CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761060Orig1s000
761060Orig2s000

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:	August 10, 2017
Application Type and Number:	BLA 761060
Product Name and Strength:	Mylotarg (gemtuzumab ozogamicin) for injection 4.5 mg/vial
Total Product Strength:	1 mg/mL after reconstitution
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer, Inc.
Panorama #:	2017-16657506-1 and 2017-16657510-1
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Mylotarg, based on the revised strength. The proposed proprietary name, Mylotarg, was found acceptable in OSE review # 2014-45070 dated May 11, 2015[a] and OSE review # 2016-11204176 dated January 11, 2017[b]. The product strength was originally presented as 5 mg per vial. Based on the recommendation by the Office of Product Quality (OPQ), Pfizer, Inc. revised the strength of the product to more accurately represent the deliverable amount of product and extractable volume after reconstitution. The strength of Mylotarg is now 4.5 mg per vial.[c]

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously proprietary name review dated January 11, 2017 to assess whether the change in strength would alter our previous conclusion regarding the acceptability of the proposed proprietary name. We searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates[d]. Our search did not identify any USAN stems present in the proprietary name.

We evaluated the results of our previous POCA search in OSE review# 2016-11204176[e] to identify names with overlapping strength and/or dose with the new 4.5 mg strength. Our search did not identify any names with an overlap in strength and/or dose with the 4.5 mg strength.

Additionally, since Mylotarg is being proposed in a strength that is not commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Mylotarg that were not identified in POCA, and found to have an overlap in strength with Mylotarg[f]. Our search did not identify any new names with an overlap in strength and/or dose with the 4.5 mg strength.

Our USAN stem search, evaluation of previous POCA search results, and eDRLS search did not identify any new names that represent a potential source of drug name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

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[a] Rutledge M. Proprietary Name Review for Mylotarg (IND 046635). 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); 2015 May 11. 27 p. OSE RCM No.: 2014-45070.

[b] Rahimi L. Proprietary Name Review for Mylotarg (BLA 761060). 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); 2017 Jan 11. 20 p. OSE RCM No.: 2016-11204176.

[c] Office of Product Quality Type C Meeting Minutes. Silver Spring (MD): FDA, CDER, OND, DHP (US); 2017 May 6.

[d] USAN stem search conducted on August 2, 2017.

[e] POCA search conducted on November 18, 2016.

[f] eDRLS search conducted on August 1, 2017.

3 CONCLUSIONS

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 Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Mylotarg, 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.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

   Drugs@FDA

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

   RxNorm

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

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

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

   Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

   The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated

drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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

/s/

NICOLE B GARRISON
08/10/2017

HINA S MEHTA
08/14/2017

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:	11 January 2017
Application Type and Number:	BLA 761060
Product Name and Strength:	Mylotarg (gemtuzumab ozogamicin) Injection 5 mg per vial
Total Product Strength:	1 mg/mL after reconstitution
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer
Panorama #:	2016-11204176
DMEPA Primary Reviewer:	Leeza Rahimi, Pharm.D.
DMEPA Team Leader:	Hina Mehta, Pharm.D.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Mylotarg, 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 did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The proposed proprietary name, Mylotarg (gemtuzumab ozogamicin) was initially approved on 17 May 2000 in NDA 021174 as monotherapy for the treatment of patients 60 years of age or older with CD33-positive acute myeloid leukemia (AML) in first relapse who were not considered candidates for other cytotoxic chemotherapy. However, this product was withdrawn FR effective on 28 November 2011, 2011, after a post-approval clinical trial failed to verify clinical benefit.

The Applicant then re-submitted gemtuzumab ozogamicin under the proposed proprietary name, Mylotarg on 19 November, 2014 and an amendment to the name review request was submitted on 02 December, 2014 in IND 046635, for treatment of de novo acute myeloid leukemia in adult patients previously untreated with chemotherapy in combination with daunorubicin and cytarabine. DMEPA reviewed the proposed proprietary name and found it acceptable on 15 May 2015.

Currently, the Applicant submitted the application under BLA 761060 and requested a priority review. Thus, the Applicant submitted the name, Mylotarg, for review on 02 November 2016.

1.2 PRODUCT INFORMATION

The following product information is provided in the 02 November 2016 proprietary name submission.

- Intended Pronunciation: MY' loe-targ
- Active Ingredient: gemtuzumab ozogamicin
- Indication of Use: 1. In combination with daunorubicin and cytarabine, adult patients with previously untreated, de novo acute myeloid leukemia 2. the treatment of patients with AML in first relapse who were 60 years of age or older and who were not considered candidates for other cytotoxic chemotherapy.
- Route of Administration: Intravenous infusion
- Dosage Form: Lyophilized powder for intravenous injection
- Strength: 5 mg
- Dose and Frequency: Induction: The recommended dose of gemtuzumab ozogamicin is 3 mg/m^2 up to a maximum dose of 5 mg, infused over a 2 hour period on Days 1, 4, and 7 in combination with daunorubicin 60 $mg/^2m$/day infused over 30 minutes on Days 1, 2, and 3 and cytarabine 200 mg/m^2/day by continuous infusion on Days 1-7.

  Consolidation: For patients achieving complete response (CR), defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count (ANC) of more than

1.0×109 cells per L with a platelet count of 100×109 per L or more in the peripheral blood, 2 consolidation courses of intravenous daunorubicin (60 mg/m2 for 1 day [first course] or 2 days [second course]) in combination with intravenous cytarabine (1000 mg/m2 per 12 hours, infused over 2 hours on Days 1 through 4) with (b) (4) intravenous gemtuzumab ozogamicin (3 mg/m^2 up to a maximum dose of 5 mg on Day 1) are recommended.

(b) (4)

Monotherapy in AML first relapse: 9 mg/m^2 per dose for a total of 2 doses with 14 day between doses.

- How Supplied: Single-vial package with an amber glass vial containing 5 mg of Mylotarg lyophilized powder. Single-unit 5 mg package: each 20 mL vial contains 5 mg of gemtuzumab ozogamicin.
- Storage: *Prior to Reconstitution:* Gemtuzumab ozogamicin should be stored refrigerated 2° to 8° Celsius (36° to 46° F) and protected from light.

  After Reconstitution: See Table 1 below:

Table 1: Storage Condition and Time for Reconstitution, Dilution and Administration

The following time intervals for reconstitution, dilution, and administration should be followed for storage of the reconstituted solution:

Time Intervals Reconstitution	Dilution	Administration	Total Maximum Hours[a]
≤ 2 hours at refrigeration or at room Temperatur	≤16 hours at room temperature	2 hour infusion	20

[a]Total maximum time allowed for the storage of the reconstituted and diluted solutions and completion of infusion.

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 Hematology Products (DHP) 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, Mylotarg in their submission. This proprietary name is comprised of a single 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

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.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, 28 November 2016 e-mail, the Division of Hematology Products (DHP) 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

Our POCA search[b] identified 54 names with the combined score of ≥55%. We had identified and evaluated 69 names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, Table 1 lists the 9 names not previously analyzed with the combined orthographic and phonetic score of ≥55% retrieved from our POCA search organized as highly similar, moderately similar or low

[a] USAN stem search conducted on 18 November

[b] POCA search conducted on 18 November in version 4.0

similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	8
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 9 names contained in Table 1 determined none of the names pose a risk for confusion as described in Appendices C through H.

2.2.7 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving ***Mylotarg*** that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	29 November 2016
Drug Name	Mylotarg [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: MEDICATION ERROR PRODUCT NAME CONFUSION
Date Limits	23 April 2015 through 29 November 2016

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

Our search yielded *zero* cases.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on 05 January 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on 06 January 2017, they stated no additional concerns with the proposed proprietary name, Mylotarg.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Vora, Neil, OSE project manager, at 301-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your 02 November 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

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APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Mylotarg Study (Conducted on 23 November 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Mylotarg give 3mg/m² IV over 2hrs on days 1, 4, and 7	Mylotarg 5 mg intravenous infusion as directed #1
Outpatient Prescription: Mylotarg 5mg intravenous infusion as directed #1	

FDA Prescription Simulation Responses:

As of Date 12/5/2016

312 People Received Study
80 People Responded

Study Name: Mylotarg

Total	34	25	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
MILOTARG	0	2	0	2
MYCLOTARG	1	0	0	1
MYFOTARG	1	0	0	1
MYLATARG	2	0	1	3
MYLOTANG	0	0	4	4
MYLOTARG	21	20	12	53
MYLOTARG IV	0	1	0	1
MYLOTARK	0	1	0	1
MYLOTARQ	3	0	0	3
MYLOTARY	6	0	0	6
MYLOTARZ	0	0	3	3
MYLOTAUR	0	1	0	1
MYLOTAZE?	0	0	1	1

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

No.	**Proposed name:Mylotarg Established name: gemtuzumab ozogamicin Dosage form:Powder for injection Strength(s):5 mg Usual Dose:3 mg/m2 up to a maximum dose of 5 mg, infused over a 2 hour period on Days 1, 4, and 7 in combination with daunorubicin 60 mg/2m/day infused over 30 minutes on Days 1, 2, and 3 and cytarabine 200 mg/m2/day by continuous infusion on Days 1-7**	**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.	Mylotarg	100	Subject of the Study

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

No.	Name	POCA Score (%)
1.	Voltaren	56
2.	Voltarol	55

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

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	Glutaral	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Glutarol	60	International product marketed in United Kingdom and Ireland.

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

No.	Name	POCA Score (%)
1.	Glycort	55
2.	Gly-Cort	55
3.	Polycarb	56
4.	Sylatron	58

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/s/

LEEZA RAHIMI
01/13/2017

HINA S MEHTA
01/13/2017