CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761042Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	February 11, 2016
Application Type and Number:	BLA 761042
Product Name and Strength:	Erelzi and Erelzi Sensoready Pen (GP2015)[*] Injection 25 mg/0.5 mL; 50 mg/1 mL
Total Product Strength:	50 mg/mL
Product Type:	Drug-Device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sandoz
Panorama #:	2015-2121226
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH
DMEPA Deputy Director:	Lubna Merchant, PharmD, MS

[*] Erelzi and Erelzi Sensoready Pen have been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for Erelzi and Erelzi Sensoready Pen have not yet been determined, GP2015 is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary names, Erelzi and Erelzi Sensoready Pen, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) and (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** and (b) (4) *** on July 30, 2015. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the names, (b) (4) *** and (b) (4) ***, unacceptable due to (b) (4) in OSE Review # 2015-1210669 and 2015-1210671, dated October 26, 2015.

Thus, the Applicant submitted the names, Erelzi and Erelzi Sensoready Pen, for review on November 25, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 25, 2015 proprietary name submission.

- Intended Pronunciation: eh rel' zee and eh rel' zee sen soe re' dee
- Active Ingredient: GP2015*
- Indication of Use: Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older, Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Plaque Psoriasis (PsO)
- Route of Administration: Subcutaneous Injection
- Dosage Form: Injection
- Strength: 25 mg/0.5 mL; 50 mg/1 mL
- Dose and Frequency:
  - **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended
  - **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance.
  - **JIA:** patients who weigh 63 kg (138 lbs.) and above may be prescribed a weekly dose of 50 mg. For pediatric patients below 63 kg of weight, who

* Erelzi and Erelzi Sensoready Pen have been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for Erelzi and Erelzi Sensoready Pen have not yet been determined, GP2015 is used throughout this review as the nonproprietary name for this product.

require weight based dosing (0.8 mg/kg), no dose-adjustable formulation of Erelzi is currently available.

- How Supplied: 25 mg/0.5 mL and 50 mg/mL prefilled syringe (PFS); 50 mg/mL autoinjector (AI) pen.
- Storage: Erelzi prefilled syringes and Sensoready Pen must be stored refrigerated at 2-8°C (36°F-46°F). Erelzi should be stored in the original carton to protect from light or physical damage and should not be shaken or frozen.
- Container and Closure Systems:
    - GP2015 as 25 mg and 50 mg pre-filled syringe (PFS) with a Needle Safety Guard (NSG) and add-on Finger Flange.
    - GP2015 as 50 mg PFS pre-assembled in a pen.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed names would not misbrand the proposed product. DMEPA and the Division of Division of Pulmonary, Allergy and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed names.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the names.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed names, Erelzi and Erelzi Sensoready Pen, in their submission.

The proposed name, Erelzi, is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

The proposed name Erelzi Sensoready Pen is comprised of the root name, Erelzi, and modifier, Sensoready Pen. The proposed modifier, Sensoready Pen, refers to the name of the autoinjector device. This device was previously submitted to and approved by the Agency for the subcutaneous administration of Cosentyx (INN: secukinumab) with the modifiers as "Sensoready Pen". Sandoz and Novartis have co-developed a platform

[1]USAN stem search conducted on December 16, 2015.

device to be used across different medicinal products, and Sandoz would like to use the same modifier, Sensoready Pen, for the Erelzi autoinjector. We note that the naming convention of adding a modifier to represent a specific device has been used before to differentiate the autoinjector presentation from the vial and/or prefilled syringe.

We acknowledge that modifiers may sometimes be omitted. If the modifiers, Sensoready Pen, are omitted, the pharmacist would have to call the prescriber to seek clarification or the patient may receive the prefilled syringe presentation. However, since the 50 mg/mL strength is available in both the prefilled syringe and autoinjector, the patient would still be receiving the correct product and dose. Furthermore, as with any product that is available in multiple dosage forms or packaging presentation, the prescriber would need to indicate in the prescription, the intended product.

We do not anticipate that the modifiers 'Sensoready Pen' will be written on their own without the root name. Additionally, we do not anticipate any confusion between Cosentyx Sensoready Pen and Erelzi Sensoready Pen, given the root names are different. Also, we are not aware of any errors relating to the misinterpretation of the modifiers 'Sensoready Pen'. Therefore, we find the use of the modifiers, Sensoready Pen, appropriate for this product.

2.2.3 FDA Name Simulation Studies

Erelzi:

Eighty-one practitioners participated in DMEPA's prescription studies in respect to Erelzi. 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.

Erelzi Sensoready:

Seventy-seven practitioners participated in DMEPA's prescription studies in respect to Erelzi Sensoready. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 1, 2015 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the

[2] POCA search of "Erelzi" conducted on December 16, 2015.

(b) (4) and (b) (4) external name study.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	60
Low similarity name pair: combined match percentage score ≤49%	2

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

Our analysis of the 64 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 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 January 29, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPARP on February 9, 2016, they stated no additional concerns with the proposed proprietary names, Erelzi and Erelzi Sensoready Pen.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Erelzi and Erelzi Sensoready Pen, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your November 25, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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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. [3]

[3] 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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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 ≥50% 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Erelzi Study (Conducted on December 18, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Erelzi Inject 25mg once	Erelzi Inject 50 mg once weekly Dispense 4 pre-filled syringes
Outpatient Prescription: Erelzi Inject 50mg once weekly Disp #4 pre-filled syringes	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)
Study Name: Erelzi

Total	28	24	29	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ARELTI	0	1	0	1
ENELZI	1	0	0	1
ERALEI	0	0	1	1
ERALZI	0	0	1	1
ERELCI	0	0	9	9
ERELEI	0	0	4	4
ERELRI	1	0	0	1
ERELZE	0	2	0	2
ERELZI	24	4	7	35
ERELZI INJECT	0	0	1	1
ERELZI INJECTION	0	0	1	1
ERELZIE	0	2	0	2
ERELZY	0	3	0	3
ERETIA	1	0	0	1

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ARELTI	0	1	0	1
ENELZI	1	0	0	1
ERALEI	0	0	1	1
ERALZI	0	0	1	1
ERELCI	0	0	9	9
ERELEI	0	0	4	4
ERELRI	1	0	0	1
ERELZE	0	2	0	2
ERELZI	24	4	7	35
ERELZI INJECT	0	0	1	1
ERELZI INJECTION	0	0	1	1
ERELZIE	0	2	0	2
ERELZY	0	3	0	3
ERETIA	1	0	0	1
EREZI	0	0	1	1
ERILCI	0	0	1	1
ERILEI	0	0	1	1
ERILZI	0	0	1	1
ERTZI	0	0	1	1
EZELZI	1	0	0	1
HEREZELE	0	1	0	1
IRELTA	0	1	0	1
IRELZEE	0	3	0	3
IRELZI	0	5	0	5
IRELZY	0	1	0	1
IRRELDI	0	1	0	1

Figure 2. Erelzi Sensoready Study (Conducted on December 21, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Erelzi Sensoready Inject 50mg one time Outpatient Prescription: Erelzi Sensoready Inject 50mg twice weekly Disp: 8 prefilled pens	Erelzi Sensoready Inject 50 mg twice weekly Dispense 8 pre-filled pens

Study Name: Erelzi Sensoready

Total	26	24	22	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ELRESEE SENSOR READY	0	1	0	1
ERAILCELL SENSOR READY	0	1	0	1
ERALZE SENSOREADY	0	1	0	1
ERCLIZE SENSOREADY INJECT	0	0	1	1
ERCLZE SENSOREADY	0	0	1	1
ERCLZE SENSOREADY INJECT	0	0	1	1
ERCLZI SENSOREADY	0	0	1	1
ERELGI SENSOREADY	2	0	0	2
ERELGI SENSORECDY	1	0	0	1
ERELLZESENORETTI	0	1	0	1

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ERELSEY SENSOREADY	0	1	0	1
ERELSYSESRDY	0	1	0	1
ERELZE	1	0	0	1
ERELZE SENSO READY	0	1	0	1
ERELZE SENSOREADH INJECT	0	0	1	1
ERELZE SENSOREADY	0	0	4	4
ERELZEE SENSAREADY	0	1	0	1
ERELZEE SENSOREADY	0	1	0	1
ERELZI	0	1	0	1
ERELZI SENSIREADY	0	1	0	1
ERELZI SENSOREADY	14	1	8	23
ERELZI SENSOREADY INJECT	0	0	1	1
ERELZI SENSOREADY INJECTION	0	0	1	1
ERELZI SINSAREADY	0	0	1	1
ERELZY SETZEREADY	0	1	0	1
ERESLY SENSAREADY	0	1	0	1
EREZLE	0	0	1	1
ERIGI SENSOREADY	1	0	0	1
ERILGI SENSOREADY	3	0	0	3

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ERILZE SENSOREADY	0	0	1	1
ERILZI SENSOREADY	3	0	0	3
ERILZI SENSORECDY INJECTION	1	0	0	1
ERYLZEE SETSAREADY	0	1	0	1
IRELSI SENSOREADY	0	1	0	1
IRELSI SENSORIREADY	0	1	0	1
IRELZI SENSORETI	0	1	0	1
IRELZISENSIREDI	0	1	0	1
IRELZISENSIREDY	0	1	0	1
IRRELZI SENSIREADY	0	1	0	1
IRRELZY SENSOREADY	0	1	0	1
LYRLZI SENSOR READY	0	1	0	1
URALSI SENSOREADY	0	1	0	1

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

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**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.	Erelzi***	100%	This name is the subject of this review.
2.	(b) (4)***	74%	This proposed name was found unacceptable by DMEPA (OSE# 2014-25860) due to (b) (4) An alternate proposed name, Zyfrel***, was found acceptable by DMEPA (OSE# 2015-2119109). The application is pending.

* Erelzi and Erelzi Sensoready Pen have been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for Erelzi and Erelzi Sensoready Pen have not yet been determined, GP2015 is used throughout this review as the nonproprietary name for this product.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4) ***	64%
2.	Reluri	63%
3.	Xarelto	56%
4.	E-Solve 2	55%
5.	Ear-eze	54%
6.	Urelle	53%
7.	Edarbi	52%
8.	Elelyso	52%
9.	Verelan	51%
10.	Erygel	50%
11.	Evorel 25	50%
12.	Evorel 50	50%
13.	Evorel 75	50%
14.	Evorel 100	50%
15.	Relera	50%
16.	Serelaxin	50%

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Eraldin	69%	The suffix of this name pair has sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.
2.	Erevit	62%	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
3.	Erylik	60%	The infix and suffix of this name pair have sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.

* Erelzi and Erelzi Sensoready Pen have been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for Erelzi and Erelzi Sensoready Pen have not yet been determined, GP2015 is used throughout this review as the nonproprietary name for this product.

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**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**
4.	Arelix	58%	The suffix of this name pair has sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.
5.	Esseliv	56%	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
6.	Eselin	53%	The suffix of this name pair has sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.
7.	Dralzine	52%	The prefix and suffix of this name pair have sufficient orthographic differences. This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8.	Eurelix	52%	The suffix of this name pair has sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
9.	Relenza	51%	The prefix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair have sufficient phonetic differences.
10.	Enbrel	50%	The suffix of this name pair has sufficient orthographic differences. This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences.
11.	(b) (4) ***	50%	The suffix of this name pair has sufficient orthographic differences. This root name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences.

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**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**
12.	Erex	50%	The suffix of this name pair has sufficient orthographic differences. This name contains fewer syllables. The second and last syllables of this name pair have sufficient phonetic differences.
13.	Terrell	50%	The infix and suffix of this name pair have sufficient orthographic differences. This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences.
14.	Telzir	50%	The prefix of this name pair has sufficient orthographic differences. This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences.
15.	Embrel	48%	The suffix of this name pair has sufficient orthographic differences. This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences.

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**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**
16.	Elidel	44%	The suffix of this name pair has sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.
17.	Ezetrol	35%	The suffix of this name pair has sufficient orthographic differences. The second and third syllable of this name pair has sufficient phonetic differences.
18.	Eliquis	34%	The infix and suffix of this name pair have sufficient orthographic differences. The last syllable of this name pair has sufficient phonetic differences.
19.	Erbitux	33%	The infix and suffix of this name pair have sufficient orthographic differences. The second and last syllables of this name pair have sufficient phonetic differences.

No.	**Proposed name:** Erelzi and Erelzi Sensoready Pen **Established name:** GP2015* **Dosage form:** Injection **Strength(s):** 25 mg/0.5 mL; 50 mg/1 mL **Usual Dose:** • **Adult RA, PsA, AS:** a dose of 50 mg once weekly is recommended • **Adult PsO:** It is recommended that adults diagnosed with PsO start at 50 mg twice weekly for 3 months and then transition to 50 mg once weekly for continued maintenance. • **JIA:** patients who weigh 63 kg (138 lbs) and above may be prescribed a weekly dose of 50 mg.	**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**
20.	Exforge	31%	The infix of this name pair has sufficient orthographic differences. This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences.
21.	Tysabri	25%	The prefix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.

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

No.	Name	POCA Score (%)
1.	Rasilez	38%
2.	Trezix	37%

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	[redacted]***	56%	This proposed proprietary name, [redacted]***, was found unacceptable by DMEPA due to [redacted] (OSE# 2008-1986). An alternate proposed proprietary name, [redacted]***, was found acceptable (OSE# 2009-337).
2.	[redacted]***	52%	The proposed proprietary name was found acceptable by DMEPA (OSE# 2012-3008). However, the entire application was withdrawn by the applicant.
3.	[redacted]***	52%	This proposed proprietary name, [redacted]***, was found unacceptable by DMEPA due to [redacted] (OSE# 2010-1780). The product was approved under an alternate proposed proprietary name, Picato, (OSE# 2011-2211).
4.	[redacted]***	51%	This was a secondary proposed proprietary name. The product was approved under another proposed proprietary name, Zutripro (OSE# 2010-2734 & 2011-425).

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

No.	Name	POCA Score (%)
1.	AREDIA	55%
2.	ARALEN	54%
3.	DEL-VI-A	54%
4.	ASOLZA	53%
5.	URALGIC	53%
6.	AFREZZA	52%
7.	CERALK	52%
8.	DELSIA	52%
9.	IPREZIV	52%
10.	URIZID	52%
11.	ARESTIN	51%
12.	AEROLIN	50%
13.	AEROLIN-400	50%
14.	ARIDIL	50%
15.	ATELVIA	50%
16.	ATREZA	50%
17.	AVRIDI	50%
18.	PYRIL D	50%
19.	TERIL	50%

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

No.	Name
1.	N/A

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/s/

MATTHEW J BARLOW
02/11/2016

MISHALE P MISTRY
02/12/2016

LUBNA A MERCHANT
02/12/2016

PROPRIETARY NAME REVIEW

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

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

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Date of This Review:	October 26, 2015
Application Type and Number:	BLA 761042
Product Name and Strength:	(b) (4) (GP2015*) Injection 25 mg/0.5 mg and 50 mg/1mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sandoz
Panorama #:	2015-1210669 and 2015-1210671
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Division Director:	Todd Bridges, RPh

* (b) (4) have been developed as a proposed biosimilar to US-licensed Enbrel (etanercept). Since the proper names for (b) (4) have not yet been determined, GP2015 is used throughout this review as the nonproprietary name for this product.

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/s/

TERESA S MCMILLAN
10/26/2015

KENDRA C WORTHY
10/26/2015

TODD D BRIDGES
10/26/2015