

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761174Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	February 10, 2020
Application Type and Number:	IND 126472 and BLA 761174
Product Name and Strength:	Jemperli (dostarlimab-gxly) ^a Injection, 50 mg/mL
Total Product Strength:	500 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	GlaxoSmithKine LLC (GlaxoSmithKine)
Panorama #:	2019-34965113 and 2019-36509136
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

^a The proposed nonproprietary name (dostarlimab-gxly) is only conditionally accepted for this product until the application is approved; see Mena-Grillasca, M. Suffix Review for Nonproprietary Name for Jemperli (BLA 761174). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 17. OSE RCM No.: 2019-2384.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Jemperli, 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. GlaxoSmithKine submitted an external name study, conducted by (b) (4) *** under IND 126472^b; as well as an updated external name study, conducted by (b) (4) for Jemperli under BLA 761174.^c Under IND 126472, GlaxoSmithKine explained they modified the proposed proprietary name from (b) (4) *** to Jemperli to aid in pronunciation, and does not believe that this minor change has any impact on the assessment made by (b) (4). We included both external studies for (b) (4) *** and Jemperli in our evaluation.

1.1 REGULATORY HISTORY

GlaxoSmithKine previously submitted the proposed proprietary name, (b) (4) ***, on December 21, 2018. However, we found the name, (b) (4) *** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4), under IND 126472 on May 16, 2019.^e

GlaxoSmithKine also previously submitted the proposed proprietary name, (b) (4) ***, on July 2, 2019. However, we found the name, (b) (4) *** unacceptable due to inclusion of a USAN stem in the proposed proprietary name under IND 126472 on September 17, 2019.^f

Thus, GlaxoSmithKine submitted the name, Jemperli, for review on October 7, 2019 under IND 126472 and on December 17, 2019 under BLA 761174.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 7, 2019 under IND 126472 and on December 17, 2019 under BLA 761174.

- Intended Pronunciation: jem-PER-lee
- Active Ingredient: dostarlimab-gxly
- Indication of Use: Treatment of adult patients with recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-

^b Amendment to Request for Proprietary Name Review. Waltham (MA): TESARO, Inc. 2019 Oct 7. IND 126472. Available from: [\\cdsesub1\evsprod\ind126472\0508\m1\us\prop-names \(b\) \(4\).pdf](\\cdsesub1\evsprod\ind126472\0508\m1\us\prop-names (b) (4).pdf).

^c Request for Proprietary Name Review. Waltham (MA): GlaxoSmithKine LLC. 2019 Dec 17. BLA 761174. Available from: <\\cdsesub1\evsprod\bla761174\0004\m1\us\pnr-jemperli-comp-review-aw.pdf>

^d Request for Proprietary Name Review. Waltham (MA): TESARO, Inc. 2019 Oct 7. IND 126472. Available from: <\\cdsesub1\evsprod\ind126472\0508\m1\us\request-jemperli.pdf>.

^e Gao, T. Proprietary Name Review for (b) (4) (IND 126472). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 May 16. Panorama No. 2018-28178242.

^f Gao, T. Proprietary Name Review for (b) (4) (IND 126472). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Sept 17. Panorama No. 2019-32871743.

containing regimen whose tumors are mismatch repair deficient (dMMR), as determined by an FDA-approved test

- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 500 mg/10 mL (50 mg/mL)
- Dose and Frequency: 500 mg or 1000 mg every 3 weeks for 4 doses followed by every 6 weeks until disease progression.
- How Supplied: Single-dose vial packaged within individual carton
- Storage: Refrigerate at 2°C to 8°C

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 13, 2019 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to Jemperli at the initial phase of the review.

[§] USAN stem search conducted on November 1, 2019.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^h identified 67 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.

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 $\leq 69\%$	65
Low similarity name pair: combined match percentage score $\leq 54\%$	4

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

Our analysis of the 70 names contained in Table 1 determined none of the names will pose a risk for confusion with Jemperli as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on February 6, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on February 10, 2020, they stated no additional concerns with the proposed proprietary name, Jemperli.

^h POCA search conducted on October 31, 2019 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Jemperli, is acceptable.

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

3.1 COMMENTS TO GLAXOSMITHKINE LLC

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

If any of the proposed product characteristics as stated in your submission, received on October 7, 2019 and December 17, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

ⁱ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^j. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none">• 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	<p>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.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Jemperli Study (Conducted on October 25, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Jemperli 1000mg IV every 3 weeks for 4 doses</i></p>	<p>Jemperli</p> <p>Bring to clinic</p> <p>Dispense two vials</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Jemperli</i></p> <p><i>bring to clinic</i></p> <p><i># 2 vials</i></p>	
<p>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</p> <p>Jemperli</p>	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Jemperli

214 People Received Study

97 People Responded

	19	41	16	21	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
GEMPEARLY	0	0	2	0	2
GEMPERLEE	0	0	1	0	1
GEMPERLI	0	0	3	0	3
GEMPERLY	0	0	6	0	6
JAMPERLY	0	0	1	0	1
JEMPERLI	16	41	1	4	62
JEMPERLIV	1	0	0	0	1
JEMPERLY	0	0	1	0	1
JEMPURELY	0	0	1	0	1
JENPERLI	1	0	0	14	15
JENPERTI	0	0	0	1	1
JERNPERLI	1	0	0	0	1
TEMPERLI	0	0	0	1	1
TENPRELI	0	0	0	1	1

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

No.	Proposed name: Jemperli Established name: dostarlimab-gxly Dosage form: Injection Strength(s): 50 mg/mL Usual Dose: 500 mg or 1000 mg every 3 weeks for 4 doses followed by every 6 weeks until disease progression.	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.	Jemperli	100	Name is 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 (%)
2.	Centergy	56
3.	Empirin	63
4.	Genpril	66
5.	Jinteli	66
6.	Zemplar	60

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: Jemperli Established name: dostarlimab-gxly Dosage form: Injection Strength(s): 50 mg/mL Usual Dose: 500 mg or 1000 mg every 3 weeks for 4 doses followed by every 6 weeks until disease progression.	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
7.	(b) (4) ***	66	This name pair has sufficient orthographic and phonetic differences.
8.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
9.	Fam-pericols	55	This name pair has sufficient orthographic and phonetic differences.
10.	Generlac	60	This name pair has sufficient orthographic and phonetic differences.
11.	Ixempra	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Jemperli Established name: dostarlimab-gxly Dosage form: Injection Strength(s): 50 mg/mL Usual Dose: 500 mg or 1000 mg every 3 weeks for 4 doses followed by every 6 weeks until disease progression.	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
12.	Permitil	56	This name pair has sufficient orthographic and phonetic differences.
13.	Primperan	58	This name pair has sufficient orthographic and phonetic differences.
14.	Tempra	58	This name pair has sufficient orthographic and phonetic differences.
15.	Tempra 1	58	This name pair has sufficient orthographic and phonetic differences.
16.	Tempra 2	58	This name pair has sufficient orthographic and phonetic differences.
17.	Tempra 3	58	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 (%)
18.	Dream Pure BB	50
19.	Epilim	52
20.	Gemcitabine	34
21.	Gemfibrozil	53
22.	Gemzar	50
23.	Iampur	46
24.	Januvia	31
25.	Jakafi	30
26.	Lisinopril	44
27.	Menopur	47
28.	Penidural-LA	54
29.	Perlite	53
30.	Remodulin	50

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
31.	Benperidol	60	International product marketed in United Kingdom.
32.	Bromperidol	56	International product marketed in Belgium, Italy, Japan, and Germany.
33.	Imperialine	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	(b) (4) ***	66	Proposed proprietary name for NDA 209355 found unacceptable by DMEPA (OSE# 2017-19447995). NDA 209355 approved under the proprietary name Bryhali.
35.	(b) (4) ***	56	Proposed proprietary name withdrawn by the Applicant. NDA 209570 was approved on August 29, 2017 under the established name, Benznidazole.
36.	Xamoterol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
37.	Amprolium	57
38.	Bemiparin	63
39.	Benazpepril	56
40.	Benzepiril	58
41.	Brompheril	65
42.	Campral	57
43.	(b) (4) ***	56
44.	(b) (4) ***	58
45.	Complera	58
46.	Demelverin	56
47.	Demerol	64
48.	Demser	57
49.	Dermestril 100	56

^k Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
50.	Dermestril 25	56
51.	Dermestril 50	56
52.	Dm-Pe-Chlor	56
53.	Donepezil	56
54.	Embelin	58
55.	Embeline E	55
56.	Emcor Ls	56
57.	Emetrol	56
58.	Fenoterol	56
59.	Genprin	59
60.	Limbrel	57
61.	M-Predrol	56
62.	Ramipril	58
63.	Respirol	58
64.	Rimiterol	62
65.	Sermorelin	56
66.	Simeprevir	55
67.	Simparica	56
68.	Simplet	55
69.	Simply Sleep	55
70.	Tanderil	55
71.	Temaril	58
72.	Temaril-P	57
73.	Temoporfin	57
74.	Tensopril	56
75.	Vanceril	56
76.	X-Seb T Pearl	58
77.	Zemdri	59
78.	(b) (4) ***	58
79.	Zipeprol	58

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/s/

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MEMORANDUM
SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

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

Date of This Review:	January 17, 2020
Responsible OND Division:	Division of Oncology 1 (DO1)
Application Type and Number:	BLA 761174
Product Name and Strength:	Jemperli (dostarlimab-gxly) injection 500 mg/10 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	GlaxoSmithKline LLC (GSK)
FDA Received Date:	November 26, 2019
OSE RCM #:	2019-2384
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by GSK for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761174.

1.1 Regulatory History

GSK was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter^a.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On November 26, 2019, GSK submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product^b. GSK also provided their own evaluation^b of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by GSK:

1.	qxly
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

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

2.1 dostarlimab-gxly

GSK's first proposed suffix, -gxly, is comprised of 4 distinct letters. We note that the letters 'xl' in the suffix represent the medical abbreviation for 'extended-release'. We considered whether the inclusion of the letters 'xl' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -gxly, 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 Harris, D. General Advice Letter for BLA 761174. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Nov 18.

^b Request for Suffix Review BLA 761174. Philadelphia (PA): GlaxoSmithKline LLC; 2019 Nov 26. Available from: <\\cdsesub1\evsprod\bla761174\0003\m1\us\proprietary-names.pdf>

^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>

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated January 10, 2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology 1 (DO1) via e-mail on January 16, 2020.

4 CONCLUSION

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

4.1 Recommendations for GlaxoSmithKline LLC

We find the nonproprietary name, dostarlimab-gxly, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, dostarlimab-gxly 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 would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
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DANIELLE M HARRIS
01/24/2020 08:53:57 AM