

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761309Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	4/18/2023
Responsible OND Division:	Division of Hematologic Malignancies 2 (DHM 2)
Application Type and Number:	BLA 761309
Product Name and Strength:	Columvi (glofitamab-gxbm) injection 2.5 mg/2.5 mL and 10 mg/10 mL (1 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
FDA Received Date:	November 1, 2022
Nexus NPNS ID #:	2022-141
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Genentech for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761309.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 1, 2022, Genentech submitted a list of 3 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Genentech also provided their own evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration.

Table 1 presents a list of suffixes submitted by Genentech:

Table 1. Suffixes submitted by Genentech***	
1.	gxbm
2.	(b) (4)
3.	

We reviewed Genentech's proposed suffixes in the order of preference listed by Genentech, along with the supporting data they submitted, using the principles described in the applicable guidance.^b

2.1 glofitamab-gxbm

Genentech's first proposed suffix, -gxbm, is comprised of 4 distinct letters.

We determined that the proposed suffix -gxbm, 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.

^a Request for Comments and Advice (Request for Suffix Review) BLA 761309. San Francisco (CA): Genentech, Inc.; 2022 Nov 01. Available from: [\\CDSESUB1\EVSPROD\bla761309\0004\m1\us\comments-advice-req-suffix-review.pdf](#)

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

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On April 12, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) on April 18, 2023.

4 CONCLUSION

We find Genentech's proposed suffix -gxbm acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to glofitamab-gxbm. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Genentech, Inc.

We find the nonproprietary name, glofitamab-gxbm, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, glofitamab-gxbm will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. 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 suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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
04/18/2023 01:36:00 PM

CHI-MING TU
04/18/2023 02:05:27 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 2, 2023
Application Type and Number:	IND 138178 and BLA 761309
Product Name and Strength:	Columvi (glofitamab-xxxx*) Injection, 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genentech, Inc. (Genentech)
PNR ID #:	2022-1044724570 and 2022-1044724828
DMEPA 2 Safety Evaluator:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

* The proper name for Columvi has not yet been determined; therefore, “glofitamab-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.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment.....	2
3	CONCLUSION	5
3.1	Comments to the Applicant/Sponsor	5
4	REFERENCES	7
	APPENDICES	8

1 INTRODUCTION

This review evaluates the proposed proprietary name, Columvi, 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. Genentech submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 1, 2022.

- Intended Pronunciation: co-LUM-vee
- Nonproprietary Name: glofitamab-xxxx
- Indication of Use: For the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, (b) (4)
- Route of Administration: Intravenous infusion
- Dosage Form: Injection
- Strength: 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL)
- Dose and Frequency: 2.5 mg intravenously on Cycle 1 Day 8, 10 mg intravenously on Cycle 1 Day 15, and 30 mg intravenously on Day 1 of Cycle 2 to Cycle 12. Each treatment cycle is 21 days.
- How Supplied:

Carton Contents	NDC
One single-dose vial, 2.5 mg glofitamab-xxxx /2.5 mL (1 mg/mL)	NDC 50242-125-01
One single-dose vial, 10 mg glofitamab-xxxx /10 mL (1 mg/mL)	NDC 50242-127-01

- Storage: Store refrigerated at 36°F to 46°F (2°C to 8°C) in original carton to protect from light (b) (4) Do not freeze. Do not shake.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Columvi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2

(DMEPA 2) concurred with the findings of OPDP’s assessment for Columvi. The Division of Hematologic Malignancies 2 (DHM 2) did not comment on the findings of OPDP’s assessment for Columvi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Genentech did not provide a derivation or intended meaning for the proposed proprietary name, Columvi, 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 can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

The Division of Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Columvi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (n = 90) practitioners participated in DMEPA’s prescription studies for Columvi. 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 prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^b identified 49 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are 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, and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

^a USAN stem search conducted on December 12, 2022.

^b POCA search conducted on November 29, 2022 in version 5.0.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	47
Low similarity name pair: combined match percentage score $\leq 54\%$	3

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

Our analysis of the 51 names contained in Table 1 determined none of the names will pose a risk for confusion with Columvi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On February 2, 2023, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

3 CONCLUSION

The proposed proprietary name, Columvi, is conditionally acceptable.

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

3.1 COMMENTS TO GENENTECH, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 1, 2022, 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. ^c

^c National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

***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^d. 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

^d 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.

Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

- 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.

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. Columvi Study (Conducted on November 18, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Columvi 10mg IV infusion today</i>	Columvi 2.5 mg/2.5 mL Bring to clinic # 1 vial
<u>Outpatient Prescription:</u> <i>Columvi 2.5 mg/2.5 mL</i> <i>Bring to clinic</i> <i># 1 vial</i>	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Columvi	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received

Study

90 People Responded

Study Name: Columvi

Total	17	25	23	25	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
COLEMVY	0	0	1	0	1
COLUMBI	0	0	0	1	1
COLUMBVI	0	0	1	0	1
COLUMIVI	0	0	0	2	2
COLUMIXI	0	0	0	2	2
COLUMN1	0	0	0	1	1
COLUMRI	0	0	0	1	1
COLUMVE	0	0	1	0	1
COLUMVI	17	25	7	14	63
COLUMVI 2.5MG/2.5ML	0	0	0	1	1
COLMVY	0	0	1	0	1
COLUMXI	0	0	0	2	2
COLUNIVI	0	0	0	1	1
CULOMVY	0	0	1	0	1
FELUMBI	0	0	1	0	1
KOLOMVI	0	0	1	0	1
PALOMBI	0	0	1	0	1
PALUMBEE	0	0	1	0	1
PALUMBI	0	0	1	0	1
PILUNVY	0	0	1	0	1
POLUMVEE	0	0	1	0	1
POLUMVI	0	0	2	0	2
PULUMVY	0	0	2	0	2

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

No.	Proposed name: Columvi Established name: glofitamab-xxxx Dosage form: Injection Strength(s): 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL) Usual Dose: 2.5 mg on cycle 1 Day 8, 10 mg on cycle 1 Day 15, and 30 mg on Day 1 of cycle 2 to cycle 12	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.	columvi***	100	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.	Co-Lav	61
2.	Cablivi	60
3.	C-Solve-2	58
4.	Briumvi***	58
5.	colazal	57
6.	colicon	56
7.	coly Mycin S	55

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: Columvi Established name: glofitamab-xxxx Dosage form: Injection Strength(s): 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL) Usual Dose: 2.5 mg on cycle 1 Day 8, 10 mg on cycle 1 Day 15, and 30 mg on Day 1 of cycle 2 to cycle 12	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.	Clomid	64	This name pair has sufficient orthographic and phonetic differences.
2.	Crolom	60	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Columvi Established name: glofitamab-xxxx Dosage form: Injection Strength(s): 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL) Usual Dose: 2.5 mg on cycle 1 Day 8, 10 mg on cycle 1 Day 15, and 30 mg on Day 1 of cycle 2 to cycle 12	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.	Calmicid	58	This name pair has sufficient orthographic and phonetic differences.
4.	colyte	57	This name pair has sufficient orthographic and phonetic differences.
5.	Calcium	57	This name pair has sufficient orthographic and phonetic differences.
6.	Calcium 600	57	This name pair has sufficient orthographic and phonetic differences.
7.	(b) (4)***	57	This name pair has sufficient orthographic and phonetic differences.
8.	coly Mycin M	56	This name pair has sufficient orthographic and phonetic differences.
9.	Cobolin-M	56	This name pair has sufficient orthographic and phonetic differences.
10.	lumify	56	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4)***	56	(b) (4)

No.	Proposed name: Columvi Established name: glofitamab-xxxx Dosage form: Injection Strength(s): 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL) Usual Dose: 2.5 mg on cycle 1 Day 8, 10 mg on cycle 1 Day 15, and 30 mg on Day 1 of cycle 2 to cycle 12	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			(b) (4)
12.	Voluven	56	This name pair has sufficient orthographic and phonetic differences.
13.	Combivir	55	Orthographically, the ending of the prefixes, ('Co-' vs. 'Com-') and the infixes ('-lum-' vs. '-bi-') provides sufficient orthographic differences. Phonetically, the ending of the first syllables ('co-' vs. 'com-') and the second syllables ('-lum-' vs. '-bih') provides notable differences between the name pair when spoken. Although Columvi and Combivir share numerical similarity in dose (10 mg vs. 1 tablet), Columvi does not overlap with Combivir in strength (2.5 mg/2.5 mL and 10 mg/10 mL vs. 150 mg/300 mg), route of administration (intravenous vs. oral), dosage form (injection vs. tablet) and frequency of administration (day 8, day 15 in cycle

No.	Proposed name: Columvi Established name: glofitamab-xxxx Dosage form: Injection Strength(s): 2.5 mg/2.5 mL (1 mg/mL) and 10 mg/10 mL (1 mg/mL) Usual Dose: 2.5 mg on cycle 1 Day 8, 10 mg on cycle 1 Day 15, and 30 mg on Day 1 of cycle 2 to cycle 12	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 and day 1 in cycle 2 to cycle 12 vs. twice daily). Additionally, Columvi is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the difference in frequency of administration is minimized. Thus, in this specific case, the risk of name confusion between this name pair is minimized. When the above is considered in totality, we find the potential for name confusion with this name pair to be minimal.
14.	Coumadin	55	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 (%)
1.	Calcium Ion	52
2.	Gleevec	40
3.	Korsuva	40

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.	colomycin	66	International product marketed in the UK, Singapore, Greece, Malaysia, Czech Republic, Hong Kong, Hungary, Ireland, and Ukraine.
2.	C10-36 Olefin	62	Product is not a drug. It is a chemical used in compounding.
3.	C24-28 Olefin	62	Product is not a drug. It is a chemical used in compounding.
4.	C30-38 Olefin	62	Product is not a drug. It is a chemical used in compounding.
5.	C30-45 Olefin	62	Product is not a drug. It is a chemical used in compounding.
6.	colovage	60	Branded generic discontinued with no generic equivalents available. ANDA 071320 withdrawn FR effective 02/02/2001.
7.	Climaval	60	International product formerly marketed in the UK.
8.	colax	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	coldmist	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
10.	colonaid	58	Branded generic discontinued with no generic equivalents available. ANDA 085735 and ANDA 085737 withdrawn FR effective 06/09/1993.
11.	(b) (4)***	58	(b) (4)
12.	Calomel	58	This is not a drug, but a very heavy, soft, white, odourless, and tasteless halide mineral.
13.	Cholovue	58	Brand discontinued with no generic equivalents available. NDA 018076 and NDA 018077 withdrawn FR effective 03/13/2009.
14.	Calimal	56	International product marketed in the UK.
15.	Calomist	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Clinium	56	International product formerly marketed in the UK, India, Indonesia, France Netherlands, Germany, S. Africa, and Chile..
17.	Clinsol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
18.	cologel	55	International product formerly marketed in the UK.
19.	(b) (4)***	55	Proposed proprietary name for IND 127210 found unacceptable by DMEPA (OSE# 2018-23255914, 2018-23257053, and 2018-23257497 dated 11/15/2018). BLA 761109 approved under the proprietary name Lyumjev.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion^{8F}^e.

No.	Name	POCA Score (%)
1.	(b) (4)***	60
2.	(b) (4)***	56
3.	Ocaliva	56
4.	(b) (4)***	56
5.	Polivy	56
6.	(b) (4)***	56
7.	Zolanza	56

^e 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/

NICOLE F IVERSON
02/02/2023 01:36:34 PM

HINA S MEHTA
02/02/2023 01:43:27 PM

CHI-MING TU
02/02/2023 02:20:40 PM