CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761164Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	October 12, 2021
Application Type and Number:	BLA 761164
Product Name and Strength:	Enjaymo (sutimlimab-jome[a]) Injection, 1,100 mg/22 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bioverativ USA Inc. (Bioverativ)
PNR ID #:	2021-1044724103
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

[a] The proposed nonproprietary name (sutimlimab-jome) is only conditionally accepted for this product until the application is approved; see Mena-Grillasca, C M. Suffix Review for Nonproprietary Name for Enjaymo (BLA 761164). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUNE 26. OSE RCM No.: 2020-960.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Bioverativ previously submitted the proposed proprietary name, Enjaymo***, on April 19, 2019 under IND 128190 and it was subsequently found conditionally on June 18, 2019.[b] On February 28, 2020, Bioverativ submitted the name Enjaymo*** for review as a part of the marketing package under BLA 761164. We found the proposed proprietary name Enjaymo*** conditionally acceptable on May 13, 2020 under BLA 761164.[c] However, BLA 761164 received a complete response (CR) letter on November 13, 2020.

Thus, Bioverativ submitted the name, Enjaymo, for review on August 5, 2021 as a part of the resubmission for BLA 761164. We note that none of the product characteristics have changed since our last review.[c]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 5, 2021.

- Intended Pronunciation: en-jaye'-moe
- Nonproprietary Name: sutimlimab-jome
- Indication of Use: A classical complement inhibitor indicated for treatment of hemolysis in adult patients with cold agglutinin disease (CAD).
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 1,100 mg/22 mL (50 mg/mL)
- Dose and Frequency: Weight-based dosage weekly for two weeks then every two weeks:
    - For patients weighing 39 kg to less than 75 kg: 6,500 mg by intravenous infusion.
    - For patients weighing 75 kg or more: 7,500 mg by intravenous infusion.
- How Supplied: ENJAYMO (sutimlimab-jome) injection is a clear to slightly opalescent, colorless to slightly yellow, preservative-free solution supplied as one 1,100 mg/22 mL (50 mg/mL) single-dose vial per carton.

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[b] Mena-Grillasca, C. Proprietary Name Review for Enjaymo (IND 128190). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 28. PNR ID No. 2019-30931668.

[c] Iverson, N. Proprietary Name Review for Enjaymo (BLA 761164). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAY 13. PNR ID No. 2020-39049106.

- Storage: Store ENJAYMO vials refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not freeze. Do not shake. Discard unused portion.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Enjaymo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Enjaymo.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Bioverativ did not provide a derivation or intended meaning for the proposed proprietary name, Enjaymo, 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

On August 23, 2021, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Enjaymo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One Hundred and one (101) practitioners participated in DMEPA's prescription studies for Enjaymo. 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[e] identified 46 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in

[d] USAN stem search conducted on September 28, 2021.

[e] POCA search conducted on September 8, 2021 in version 4.4.

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, we identified 9 names not previously analyzed. 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. 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 ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	7
Low similarity name pair: combined match percentage score ≤54%	2

2.2.7 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 will pose a risk for confusion with Enjaymo as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Non-Malignant Hematology (DNH). At that time we also requested additional information or concerns that could inform our review. On October 11, 2021, the Division of Non-Malignant Hematology (DNH) stated no additional concerns with the proposed proprietary name, Enjaymo.

3 CONCLUSION

The proposed proprietary name, Enjaymo, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO BIOVERATIV USA INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 5, 2021, 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. [f]

[f] 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 ≥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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., 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

[g] 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. 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.

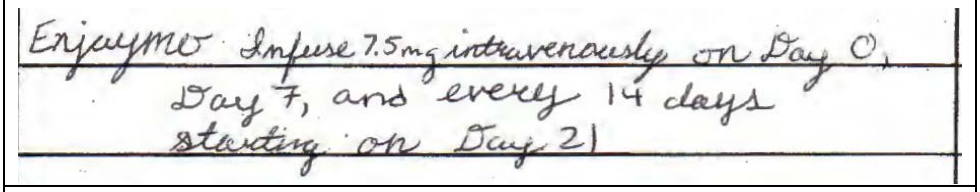
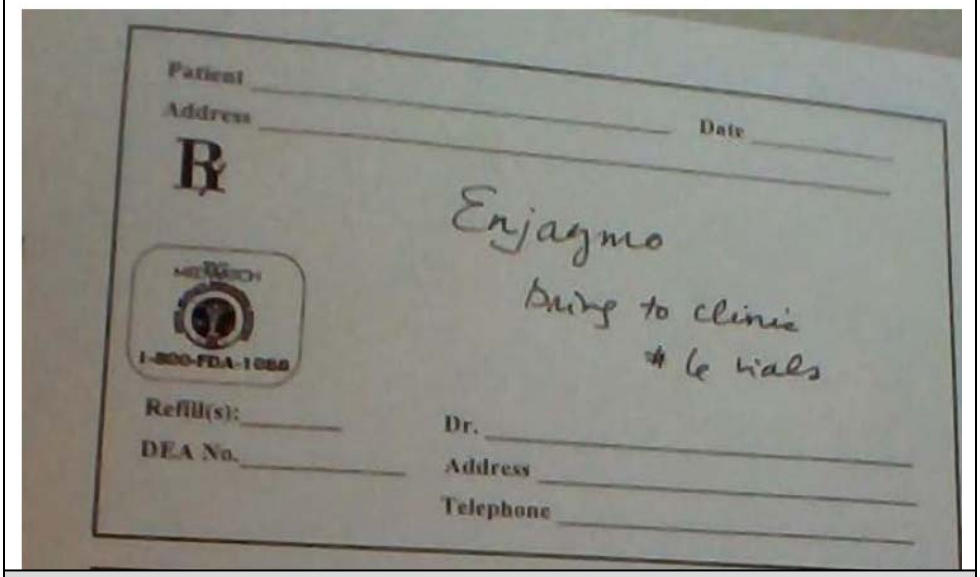
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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. Enjaymo Study (Conducted on September 17, 2021)

<table>
<tr><th>Handwritten Medication Order/Prescription</th><th>Verbal Prescription</th></tr>
<tr><td>Medication Order:
 
</td><td rowspan="4">Enjaymo
Bring to Clinic
#6 vials</td></tr>
<tr><td>Outpatient Prescription:
 
</td></tr>
<tr><td>CPOE Study Sample (displayed as sans-serif, 12-point, bold font)</td></tr>
<tr><td>Enjaymo</td></tr>
</table>

FDA Prescription Simulation Responses (Aggregate Report)

261 People Received Study
101 People Responded

Study Name: Enjaymo

Total	29	28	22	22	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
EJAYMO	0	0	0	1	1
EMJAMO	0	0	1	0	1
EMJAYMO	0	0	1	0	1
ENJAGMO	7	0	0	0	7
ENJAMEO	0	0	1	0	1
ENJAMO	1	0	4	0	5
ENJAYMO	18	28	9	17	72
ENJAYMO INFUSE	0	0	0	1	1
ENJAZMO	3	0	0	0	3
ENJEMO	0	0	1	0	1
ENJUYMO	0	0	0	1	1
ERJAYMO	0	0	0	2	2
FENJAMO	0	0	1	0	1
INJAMO	0	0	1	0	1
NJAYMO	0	0	2	0	2
N-JAYMO	0	0	1	0	1

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

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 – N/A

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

No.	**Proposed name:** Enjaymo **Established name:** sutimlimab-jome **Dosage form:** Injection **Strength(s):** 1,100 mg/22 mL (50 mg/mL) **Usual Dose:** 6.5 g or 7.5 g intravenous infusion once weekly for 2 weeks and then once every 2 weeks.	**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.	(b) (4) ***	8	(b) (4)
2.	(b) (4) ***	6	

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

No.	Name	POCA Score (%)
1.	(b) (4)***	54
2.	**	52

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	55	(b) (4)
2.	Jasmone	55	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[h].

No.	Name	POCA Score (%)
1.	Menthone, (+)-	58
2.	(b) (4)***	56
3.	(b) (4)***	56

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEVIN R KANE
10/12/2021 11:00:12 AM

HINA S MEHTA
10/12/2021 02:17:45 PM

CHI-MING TU
10/12/2021 03:15:50 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

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:	9/29/2021
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761164
Product Name and Strength:	Enjaymo (sutimlimab-jome) injection 1,100 mg/22 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Bioverativ USA Inc. (Bioverativ)
Nexus NPNS ID #:	2021-52
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
OMEPRM Deputy Office Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -jome, for BLA 761164, which was found conditionally acceptable on February 14, 2020[a] and June 26, 2020[b], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761164.

1.1 Regulatory History

On September 11, 2019, Bioverativ submitted a list of suffixes to IND 128190, in their order of preference, to be used in the nonproprietary name of their product. Bioverativ also submitted findings from an external study conducted by the (b) (4) FDA found Bioverativ's proposed suffix -jome conditionally acceptable on February 14, 2020[a]. On February 28, 2020 Bioverativ submitted proposed suffixes to their rolling submission for BLA 761164 to the Agency for review, including the conditionally acceptable suffix -jome. On June 26, 2020[b], DMEPA found the suffix -jome conditionally acceptable upon review. However, BLA 761164 received a Complete Response letter on November 13, 2020.

On August 5, 2021 Bioverativ re-submitted BLA 761164 to the Agency for review.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

sutimlimab-jome

We reassessed the previously proposed four-letter suffix, -jome, using the principles described in the applicable guidance[c].

We determined that the proposed suffix -jome, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for sutimlimab-jome (IND 128190). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Feb 14. RCM No.: 2019-2053.

[b] Mena-Grillasca, C. Nonproprietary Name Suffix Review for sutimlimab-jome (BLA 761164). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jun 26. RCM No.: 2020-960.

[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

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.

3 COMMUNICATION OF DMAMES' ANALYSIS

These findings were shared with OPDP. On September 29, 2021, OPDP did not identify any concerns that would render this suffix unacceptable. DMAMES also communicated our findings to the Division of Non-Malignant Hematology (DNH) on September 29, 2021.

4 CONCLUSION

We find the suffix -jome acceptable and recommend the nonproprietary name sutimlimab-jome be used throughout the labels and labeling.

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/s/

CARLOS M MENA-GRILLASCA
09/29/2021 03:03:17 PM

DANIELLE M HARRIS
10/01/2021 08:15:35 AM
Signed on behalf of Lubna Merchant

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:	June 26, 2020
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761164
Product Name and Strength:	Enjaymo (sutimlimab-jome) injection 1,100 mg/22 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Bioverativ USA Inc. (Bioverativ)
FDA Received Date:	February 28, 2020
OSE RCM #:	2020-960
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Bioverativ for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761164.

2 REGULATORY HISTORY

On September 11, 2019, Bioverative submitted a list of 10 suffixes to IND 128190 for FDA review. We found the proposed suffix -jome conditionally acceptable on March 2, 2020 during the review of the suffixes submitted to IND 128190[a].

On February 28, 2020 Bioverative submitted the same list of 10 suffixes previously submitted to the IND to BLA 761164 for FDA review.

3 ASSESSMENT OF THE NONPROPRIETARY NAME

On February 28, 2020, Bioverativ submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[b]. Bioverativ also provided findings from an external study conducted by the (b) (4)[c], evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Bioverativ:

Table 1. Suffixes submitted by Bioverativ***

1.	(b) (4)
2.	
3.	jome
4.	(b) (4)

[a] Harris, D. General Advice Letter (IND 128190). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Mar 02

[b] Request for Proprietary/Nonproprietary Name Review (BLA 761164). Waltham (MA): Bioverative USA Inc; 2020 Feb 28. Available from: \\CDSESUB1\evsprod\bla761164\0002\m1\us\prop-naming-review.pdf

[c] Data Summary Report for Proposed Suffixes (BLA 761164). (b) (4) 2019 Sep 05. Available from: \\CDSESUB1\evsprod\bla761164\0002\m1\us\suffix-report.pdf

Table 1. Suffixes submitted by Bioverativ***			
5.		(b) (4)	
6.			
7.			
8.			
9.			
10.			

We reviewed Bioverativ's proposed suffixes in the order of preference listed by Bioverativ, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

3.1 sutimlimab-(b) (4)

Bioverativ's first proposed suffix, (b) (4) is comprised of 4 distinct letters. (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Product guidance[c].

3.2 sutimlimab-(b) (4)

Bioverativ's second proposed suffix, (b) (4) is comprised of 4 distinct letters. (b) (4) is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Product guidance[a].

[a] See Section VI which describes that any suffix should be devoid of meaning in the Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

3.3 sutimlimab-jome

Bioverativ's third proposed suffix, -jome, is comprised of 4 distinct letters.

We determined that the proposed suffix -jome, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

4 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated June 23,2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on June 26, 2020.

5 CONCLUSION

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

5.1 Recommendations for Bioverativ USA Inc.

We find the nonproprietary name, sutimlimab-jome, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, sutimlimab-jome 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.

We also note that the first 2 proposed suffixes are unacceptable for the following reasons:

1. sutimlimab-[redacted]

We find your proposed suffix, [redacted] unacceptable. [redacted], is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a]. We acknowledge that our evaluation differs from that of the external study performed by the [redacted]

2. sutimlimab-[redacted]

We find your proposed suffix, [redacted] unacceptable. [redacted] is not devoid of meaning and is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a]. We acknowledge that our evaluation differs from that of the external study performed by the [redacted].

[a] See Section VI which describes that any suffix should be devoid of meaning in the Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/s/

CARLOS M MENA-GRILLASCA
06/26/2020 09:40:28 AM

LUBNA A MERCHANT on behalf of DANIELLE M HARRIS
06/29/2020 08:31:10 AM

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:	May 13, 2020
Application Type and Number:	BLA 761164
Product Name and Strength:	Enjaymo (sutimlimab-xxxx*) Injection, 1,100 mg/22 mL (50 mg/mL)
Total Product Strength:	1,100 mg/22 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bioverativ USA, Inc. (Bioverativ)
Panorama #:	2020-39049106
DMEPA Safety Evaluator:	Nicole Iverson, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* The proper name for Enjaymo has not yet been determined; therefore, "sutimlimab-xxxx" is used throughout this review as the proper name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Enjaymo, which was found conditionally acceptable under IND 128190 on June 28, 2019.[a] Thus, Bioverativ submitted the name, Enjaymo, under BLA 761164 for review on February 28, 2020. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Enjaymo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Enjaymo.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 proposed proprietary name. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 9, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Enjaymo.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on May 4, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Non-Malignant Hematology (DNH) on May 11, 2020, they stated no additional concerns with the proposed proprietary name, Enjaymo.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Enjaymo, is acceptable.

If you have any questions or need clarifications, please contact Linda Park, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO BIOVERATIV USA, INC.

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

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[a] Mena-Grillasca, C. Proprietary Name Review for Enjaymo (IND 128190). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 28. Panorama No.: 2019-30931668.

If any of the proposed product characteristics as stated in your submission, received on February 28, 2020 are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

NICOLE F IVERSON
05/13/2020 05:22:47 PM

HINA S MEHTA
05/14/2020 04:35:52 PM