CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125547Orig1s000

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:	January 28, 2015
Application Type and Number:	BLA 125547
Product Name and Strength:	Portrazza (necitumumab) Injection, 800 mg/50 mL (16 mg/mL)
Product Type:	Single-ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eli Lilly and Company
Submission Date:	December 2, 2014
Panorama #:	2014-44222
DMEPA Primary Reviewer:	Otto L. Townsend, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Portrazza, 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 [(b) (4)] for this product. However, the study was submitted in 2012 as part of a Proprietary Name Review Request under IND 102512 for the proposed proprietary name, [(b) (4)] *** (see Regulatory History). Thus, the study was not applicable to the review of the proposed proprietary name, Portrazza.

1.1 REGULATORY HISTORY

As stated above, the sponsor previously submitted the proposed proprietary name, [(b) (4)] *** on November 21, 2012. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, [(b) (4)] *** unacceptable [(b) (4)] [(b) (4)]. DMEPA communicated this finding to the Sponsor on March 14, 2013 during a teleconference.[1]

Thus, the sponsor submitted the name, Portrazza, for review on July 29, 2013 under IND 102512. The proposed proprietary name, Portrazza, was found conditionally acceptable under the IND.[2] Eli Lilly and Company (Lilly) is now submitting the proposed proprietary name, Portrazza, for review under the NDA.

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[1] Cato, M. Proprietary Name Memo to File (Advice/Information Request) for [(b) (4)] *** (necitumumab) (IND 102512). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Regulatory Project Management Staff (US); 2013 MAR 14. 2 p. OSE RCM No.: 2012-2790.

[2] Townsend O. Proprietary Name Review for Portrazza *** (necitumumab) (IND102512). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 NOV 20. 22 p. OSE RCM No.: 2013-1777.

1.2 PRODUCT INFORMATION

Lilly provided the following product information in the December 2, 2014 proprietary name submission.

Intended Pronunciation	pōr - 'trä - zə
Pharmacologic Category	Epidermal Growth Factor Receptor (EGFR) Inhibitor
Active Ingredient	Necitumumab
Indication of Use	In combination with gemcitabine and cisplatin for the first-line treatment of patients with locally advanced or metastatic squamous non-small cell lung cancer.
Route of Administration	Intravenous infusion
Dosage Form	Injection for intravenous infusion
Strength	800 mg/50 mL (16 mg/mL)
Dose and Frequency	800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.
How Supplied	Single-dose glass vial with (b) (4) (b) (4) stopper with aluminum flip-off seal.
Storage	Store refrigerated at 2°C to 8°C

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name.[3]

[3]USAN stem search conducted on December 5, 2014.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Portrazza in their submission. This proprietary name is comprised of a single word that does not contain any components, such as a modifier, route of administration, or dosage form that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-nine (99) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Fifty-six (56) participants correctly identified the proposed proprietary name as Portrazza. Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 18, 2014 e-mail, DOP2 did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 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[4] organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	93
Low similarity name pair: combined match percentage score ≤49%	0

[4] POCA search conducted on December 5, 2014.

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

Our analysis of the ninety-four (94) names contained in Table 1 determined none of the names would pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DOP2 via e-mail on January 19, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP2 on January 21, 2015, they stated no additional concerns with the proposed proprietary name, Portrazza.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0982.

3.1 COMMENTS TO THE APPLICANT

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

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [5]

[5] 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 do 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o 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.

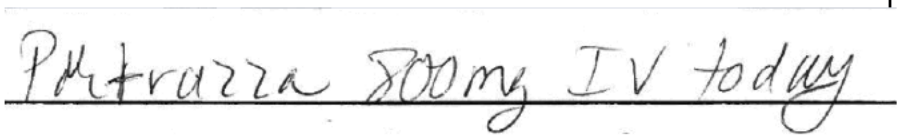
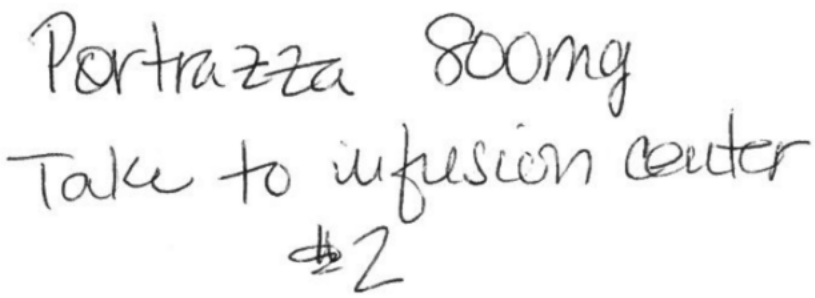
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Portrazza Study (Conducted on 12/12/2014)

Handwritten Requisition Medication Order	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Portrazza 800 mg. Take to infusion center. Dispense #2.

Study Name: Portrazza
As of Date 12/30/2014

253 People Received Study
99 People Responded

Study Name: Portrazza

Total	33	36	30	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
FORTRAVA	0	1	0	1
PATRAVA 800MG	0	1	0	1
PERTRAZZA	1	0	0	1
PIRTRAZZA	0	0	1	1
PORTAZZA	1	0	0	1
PORTRABA	0	1	0	1
PORTRAVA	0	4	0	4
(b) (4)	0	23	0	23
(b) (4)	0	1	0	1
PORTRAZYL	0	1	0	1
PORTRAZZA	31	1	24	56
PORTRUZZA	0	0	4	4
PRITRUZZA	0	0	1	1
PROTRASA	0	1	0	1
PROTRAVA	0	1	0	1
(b) (4)	0	1	0	1

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

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b)(4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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.	Portrazza ***	100	Name is the subject of this review.

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.	Proposed Name	POCA Score (%)
1.	AFREZZA	50
2.	CONTRAVE	54
3.	CORTALO	52
4.	Cortastat	52
5.	Cortastat 10	52
6.	CORTEF	50
7.	Cortizone-10	50
8.	Cortizone-5	50
9.	CORTRIL	60
10.	DAYTRANA	56
11.	Mitrazol	50
12.	NORTHERA	54
13.	Nortrel	56
14.	NORTREL 0.5/35-21	56
15.	NORTREL 0.5/35-28	56
16.	NORTREL 1/35-21	56
17.	NORTREL 1/35-28	56
18.	NORTREL 7/7/7	56
19.	PARAGARD T 380A	50
20.	PARCOPA	54
21.	Pardryl	54
22.	Pedtrace-4	52
23.	Pentrax	54

No.	Proposed Name	POCA Score (%)
24.	Peroxin A	50
25.	Peroxin A 10	50
26.	PERTZYE	52
27.	Polar Freeze	50
28.	Polytracin	55
29.	POLYTRIM	54
30.	Pretz Nasal	50
31.	PROGRAF	52
32.	Purgasol	50
33.	Purklenz	54
34.	Ultrasal	53
35.	ZORTRESS	58

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:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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.	CORTAN	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Portrazza contains an extra syllable.
2.	CORTROSYN	55	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
3.	Foltrate	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different, and Portrazza contains an extra syllable.
4.	FORTAZ	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Portrazza contains an extra syllable.
5.	FORTESTA	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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**
6.	(b) (4) ***	58	(b) (4)
7.	PENTASA	56	The suffixes of this name pair have sufficient orthographic differences. None of the syllables of this name pair sound similar. Pentasa (Mesalamine) capsules are available in multiple non-overlapping strengths (250 mg and 500 mg), thus reduce the risk for name confusion.
8.	PERCODAN	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
9.	PERJETA	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
10.	Pertussin	52	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Pertussin (root name alone) is not a drug product. Drugs are marketed under the name Pertussin ES, Pertussin PM, Pertussin DM (deactivated per Redbook), and Pertussin CS (deactivated per Redbook).

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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**
11.	pertuzumab	52	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different and pertuzumab contains an extra syllable.
12.	Photrexa ***	60	The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
13.	PIMTREA	54	The suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
14.	Polycitra	50	The infixes and suffixes of this name pair have sufficient orthographic differences. None of the syllables of this name pair sound similar and Polycitra has four syllables.

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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**
			(b) (4)
16.	PORTALAC	66	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
17.	PORTIA-21	66	Excluding the modifier, the suffixes of this name pair have sufficient orthographic differences. Excluding the modifier, the second syllables of this name pair sound different and Portrazza has an extra syllable.

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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**
18.	PORTIA-28	66	Excluding the modifier, the suffixes of this name pair have sufficient orthographic differences. Excluding the modifier, the second syllables of this name pair sound different and Portrazza has an extra syllable.
19.	Potaba	58	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
20.	POTIGA	54	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	Proprinal	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
22.	PURIXAN	51	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
23.	Titralac	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

No.	**Proposed name:** Portrazza (necitumumab) **Strength:** 800 mg/50mL (16 mg/mL) vials **Usual Dose:** 800 mg via intravenous infusion over (b) (4) minutes on Day 1 and Day 8 of a 3 week cycle.	**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**
24.	Uptravi ***	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Not applicable.	

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.	CERTRAID ***	56	Both Certraid*** and Certriad *** reference NDA (b) (4). Certraid *** was most likely misspelled in AIMS as Certraid (see below for more details on Certriad ***). The proprietary name review request for NDA (b) (4) lists name as Certriad ***.
2.	Certriad ***	58	Proposed Proprietary Name found acceptable by DMEPA (OSE# 2009-2406). However, the Applicant withdrew the entire application (NDA (b) (4)) on 03/07/2011.
3.	(b) (4) ***	67	Proposed Proprietary Name found unacceptable by DMEPA (OSE 2013-1317). Alternative name, (b) (4) *** found conditionally acceptable. However, the Applicant withdrew NDA (b) (4) on 12/03/2014.

No.	Name	POCA Score (%)	Failure preventions
4.	(b) (4) ***	64	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in commonly used drug databases.
5.	(b) (4) ***	80	Proposed Proprietary Name withdrawn by the Applicant (Panorama # 2014-16943). Alternative name, (b) (4) ***, found conditionally acceptable (Panorama # 2014-17328)
6.	(b) (4) ***	68	Name identified in Names Entered by Safety Evaluator database Unable to find product characteristics in commonly used drug databases.
7.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2014-16850). The proposed name, (b) (4) *** was found conditionally acceptable. However, the application received a Complete Response on 11/26/2014.
8.	(b) (4) ***	51	The Applicant withdrew the name.

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

No.	Name	POCA Score (%)
1.	Aspir-trin	50
2.	Atreza	54
3.	Bosatria ***	52
4.	Certiva	54
5.	Chlor-Tan A 12	52
6.	CLORPRES	50
7.	CORDRAN	58
8.	CORDRAN-N	56
9.	Cordron-12 D	50
10.	Cordron-D	50
11.	Durlaza ***	58
12.	Formalaz	51
13.	Forma-Ray	51
14.	KEYTRUDA	50
15.	Milprosa ***	50
16.	Norprolac	51

No.	Name	POCA Score (%)
17.	Nostrilla	56
18.	(b) (4) ***	60
19.	SUPRENZA	53
20.	TARCEVA	53
21.	Testro-L.A.	54
22.	(b) (4) ***	59
23.	(b) (4) ***	56
24.	Tudorza ***	50
25.	ULTRESA	52
26.	Zorblisa ***	51

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/s/

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01/28/2015

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