

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761074Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	July 19, 2017
Application Type and Number:	BLA 761074
Product Name and Strength:	Ogivri (trastuzumab-dkst) for Injection, 420 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Mylan
Panorama #:	2016-11135635-1
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ogivri, since the strength is revised from 440 mg/vial to 420 mg/vial based on recommendation from Office of Pharmaceutical Quality (OPQ). The proposed proprietary name, Ogivri, was found acceptable under BLA 761074 on December 9, 2016.^a

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in strength. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 18, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that 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.

^a Gao, T. Proprietary Name Review for Ogivri. 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); 2016 DEC 9. Panorama No. 2016-10316992 and 2016-11135635.

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.

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/s/

TINGTING N GAO
07/19/2017

CHI-MING TU
07/19/2017

**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)

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Date of This Review:	June 30, 2017
Requesting Office or Division:	Division of Oncology Products 1 (DOP1)
Application Type and Number:	BLA 761074
Product Name and Strength:	Ogivri (trastuzumab-dkst) for Injection, 420 mg/vial
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Mylan
Panorama #:	2017-1078
DMEPA Primary Reviewer:	Tingting Gao, PharmD
OMEPRM Deputy Director (Acting):	Lubna Merchant, MS, PharmD

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 761074.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

FDA has determined that the use of a distinguishing suffix in the nonproprietary name for Mylan's Ogivri product is necessary to distinguish this proposed product from Herceptin (trastuzumab). As explained in FDA's Guidance for Industry, Nonproprietary Naming of Biological Products, FDA expects that a nonproprietary name for Ogivri include a distinguishing suffix that will facilitate safe use and optimal pharmacovigilance.

On May 17, 2017, Mylan requested the Agency^a designate an FDA-generated a four-letter suffix to be used in the nonproprietary name of their product in response to Agency's Information Request.^b

1. trastuzumab-dkst

FDA generated a four letter suffix, "-dkst". This suffix was evaluated the suffix against the criteria described in the guidance^c.

We determined that the FDA-generated suffix "-dkst", 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.

These findings were shared with the TBBS, ORP, OCC and OPDP. In email correspondence dated June 30, 2017, the workgroup concurred with DMEPA's assessment and conclusion.

3 CONCLUSION

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

3.1 RECOMMENDATIONS FOR MYLAN

1. We find the nonproprietary name, trastuzumab-dkst, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, trastuzumab-dkst 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 the proposed suffix will be

^a Militzer, B. "IMPT: Mylan's BLA 761074 – Suffix." Message to Frances Fahnbulleh. 17 May 2017. E-mail.

^b Merchant, L. Information Request for BLA 761074. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 APR 3.

^c 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>

re-evaluated when you respond to the deficiencies. If we find the proposal unacceptable upon our re-evaluation, we would inform you of our finding.

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/s/

TINGTING N GAO
06/30/2017

LUBNA A MERCHANT
07/10/2017

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)

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Date of This Review:	December 9, 2016
Application Type and Number:	IND 113682 and BLA 761074
Product Name and Strength:	Ogivri (trastuzumab-xxxx) for Injection, 440 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Mylan
Panorama #:	2016-10316992 and 2016-11135635
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Ogivri, 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 [REDACTED]^{(b) (4)}, for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the September 22, 2016 (IND) and November 3, 2016 (NDA) proprietary name submissions.

- Intended Pronunciation: Oh-Give-ree
- Active Ingredient: trastuzumab-xxxx (no nonproprietary name has been submitted for review)
- Indication of Use:
 - adjuvant treatment of HER2 overexpressing node positive or node negative breast cancer
 - treatment of HER2-overexpressing metastatic breast cancer
 - the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma
- Route of Administration: intravenous
- Dosage Form: lyophilized powder for injection
- Strength: 440 mg/vial
- Dose and Frequency:
 - initial dose of 4 mg/kg as a 90-minute IV infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute IV infusions until disease progression
 - 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 during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). One week following the last weekly dose of Ogivri, administer Ogivri at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks
 - 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
 - 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 until disease progression.

- 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 until disease progression.
- How Supplied: Ogivri is supplied in a multi-use vial containing 440 mg trastuzumab lyophilized powder. Each carton will contain 1 vial of Ogivri and 1 vial (20 mL) of Bacteriostatic Water for Injection, USP, containing 1.1% benzyl alcohol as a preservative.
- Storage: 2°C to 8°C (36°F to 46°F) prior to reconstitution
- Container and Closure Systems: multi-use vial

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 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^a.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Ogivri 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 *FDA Name Simulation Studies*

Ninety-eight 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. In the written studies, 11 of 67 participants correctly interpreted the proposed name as "Ogivri". Common misinterpretations in the written study include "Ogivi", "Ogivii", "Ogivu", and "Ogivir". In the voice study, 4 of 31 participants correctly interpreted the proposed name as "Ogivri". Common misinterpretations in

^a USAN stem search conducted on November 4, 2016.

the voice study include “Ogivry”. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 6, 2016 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 55\%$ retrieved from our POCA search^b organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4).

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	2
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	35
Low similarity name pair: combined match percentage score $\leq 54\%$	3

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Ogivri will be available in strength of 440 mg/vial. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Ogivri that were not identified in POCA.

Table 1A. eDRLS Search Results^c	POCA Score (%)
N/A	

^b POCA search conducted on November 2, 2016 in version 4.0.

^c eDRLS search conducted on November 4, 2016.

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

Our analysis of the 40 names contained in Table 1 determined 40 names will not pose a risk for confusion as described in Appendices C through I.

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 December 1, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on December 7, 2016, they stated no additional concerns with the proposed proprietary name, Ogivri.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 22, 2016 and November 3, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.^d

^d 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 $\geq 70\%$.
 - 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 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 $\geq 70\%$).

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 <i>z</i> and <i>f</i>), 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 <i>z</i> and <i>f</i>), 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 as 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 $\leq 54\%$).

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. Ogivri Study (Conducted on October 6, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Ogivri 300 mg Infuse IV over 90	Ogivri Bring to clinic Dispense one vial
Outpatient Prescription: Ogivri Bring to Clinic #1 vial	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Ogivri

As of Date 11/4/2016

316 People Received Study

98 People Responded

Total	39	31	28	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
OCIVRY	0	1	0	1
OGAVRE	0	1	0	1
OGBRIN	0	1	0	1
OGEVRI	0	1	0	1
OGIBRY	0	1	0	1
OGIVCA	0	0	1	1
OGIVEA	0	0	1	1
OGIVEE	0	0	1	1
OGIVEI	2	0	1	3
OGIVERA	0	1	0	1
OGIVERE	0	1	0	1
OGIVERY	0	1	0	1
OGIVI	8	0	0	8
OGIVII	6	0	0	6
OGIVII?	0	0	1	1
OGIVIR	0	0	7	7
OGIVRE	0	2	0	2
OGIVREE	0	1	0	1
OGIVRI	9	4	2	15
OGIVRS	0	0	1	1
OGIVRY	0	14	0	14
OGIVU	12	0	11	23
OGRIVI	1	0	0	1
OGWU	0	0	1	1
OGYVRI	0	1	0	1
OLGIVERY	0	1	0	1
OQWII	0	0	1	1
ORGIVII	1	0	0	1

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

No.	Proposed name: Ogivri Established name: trastuzumab Dosage form: for injection Strength(s): 440 mg/vial Usual Dose: 2 mg/kg to 4 mg/kg	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.	Gocovri***	74	Orthographic difference: The name pair begins with different letters (O vs. G). Ogivri has a downstroke letter on the second position which is absent in Gocovri***. Gocovri has the letter string “co” in the 3rd and 4th positions of the name which gives the name an longer shape than Ogivri (narrow “i” in the 3rd position) when scripted. Phonetic difference: The first syllable “Oh” and the second syllable “give” in Ogivri sounds different from the first syllable “Goh” and second syllable “KUV” in Gocovri. Product characteristics differences: Ogivri is given intravenously whereas Gocovri*** is given orally.
2.	Ogivri	100	Name is the subject of this review.

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 (%)
1.	Ocu-Phrin	56
2.	Optivar	61
3.	Oravig	56
4.	Otrivin	56
5.	Pedi-Dri	58

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: Ogivri Established name: trastuzumab Dosage form: for injection Strength(s): 440 mg/vial Usual Dose: 2 mg/kg to 4 mg/kg	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.	Obizur	59	Ogivri has a downstroke letter “g” in the second position, and Obizur has an upperstroke letter “b” in the second position. The second and third syllables of this name pair sound different.
2.	Oby-Trim	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
3.	Omidria	64	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
4.	Otiprio	66	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
5.	Ovidrel	66	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
6.	Nudovra***	59	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Ogen	42
2.	Ornigrein	50
3.	Oseltamivir	36

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.	(b) (4)***	56	(b) (4)
2.	(b) (4)***	64	Proposed proprietary name for ANDA 076681 found unacceptable by DMEPA (OSE# 2011-1221 and 2011-1222). ANDA 076681 was approved under the name Kimidess.

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

No.	Name	POCA Score (%)
1.	Auro-Dri	55
2.	Combivir	56
3.	Dovaril	60
4.	Epidri	58
5.	Epivir	56
6.	(b) (4)***	58
7.	Gonitro	59
8.	Ilevro	62
9.	(b) (4)***	59
10.	(b) (4)***	59
11.	Lofibra	58
12.	Trivora	57
13.	Trivora-21	57
14.	Trivora-28	57

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No.	Name	POCA Score (%)
15.	Uniprim	55
16.	Univer	58
17.	Vivarin	63
18.	(b) (4)***	58
19.	Xigris	56

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

No.	Name
1.	UREVAZ

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
12/09/2016

CHI-MING TU
12/09/2016