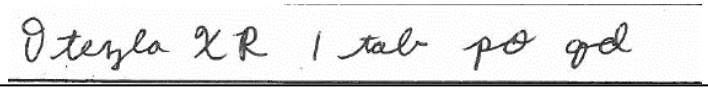
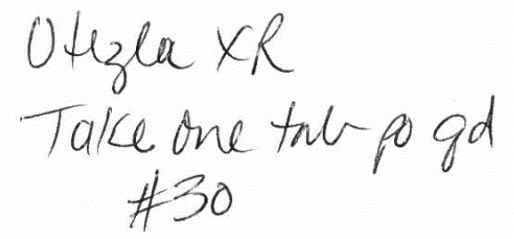
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity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

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Otezla XR Study (Conducted on January 19, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Otezla XR Take one tablet by mouth once daily. Dispense #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 3/5/2018

296 People Received Study

85 People Responded

Study Name: Otezla XR

Total	31	30	24	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
OSTELA	0	1	0	1
OTENSLA SR	0	1	0	1
OTESLA XR	0	6	0	6
OTESSLA XR	0	1	0	1
OTEYLA XR	0	0	2	2
OTEZLA	1	0	0	1
OTEZLA SR	0	1	0	1
OTEZLA XR	29	20	22	71
UTEZLA XR	1	0	0	1

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

/s/

CARLOS M MENA-GRILLASCA
03/28/2018

SARAH K VEE
03/28/2018

MISHALE P MISTRY
03/28/2018