

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761073Orig1s000

PROPRIETARY NAME REVIEW(S)

**MEMORANDUM
NONPROPRIETARY NAME SUFFIX**

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

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

Date of This Review:	April 4, 2019
Requesting Office or Division:	Division of Oncology Products 1 (DOP1)
Application Type and Number:	BLA 761073
Product Name and Strength:	Kanjinti (trastuzumab-anns) for Injection, 420 mg/vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Amgen, Inc.
OSE RCM #:	2017-1513-1
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum is to reassess the proposed four letter suffix, -anns, for BLA 761073, which was found conditionally acceptable on January 30, 2018^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761073.

2 REGULATORY HISTORY

On July 28, 2017, Amgen submitted a list of three suffixes, in their order of preference, to be used in the nonproprietary name of their product^b. However, we identified preliminary concerns with the repeated use of same letter strings across multiple Amgen products because it would create an implied meaning of “Amgen” for all products with such similar suffixes^c. Thus, Amgen submitted four alternative suffixes, in their order of preference, to be used in the nonproprietary name of their product on October 30, 2017^d.

FDA found Amgen’s four-letter suffix, -anns, conditionally acceptable for BLA 761073 on January 30, 2018^a. However, BLA 761073 received a Complete Response (CR) letter on May 25, 2018^e. Thus, Amgen submitted a Class 2 Resubmission on December 28, 2018, including a request for nonproprietary name review. We note that Amgen resubmitted the same list of suffixes as in the submission from October 30, 2017.

3 ASSESSMENT OF THE NONPROPRIETARY NAME

trastuzumab-anns

We reassessed the proposed four-letter suffix, -anns, using the principles described in the applicable guidance^f.

We determined that the proposed suffix -anns, 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.

4 COMMUNICATION OF DMEPA’S ANALYSIS

These findings were shared with OPDP. In email correspondence dated April 2, 2019, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on April 4, 2019.

5 CONCLUSION

We find the suffix -anns acceptable. Should the 351(k) BLA be approved during this review cycle, trastuzumab-anns will be the proper name designated in the license.

^a Gao, T. Nonproprietary Name Suffix Memorandum for trastuzumab-anns (BLA 761073). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 30 JAN 2018. RCM No.: 2017-1513.

^b Amgen. Request for Nonproprietary Name Review. 2017 July 28. Available at <\\cdsesub1\evsprod\bla761073\0001\m1\us\request-for-nonproprietary-name-review.pdf>

^c Fahnbulleh, F. Personal Communication: BLA 761073 ABP 980. Silver Spring (MD): FDA, CDER, OSE, PMS (US); 2017 Aug 15. BLA 761073.

^d Amgen. Response to FDA Request for Information: Proposed alternative suffixes for nonproprietary naming and manufacturing schedule. 2017 Oct 30. Available at

<\\cdsesub1\evsprod\bla761073\0009\m1\us\cover-letter.pdf>

^e Amiri-Kordestani, L. Complete Response Letter for BLA 761073. Silver Spring (MD); FDA, CDER, OHOP, DOP1 (US) 2018 MAY 25.

^f 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>

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
04/04/2019 12:07:32 PM

DANIELLE M HARRIS
04/04/2019 04:58:30 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:	February 7, 2019
Application Type and Number:	BLA 761073
Product Name and Strength:	Kanjinti (trastuzumab-anns) for injection, 420 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Amgen Inc. (Amgen)
Panorama #:	2018-28372511
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1	INTRODUCTION	1
1.1	Regulatory History	1
1.2	Product Information	1
2	RESULTS.....	2
2.1	Misbranding Assessment	2
2.2	Safety Assessment.....	2
3	CONCLUSION	4
3.1	Comments to the Applicant/Sponsor	4
4	REFERENCES	5
	APPENDICES	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Kanjinti, 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. Amgen submitted an external name study, conducted by (b) (4) for this proposed proprietary name.^a

1.1 REGULATORY HISTORY

Amgen previously submitted the proposed proprietary name, Kanjinti*** on September 9, 2016 under IND 115424, and on July 28, 2017 under BLA 761073. We found the name, Kanjinti*** conditionally acceptable under both IND 115424^b and BLA 761073^c.

However, BLA 761073 received a Complete Response letter on May 25, 2018 due to issues with facility inspections.^d

Thus, Amgen submitted the name, Kanjinti, for review on December 28, 2018, as part of resubmission that includes a complete response to the Agency's Complete Response letter on December 28, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 28, 2018^e, and amendment received on February 6, 2019.^f

- Intended Pronunciation: kan jin' tee
- Active Ingredient: trastuzumab-anns
- Indication of Use: breast cancer
- Route of Administration: intravenous
- Dosage Form: for injection
- Strength: 420 mg/vial

^a The names identified in the (b) (4) External Name Study were evaluated under IND 115424 in Gao, T. Proprietary Name Review for Kanjinti (IND 115424). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JAN 9. Panorama No. 2016-10132437.

^b Gao, T. Proprietary Name Review for Kanjinti (IND 115424). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JAN 9. Panorama No. 2016-10132437

^c Gao, T. Proprietary Name Review for Kanjinti (BLA 761073). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Sept 21. Panorama No. 2017-16683741.

^d Amiri-Kordestani, L. Complete Response for BLA 761073. Silver Spring (MD): FDA, CDER, OND, DOP1 (US); 2018 MAY 25. BLA 761073.

^e ABP 980 (biosimilar candidate to Herceptin) PIND 115424 (SN. 0012) Request for Proprietary Name Review. Thousand Oaks (CA): Amgen Inc. 2018 Dec 28. Available from:
<\\cdsesub1\evsprod\bla761073\0037\m1\us\request-for-proprietary-name-review-kanjinti.pdf>.

^f ABP 980 (biosimilar candidate to Herceptin®) BLA 761073 (SN. 0041) Request for Proprietary Name Review. Thousand Oaks (CA): Amgen Inc. 2019 Feb 6. Available from:
<\\cdsesub1\evsprod\bla761073\0041\m1\us\proprietary-name-review-kanjinti.pdf>.

- Dose and Frequency:
 - Adjuvant Treatment of HER2-Overexpressing Breast Cancer
 - Initial dose of 4 mg/kg over 90 minute intravenous infusion, then 2 mg/kg over 30 minute intravenous infusion weekly for 52 weeks
 - Metastatic HER2-Overexpressing Breast Cancer
 - Initial dose of 4 mg/kg as a 90 minute intravenous infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute intravenous infusions.
- How Supplied: Each carton contains one vial of Kanjinti.
- Storage: Store Kanjinti vials in the original carton to protect from light in the refrigerator at 2°C to 8°C (36°F to 46°F) until time of reconstitution.
- Reference Product: Herceptin, BLA 103792

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Kanjinti would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment for Kanjinti.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^g.

2.2.2 *Components of the Proposed Proprietary Name*

Amgen did not provide a derivation or intended meaning for the proposed proprietary name, Kanjinti, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, January 15, 2019 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to Kanjinti at the initial phase of the review.

^g USAN stem search conducted on January 4, 2019.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^h identified 75 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name reviews. 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 the usual dose was changed from "2 mg/kg to 8 mg/kg" to "2 mg/kg to 4 mg/kg" and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 1 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 $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	1
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 1 name contained in Table 1 determined none of the names will pose a risk for confusion with Kanjinti 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 Oncology Products 1 (DOP1) via e-mail on February 1, 2019. At that time we also requested additional information or concerns that

^h POCA search conducted on January 4, 2019 in version 4.3.

could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on February 7, 2019, they stated no additional concerns with the proposed proprietary name, Kanjinti.

3 CONCLUSION

The proposed proprietary name, Kanjinti, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO AMGEN INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 28, 2018, and your amendment received on February 6, 2019, 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.ⁱ

ⁱ 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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^j. 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

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

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 $\geq 70\%$).

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as 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 $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

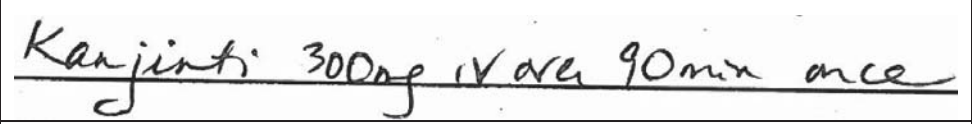
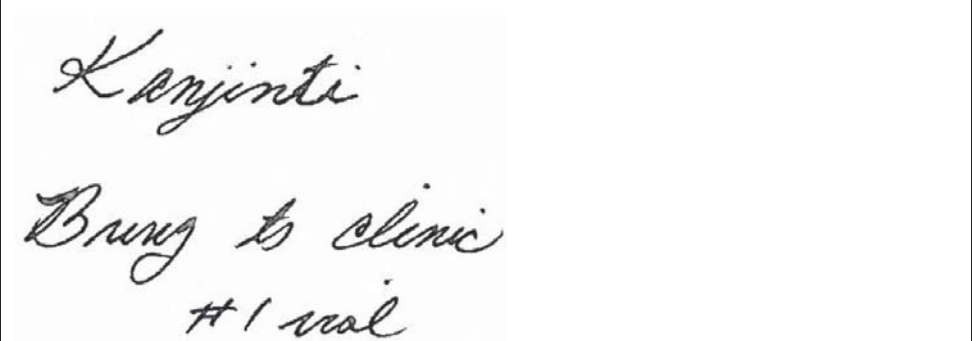
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 $\leq 54\%$).

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. Kanjinti Study (Conducted on January 11, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Kanjinti Bring to clinic Dispense one vial
<u>Outpatient Prescription:</u> 	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Kanjinti

As of Date 1/23/2019

304 People Received Study

95 People Responded

Total	55	14	26	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CANGENTI	0	3	0	3
CANGENTY	0	4	0	4
CANGENTY VIAL	0	1	0	1
CANGET	0	1	0	1
CANGINTEE	0	1	0	1
CANGINTI	0	1	0	1
CANJINTI	0	1	0	1
KAMJINITE	1	0	0	1
KANGENTI	0	1	0	1
KANIJINTI	2	0	0	2
KANIJNTI	2	0	0	2
KANINJINTI	1	0	0	1
KANJENTI	0	1	0	1
KANJINTA	2	0	0	2
KANJINTI	42	0	24	66
KANJITI	0	0	1	1
KANZINTE	1	0	0	1
KARJINTI	0	0	1	1
KARYINTI	1	0	0	1
KAZINTI	1	0	0	1
KENJINTI	1	0	0	1
KINJANTI	1	0	0	1

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

No.	Proposed name: Kanjinti Established name: trastuzumab-anns Dosage form: for injection Strength(s): 420 mg/vial Usual Dose: 2 mg/kg to 4 mg/kg intravenous infusion (frequency varies depending on the indication)	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.
	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
	N/A	

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Kanjinti Established name: trastuzumab-anns Dosage form: for injection Strength(s): 420 mg/vial Usual Dose: 2 mg/kg to 4 mg/kg intravenous infusion (frequency varies depending on the indication)	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.	Consensi	61	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
	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		

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

No.	Name	POCA Score (%)
	N/A	

^k 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

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/

TINGTING N GAO
02/07/2019 12:53:09 PM

CHI-MING TU
02/07/2019 01:22:25 PM

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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 30, 2018
Requesting Office or Division:	Division of Oncology Products 1 (DOP1)
Application Type and Number:	BLA 761073
Product Name and Strength:	Kanjinti (trastuzumab-anns) for Injection, 420 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Amgen, Inc
Panorama #:	2017-1261
DMEPA Primary Reviewer:	Tingting Gao, PharmD
OMEPRM:	Kellie Taylor, PharmD, MPH

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761073.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On July 28, 2017, Amgen submitted a list of three suffixes, in their order of preference, to be used in the nonproprietary name of their product.^a However, we identified preliminary concerns with the repeated use of same letter strings across multiple Amgen products because it would create an implied meaning of “Amgen” for all products with such similar suffixes.^b Thus, Amgen submitted four alternative suffixes, their order of preference, to be used in the nonproprietary name of their product on October 30, 2017.^c

We reviewed the proposed suffixes in the order of preference listed by Amgen against the principles described in the applicable guidance.^d

2.1 Trastuzumab-anns

Amgen’s first proposed suffix, -anns, is composed of the first and last letters of the company name (**Amgen**). Although these letters overlap, the letter, s, is not common to the Amgen company name. Given that the proposed suffix includes distinct letter in the fourth position, we find this suffix does not readily connote the company name.

We also determined that -anns 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, and does not make any misrepresentations with respect to safety or efficacy of this product. Therefore, we find the proposed suffix -anns acceptable for this product.

These findings were shared with the TBBS, ORP, and OPDP. In email correspondence dated January 30, 2018, the workgroup concurred with DMEPA’s assessment and conclusion.

3 CONCLUSION

We find the suffix –anns acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to trastuzumab-anns.

^a Amgen. Request for Nonproprietary Name Review. 2017 July 28. Available at <\\cdsesub1\evsprod\bla761073\0001\m1\us\request-for-nonproprietary-name-review.pdf>.

^b Fahnbulleh, F. Personal Communication: BLA 761073 ABP 980. Silver Spring (MD): FDA, CDER, OSE, PMS (US); 2017 Aug 15. BLA 761073.

^c Amgen. Response to FDA Request for Information: Proposed alternative suffixes for nonproprietary naming and manufacturing schedule. 2017 Oct 30. Available at <\\cdsesub1\evsprod\bla761073\0009\m1\us\cover-letter.pdf>

^d See Section VI in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

4 COMMENTS TO THE APPLICANT

We find the nonproprietary name, trastuzumab-anns, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, trastuzumab-anns will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. 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 proposal unacceptable upon our re-evaluation, we would inform you of our finding.

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

/s/

TINGTING N GAO
01/31/2018

KELLIE A TAYLOR
02/02/2018

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:	September 21, 2017
Application Type and Number:	BLA 761073
Product Name and Strength:	Kanjinti (trastuzumab-xxxx) ^a for Injection, 420 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Amgen
Panorama #:	2017-16683741
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

^a Kanjinti has been developed as a proposed biosimilar to US-licensed Herceptin (Trastuzumab). Since the proper name for Kanjinti has not yet been determined, “trastuzumab-xxxx” is used throughout this review as the proper name for this product.

Contents

1	INTRODUCTION.....	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2	RESULTS.....	2
2.1	Misbranding Assessment.....	2
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	4
4	REFERENCES.....	5
	APPENDICES.....	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Kanjinti, 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) for this product.^b

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Kanjinti on September 9, 2016 under IND 115424. The Division of Medication Error Prevention and Analysis (DMEPA) found the name conditionally acceptable and requested the request for proprietary name review be re-submitted once the BLA is submitted.^c

Thus, the Applicant submitted the name, Kanjinti, for review on July 28, 2017 under BLA 761073.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 28, 2017 proprietary name submission.

- Intended Pronunciation: kan jin' tee
- Active Ingredient: trastuzumab-xxxx
- Indication of Use: Breast cancer, Gastric cancer
- Route of Administration: intravenous
- Dosage Form: For injection
- Strength: 420 mg/vial
- Dose and Frequency:
 - Adjuvant Treatment of HER2-Overexpressing Breast Cancer
 - Administer at either: Initial dose of 4 mg/kg over 90 minute intravenous infusion, then 2 mg/kg over 30 minute intravenous infusion weekly for 52 weeks, or
 - Initial dose of 8 mg/kg over 90 minutes intravenous infusion, then 6 mg/kg over 30–90 minutes intravenous infusion every three weeks for 52 weeks.
 - Metastatic HER2-Overexpressing Breast Cancer

^b The names identified in the (b) (6) External Name Study were evaluated under IND 115424 in Gao, T. Proprietary Name Review for Kanjinti (IND 115424). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JAN 9. Panorama No. 2016-10132437.

^c Gao, T. Proprietary Name Review for Kanjinti (IND 115424). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 JAN 9. Panorama No. 2016-10132437.

- Initial dose of 4 mg/kg as a 90 minute intravenous infusion followed by subsequent weekly doses of 2 mg/kg as 30 minute intravenous infusions.
- Metastatic HER2-Overexpressing Gastric Cancer
 - Initial dose of 8 mg/kg over 90 minutes intravenous infusion, followed by 6 mg/kg over 30 to 90 minutes intravenous infusion every 3 weeks.
- How Supplied: Each carton contains one multiple-dose vial of [ABP-TRADENAME] (b) (4)
- Storage: 2°C to 8°C (36°F to 46°F)
- Container and Closure Systems: The primary container closure system for the 420 mg presentation consists of a 50 cc (b) (4) glass vial with a 20 mm (b) (4) stopper and an aluminum seal with flip-off dust cover.
- Reference Product: US-licensed Herceptin (Trastuzumab), BLA 103792

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 Product 1 (DOP1) 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^d.

2.2.2 Components of the Proposed Proprietary Name

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

^d USAN stem search conducted on August 11, 2017.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 23, 2017 e-mail, the Division of Oncology Product 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We had identified and evaluated 81 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 and the change in strength (440 mg/vial to 420 mg/vial), which may have altered our previous conclusion regarding the acceptability of the name. Our re-evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Our current POCA search^e identified 74 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. Because some of the names of concern identified in the current POCA search overlapped with the 81 names identified in our previous name review, our current POCA search identified 7 new names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Kanjinti will be available in 420 mg/vial strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

^e POCA search conducted on August 11, 2017 in version 4.1.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	5

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

Our analysis of the 7 names contained in Table 1 determined 7 names will not pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on September 12, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on September 21, 2017, they stated no additional concerns with the proposed proprietary name, Kanjinti.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 28, 2017 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 support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^f

^f 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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^g. 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.,

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

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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

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

- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator 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 $\geq 70\%$).

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 $\geq 55\%$ to $\leq 69\%$).

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
--------	--

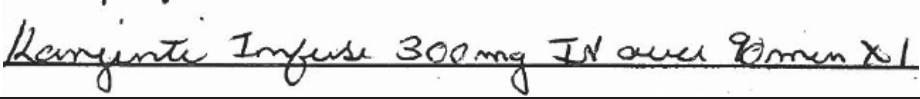
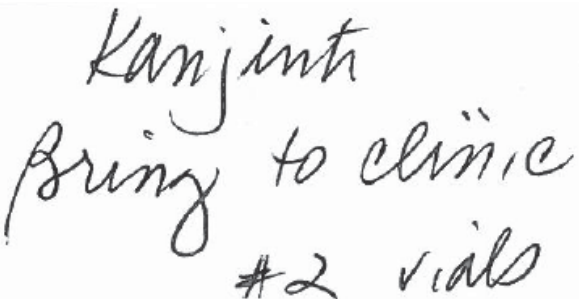
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.		
	<table border="1"> <tr> <td data-bbox="284 367 868 1281"> 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 data-bbox="868 367 1344 1281"> 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>	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?
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 $\leq 54\%$).

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. Kanjinti Study (Conducted on August 18, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Kanjinti Bring to clinic Dispense two vials
<u>Outpatient Prescription:</u> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Kanjinti

291 People Received Study

80 People Responded

Total	28	28	24	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CANGENTE	0	2	0	2
CANGENTEE	0	2	0	2
CANGENTI	0	8	0	8
CANGENTY	0	4	0	4
CANGINTI	0	1	0	1
CANGINTY	0	2	0	2
CANJENTEE	0	1	0	1
CANJENTI	0	3	0	3
CANJENTY	0	2	0	2
CANJINTEE	0	1	0	1
DANYINTE INFUSE	0	0	1	1
GANGENTI	0	1	0	1
GIENZITI	0	1	0	1
KAMJINTH	2	0	0	2
KANGINTI	0	0	2	2
KANJENTIC	0	0	1	1
KANJINITI	1	0	0	1
KANJINTA	1	0	0	1
KANJINTC	0	0	1	1
KANJINTE	0	0	1	1
KANJINTH	2	0	0	2
KANJINTI	17	0	7	24
KANJINTI INFUSE	0	0	2	2
KANJINTI INFUSION	0	0	1	1
KANJINTIC	0	0	1	1
KANJINTR	5	0	0	5
KANJUNTI	0	0	1	1
KANYINITI	0	0	1	1
KANZINTIC	0	0	1	1
KARJINTI INFUSE	0	0	1	1
KARNYINTE INFUSE	0	0	1	1
KEMJINTI	0	0	1	1
RENJINTE	0	0	1	1

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

No.	Proposed name: Kanjinti Established name: Trastuzumab-xxxx Dosage form: For Injection Strength(s): 420 mg/vial Usual Dose: 2 mg/kg to 8 mg/kg intravenous infusion (frequency varies depending on the indication)	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.	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

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

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Kanjinti Established name: Trastuzumab-xxxx Dosage form: For Injection Strength(s): 420 mg/vial Usual Dose: 2 mg/kg to 8 mg/kg intravenous infusion (frequency varies depending on the indication)	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
3.	N/A		

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

No.	Name	POCA Score (%)
4.	Ak-Taine	42
5.	Jinteli	54
6.	Kainair	52
7.	Kao-Tin	53
8.	Tandem F	54

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
9.	N/A		

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

No.	Name	POCA Score (%)
10.	Gamifant***	61
11.	(b) (6)***	55

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

No.	Name
1.	Cardizem LA
2.	Diltiazem Hydrochloride
3.	MIRALAC
4.	PhysiciansCare Antacid
5.	TIAZAC

^h 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

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

/s/

TINGTING N GAO
09/21/2017

CHI-MING TU
09/21/2017