CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761151Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	3/2/2023
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761151
Product Name and Strength:	Bimzelx (bimekizumab-bkzx) injection 160 mg/mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	UCB, Inc. (UCB)
Nexus NPNS ID #:	2022-156
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -bkzx, for BLA 761151, which was found conditionally acceptable on March 12, 2021[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761151.

1.1 Regulatory History

FDA found the proposed four-letter suffix, -bkzx, conditionally acceptable for BLA 761151 on March 12, 2021. However, BLA 761151 received a Complete Response (CR) letter on May 12, 2022[b]. Thus, UCB submitted a Class 2 Resubmission on November 21, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the proposed four-letter suffix, -bkzx, using the principles described in the applicable guidance[c].

We determined that the proposed suffix -bkzx, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On March 1, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on March 2, 2023.

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[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for bimekizumab-bkzx (BLA 761151). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Mar 12. Nexus NPNS ID No.: 2020-4.

[b] Beitz, J.G. Complete Response (BLA 761151). Silver Spring (MD): FDA, CDER, OND, OII (US); 2022 May 12.

[c] Guidance for Industry:Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find the suffix -bkzx acceptable and recommend the nonproprietary name bimekizumab-bkzx be used throughout the labels and labeling.

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/

CARLOS M MENA-GRILLASCA
03/02/2023 06:33:29 PM

MISHALE P MISTRY
03/03/2023 09:29:36 AM

PROPRIETARY NAME REVIEW

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:	February 7, 2023
Application Type and Number:	BLA 761151
Product Name and Strength:	Bimzelx (bimekizumab-bkzx) injection, 160 mg/mL
Total Product Strength:	160 mg/mL per single-dose prefilled syringe and 160 mg/mL per single-dose auto-injector
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	UCB, Inc. (UCB)
PNR ID #:	2022-1044724853
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Bimzelx, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. UCB submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 128707 (see Section 1.1, below).[a]

1.1 REGULATORY HISTORY

UCB previously submitted the proposed proprietary name, Bimzelx, on July 31, 2019. We found the name, Bimzelx acceptable under IND 128707 on January 7, 2019.[b] On July 17, 2020, UCB submitted the name, Bimzelx, for review under BLA 761151. The name was found conditionally acceptable on October 13, 2020.[c] However, a Complete Response Letter (CRL) was issued for BLA 761151 on May 12, 2022.

Thus, on November 21, 2022, UCB submitted a Class 2 resubmission of BLA 761151 in response to the CRL and concurrently submitted a request for proprietary name review of Bimzelx, which is the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 21, 2022.

- Intended Pronunciation: bim zel' ex
- Nonproprietary Name: bimekizumab-bkzx
- Indication of Use: Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 160 mg/mL
- Dose and Frequency: 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, (b) (4) 4, 8, 12 and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, a dose of 320 mg every 4 weeks after week 16 may be considered.

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[a] Patel, M. Proprietary Name Review for Bimzelx (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 07. Panorama No. 2019-33521036.

[b] Patel, M. Proprietary Name Review for Bimzelx (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 07. Panorama No. 2019-33521036.

[c] Patel, M. Proprietary Name Review for Bimzelx (BLA 761151). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 13. Panorama No. 2020-41439787.

- How Supplied: *Autoinjector*: Carton of two 160 mg/mL single-dose autoinjectors. Each prefilled autoinjector is fixed with a 27-gauge ½ inch needle.

  Prefilled syringe: Carton of two 160 mg/mL single-dose prefilled syringes. Each prefilled syringe is fixed with a 27-gauge ½ inch needle with needle guard.

- Storage: Store cartons with Bimzelx refrigerated between 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect it from light until the time of use. Do not freeze. Do not shake. Do not use beyond expiration date. Bimzelx does not contain a preservative; discard any unused portion. Not made with natural rubber latex.

  When necessary, Bimzelx prefilled syringes or autoinjectors may be stored at room temperature up to 25°C (77°F)in the original carton for a single period of up to 30 days. Once Bimzelx prefilled syringes or autoinjectors have been stored at room temperature, do not place back in refrigerator. Write the date removed from the refrigerator in the space provided on the carton and discard if not used within a 30-day period.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bimzelx 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 Bimzelx. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Bimzelx.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Bimzelx.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name.[d]

2.2.2 Components of the Proposed Proprietary Name

UCB did not provide a derivation or intended meaning for the proposed proprietary name, Bimzelx, in their submission. This proprietary name is comprised of a single word that contains the medical abbreviation "im". We previously assessed this abbreviation in our initial review of the name and determined it is unlikely to lead to confusion.[e] This name does not contain any other components (i.e., a modifier, dosage form, etc.) that can contribute to medication error.

[d] USAN stem search conducted on January 24, 2023.

[e] Patel, M. Proprietary Name Review for Bimzelx (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 07. Panorama No. 2019-33521036.

2.2.3 Comments from Other Review Disciplines at Initial Review

On December 28, 2022, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Bimzelx at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-four (94) practitioners participated in DMEPA's prescription studies for Bimzelx. 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 prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 77 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified one name not previously analyzed. This name is included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. This name pair is organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	1
Low similarity name pair: combined match percentage score ≤54%	0

[f] POCA search conducted on January 24, 2023 in version 5.2.

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

Our analysis of the name contained in Table 1 determined the name will not pose a risk for confusion with Bimzelx as described in Appendix H.

2.2.8 Communication of DMEPA's Determination

On February 7, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Bimzelx, is conditionally acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE Safety Regulatory Project Manager, at 240-402-3726.

3.1 COMMENTS TO UCB, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 21, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   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.

3. ***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).

4. ***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).

5. ***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 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. [g]

***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)).

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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, Cerner RxNorm, 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[h]. 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.

Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated,

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

each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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	**Y/N**	Do the syllables have different phonologic processes, such

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

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

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

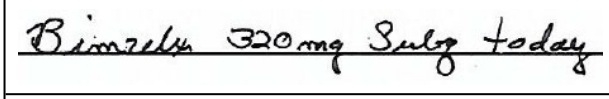
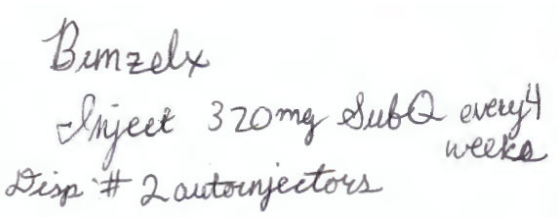
<table>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
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 B: **Prescription Simulation Samples and Results**

Figure 1. Bimzelx Study (Conducted on December 15, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
	Bimzelx Inject 320 mg subcutaneously every 4 weeks Dispense 2 autoinjectors
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Bimzelx	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Bimzelx					
259 People Received Study					
94 People Responded					
Total	24	22	23	25	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
BEMZELX	0	0	0	1	1
BENZELIX	0	0	1	0	1
BIMZELEXA	1	0	0	0	1
BIMZELIX	0	0	1	0	1
BIMZELX	20	22	0	17	59
BIMZELXI	1	0	0	0	1
BIMZELY	1	0	0	0	1
BRINZELEX	1	0	0	0	1
BUMZELX	0	0	0	4	4
BUNZELX	0	0	0	3	3
DEMZELEX	0	0	1	0	1
DEMZELIX	0	0	4	0	4
DEMZELYX	0	0	1	0	1

DENZELICS	0	0	1	0	1
DOMZELIX	0	0	1	0	1
EMZELICS	0	0	1	0	1
EMZELYX	0	0	1	0	1
GIMZELES	0	0	1	0	1
IMJELICS	0	0	1	0	1
IMZELIX	0	0	3	0	3
PIZELIX	0	0	1	0	1
RYMZELIX	0	0	1	0	1
UMZELIX	0	0	1	0	1
UNZELIX	0	0	1	0	1
VEMZELEX	0	0	1	0	1
VEMZELIX	0	0	1	0	1

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

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 — N/A

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

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**.** — N/A

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

No.	Name	POCA Score (%)
1.	Xylimelts	57

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

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/s/

LORETTA HOLMES
02/07/2023 11:46:13 AM

MADHURI R PATEL
02/07/2023 11:55:22 AM

MISHALE P MISTRY
02/07/2023 11:58:16 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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 12, 2021
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761151
Product Name and Strength:	Bimzelx (bimekizumab-bkzx) injection, 160 mg/mL
Product Type:	Combination Product (Drug-Biologic)
Applicant/Sponsor Name:	UCB, Inc. (UCB)
FDA Received Date:	July 15, 2020
OSE Nexus NPNS ID #:	2020-4
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF MEMO

This review summarizes our evaluation of the four-letter suffixes proposed by UCB for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761151.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On July 15, 2020, UCB submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. UCB also provided findings from an external study conducted (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by UCB:

Table 1. Suffixes submitted by UCB***	
1.	bkzx
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Proposed Suffixes BLA 761151. Smyrna (GA): UCB, Inc.; 2020 Jul 15. Available from: \\CDSESUB1\evsprod\bla761151\0001\m1\us\118-proprietary-names\proposed-suffixes.pdf

(b) (4)

We reviewed UCB's proposed suffixes in the order of preference listed by UCB, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 bimekizumab-bkzx

UCB's first proposed suffix, -bkzx, is comprised of 4 distinct letters.

We determined that the proposed suffix -bkzx, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. On March 10, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Dermatology and Dentistry (DDD) on March 12, 2021.

4 CONCLUSION

We find UCB's proposed suffix -bkzx acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to bimekizumab-bkzx. DMEPA will communicate our findings to the Applicant via letter.

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4.1 Recommendations for UCB, Inc.

We find the nonproprietary name, bimekizumab-bkzx, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, bimekizumab-bkzx will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
03/12/2021 02:21:01 PM

DANIELLE M HARRIS
03/12/2021 02:21:01 PM

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:	October 13, 2020
Application Type and Number:	BLA 761151
Product Name and Strength:	Bimzelx (bimekizumab-xxxx)[a] injection, 160 mg/mL
Total Product Strength:	160 mg/mL per single-use safety syringe and 160 mg/mL per single-use auto-injector
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	UCB, Inc.
Panorama #:	2020-41439787
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "bimekizumab-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Bimzelx, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. UCB, Inc. submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name, which was reviewed during our previous evaluation under IND 128707[b].

1.1 REGULATORY HISTORY

UCB, Inc. previously submitted the proposed proprietary name, Bimzelx*** on July 31, 2019. We found the name, Bimzelx*** acceptable under IND 128707 on January 7, 2019.[c]

Thus, UCB, Inc. submitted the name, Bimzelx, for review on July 17, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 17, 2020.

- Intended Pronunciation: bim zel' ex
- Nonproprietary Name: bimekizumab-xxxx
- Indication of Use: treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 160 mg/mL
- Dose and Frequency: 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12 and 16, then every 8 weeks thereafter. For some patients, a dose of 320 mg every 4 weeks after week 16 may be considered.
- How Supplied: Each autoinjector or prefilled syringe delivers 1 mL of a 160 mg/mL solution. Carton of two 160 mg/mL single-use autoinjectors (injection), Carton of two 160 mg/mL single-use prefilled syringes (injection)
- Storage: refrigerated between 2° to 8℃ (36° to 46 F). Keep the product in the original carton to protect it from light until the time of use. Do not freeze.

2 RESULTS

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

---

[b] Patel, M. Proprietary Name Review for Bimzelx*** (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 07. Panorama No. 2019-33521036.

[c] Patel, M. Proprietary Name Review for Bimzelx*** (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 07. Panorama No. 2019-33521036.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bimzelx would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Bimzelx.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Bimzelx.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[d].

2.2.2 Components of the Proposed Proprietary Name

UCB, Inc. did not provide a derivation or intended meaning for the proposed proprietary name, Bimzelx, in their submission. This proprietary name is comprised of a single word.

We note that Bimzelx contains the letter string '-im-', an abbreviation for the route of the administration 'intramuscular administration' which was evaluated in our previous review[e]. After considering the risks associated with this naming strategy, we do not have any objection to the inclusion of the '-im-' letter string and we maintain our previous decision.

Beyond this abbreviation, we note that Bimzelx does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 30, 2020 e-mail, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Bimzelx at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-two (n=82) practitioners participated in DMEPA's prescription studies for Bimzelx. 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 prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 76 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in

[d] USAN stem search conducted on August 21, 2020.

[e] Patel, M. Proprietary Name Review for Bimzelx*** (IND 128707). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 07. Panorama No. 2019-33521036.

[f] POCA search conducted on August 21, 2020 in version 4.4.

our previous proprietary name review. We re-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 name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified one name not previously analyzed. This name is included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	1
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 2 names contained in Table 1 determined none of the names will pose a risk for confusion with Bimzelx 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 Dermatology and Dentistry (DDD) via e-mail on October 6, 2020. At that time we also requested additional information or concerns that could inform our review. The Division of Dermatology and Dentistry (DDD) did not state additional concerns with the proposed proprietary name, Bimzelx.

3 CONCLUSION

The proposed proprietary name, Bimzelx, 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 UCB, INC.

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

If any of the proposed product characteristics as stated in your submission, received on July 17, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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 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. [g]

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[h]. 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.

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

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

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

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

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

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

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

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

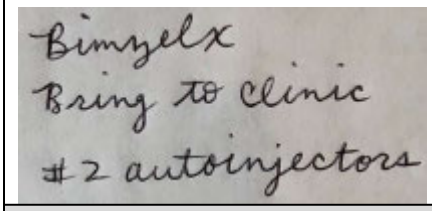
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Bimzelx Study (Conducted on August 21, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Bimzelx Bring to clinic. Dispense # 2 autoinjectors.
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Bimzelx	

FDA Prescription Simulation Responses (Aggregate Report)

207 People Received Study
82 People Responded

Study Name: Bimzelx

Total	21	26	19	16	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
BENSELEX	0	0	1	0	1
BENZELEX	0	0	1	0	1
BENZELIC	0	0	1	0	1
BENZELICK	0	0	1	0	1
BENZELIX	0	0	3	0	3
BIIMZELX	1	0	0	0	1
BIMYELX	3	0	0	0	3
BIMZELEX	1	0	0	0	1
BIMZELK	0	0	0	1	1

BIMZELX	15	26	0	14	55
BIMZELX INJECT	0	0	0	1	1
BINCELEX	0	0	1	0	1
BINSELIT	0	0	1	0	1
BINZELET	0	0	1	0	1
BINZELEX	0	0	1	0	1
BINZELIC	0	0	2	0	2
BINZELICK	0	0	1	0	1
BINZELIX	0	0	2	0	2
BINZELLIX	0	0	1	0	1
BRIMYELX	1	0	0	0	1
DINZELEX	0	0	1	0	1
DINZELIX	0	0	1	0	1

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

No.	**Proposed name:** Bimzelx **Established name:** bimekizumab-xxxx **Dosage form:** injection **Strength(s):** 160 mg/mL **Usual Dose:** 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12 and 16, then every 8 weeks thereafter. For some patients, a dose of 320 mg every 4 weeks after week 16 may be considered	**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.	Bimzelx***	100	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 (%)
	N/A	N/A

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:** Bimzelx **Established name:** bimekizumab-xxxx **Dosage form:** injection **Strength(s):** 160 mg/mL **Usual Dose:** 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12 and 16, then every 8 weeks thereafter. For some patients, a dose of 320 mg every 4 weeks after week 16 may be considered	**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**
	N/A	N/A	N/A

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

No.	Name	POCA Score (%)
	N/A	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
	N/A	N/A	N/A

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

No.	Name	POCA Score (%)
2.	Scemblix***	64

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

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/s/

MADHURI R PATEL
10/13/2020 11:27:01 AM

SEVAN H KOLEJIAN
10/13/2020 11:45:54 AM