CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761169Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	September 10, 2020
Application Type and Number:	BLA 761169
Product Name and Strength:	Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) Injection, 16.67 mg/16.67 mg/16.67 mg per mL
Total Product Strength:	241.7 mg/241.7 mg/ 241.7 mg per 14.5 mL
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
Panorama #:	2020-40320392-1
DMEPA Safety Evaluator:	Valerie S. Vaughan, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Inmazeb, based on the revised strength. The proposed proprietary name, Inmazeb, was found acceptable under BLA 761169 on August 26, 2020.[a] The strength was originally presented as (b) (4) During the review of the BLA, the strength was revised to 241.7 mg/241.7 mg/241.7 mg per 14.5 mL (16.67 mg/16.67 mg/16.67 mg per mL) (b) (4) following discussions with the review team. The Applicant was notified of the change in product strength on July 21, 2020 via electronic communication.[b]

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

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

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The September 10, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Inmazeb.

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, Inmazeb, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

[a] Vaughan, V. Proprietary Name Review for Inmazeb (BLA 761169). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 AUG 26. Panorama No.: 2020-40320392.

[b] Moruf, A. FDA Communication: Labeling Comments for atoltivimab-odesivimab-maftivimab-ebgn. Silver Spring (MD): FDA, CDER, DAV (US); 2020 JUL 21. BLA 761169.

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/

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
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Date of This Review:	August 26, 2020
Application Type and Number:	BLA 761169
Product Name and Strength:	Inmazeb (atolivimab, maftivimab, and odesivimab-ebgn) Injection, (b) (4)
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
Panorama #:	2020-40320392
DMEPA Safety Evaluator:	Valerie S. Vaughan, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Inmazeb, 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. Regeneron submitted an external name study, conducted by them for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 29, 2020 and June 4, 2020.

- Intended Pronunciation: ihn-ma-zehb
- Nonproprietary Name: atolivimab, maftivimab, and odesivimab-ebgn
- Indication of Use: Treatment of infection caused by *Zaire ebolavirus*
- Route of Administration: Intravenous infusion
- Dosage Form: Injection
- Strength: (b) (4)
- Dose and Frequency: (b) (4) single intravenous infusion (b) (4)
- How Supplied: Carton containing one (1) single-dose vial containing 14.5 mL of solution.
- Storage: Store in a refrigerator at 2° to 8°C (36° to 46°F) in the original carton. Protect from light. Do not freeze or shake.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

(b) (4)

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Regeneron did not provide a derivation or intended meaning for the proposed proprietary name, Inmazeb, in their submission. We note that the proposed proprietary name is comprised of a single word that contains the following medical abbreviation, "IN" (abbreviation for intranasal)[d].

Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of this letter string and its lack of prominence makes it unlikely that it will be separated from the surrounding letters or otherwise misinterpreted in a manner that could lead to confusion. Thus, in this particular case, we find the inclusion of this medical abbreviation acceptable.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 27, 2020 e-mail, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Inmazeb at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-two practitioners participated in DMEPA's prescription studies for Inmazeb. We note that two participants incorrectly selected the previously marketed name Imagent from a dropdown list of names in the computerized physician order entry (CPOE) portion of the FDA Prescription Simulation Study. It appears that both participants entered an incorrect sequence of letters "I-M-A" when searching for the study name. As a result, the CPOE generated a pick list that did not contain Inmazeb as a choice. The participant proceeded to incorrectly select the name Imagent as their response. Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. We evaluated the name pair further and determined that this name pair is not likely to be confused because Imagent is a discontinued product with no generic equivalents available (see Appendix G). Based on the totality of consideration above, we determined the risk for a medication error between this name pair is adequately minimized.

The remaining 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.

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[c] USAN stem search conducted on June 2, 2020.

[d] Source: Davis N. Medical Abbreviations: 32,000 Conveniences at the Expense of Communication and Safety, 15th ed. Warminster, PA: Neil M. Davis Associates. 2011.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 82 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥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, FDA Prescription Simulation Study, and Regeneron's 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 ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	61
Low similarity name pair: combined match percentage score ≤54%	22

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

Our analysis of the 83 names contained in Table 1 determined none of the names will pose a risk for confusion with Inmazeb 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 Antivirals (DAV) via e-mail on August 23, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antivirals (DAV) on August 24, 2020, they stated no additional concerns with the proposed proprietary name, Inmazeb.

[e] POCA search conducted on June 2, 2020 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Inmazeb, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO REGENERON PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 29, 2020, 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. 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 ≥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 a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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.

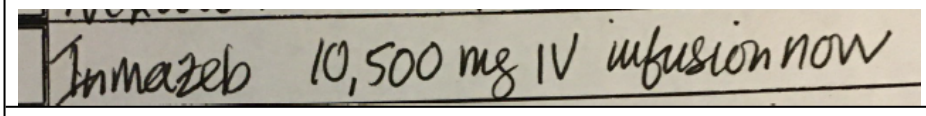
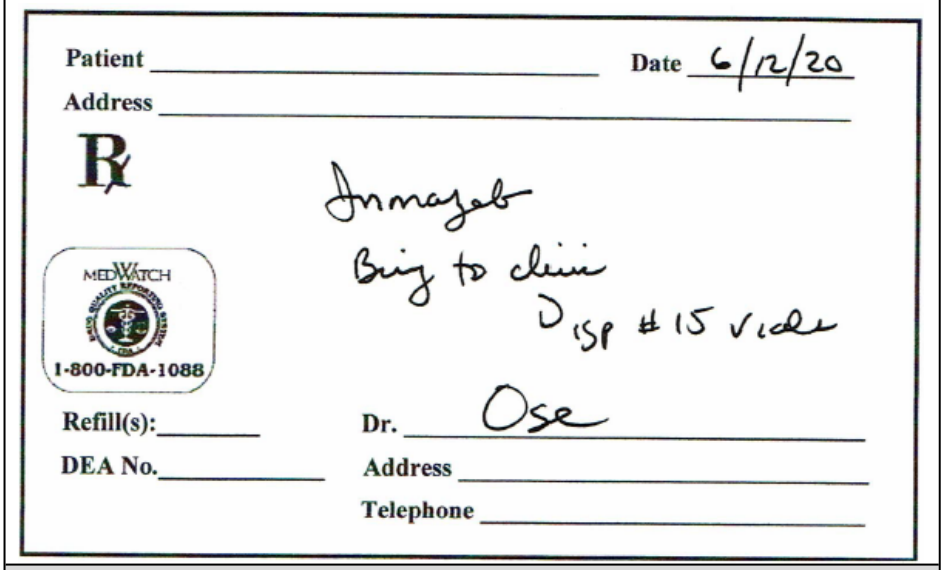
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Inmazeb Study (Conducted on April 3, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Inmazeb Bring to clinic Dispense # 15 vials
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Inmazeb	

FDA Prescription Simulation Responses (Aggregate Report)

207 People Received Study
92 People Responded

Study Name: Inmazeb

Total	17	31	23	21	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
EMAZEB	0	0	1	0	1
ENMAZEB	0	0	1	0	1
ENMOZAB	0	0	1	0	1
IMAGENT	0	2	0	0	2
IMAMEB	0	0	1	0	1
IMAVEB	0	0	1	0	1
IMAZAB	0	0	2	0	2
IMIVAB	0	0	1	0	1
IMIZEB	0	0	2	0	2
IMNAZEB	0	0	1	0	1
IMUZAB	0	0	1	0	1
INAZEB	0	0	1	0	1
INMAYEB	1	0	0	0	1
INMAZAB	0	0	1	0	1
INMAZEB	15	29	0	21	65
INMAZEG	1	0	0	0	1
INMEZAB	0	0	1	0	1
INMISEB	0	0	1	0	1
INMIZAB	0	0	1	0	1
INMIZEB	0	0	1	0	1

INMOZAB	0	0	1	0	1
INMOZAV	0	0	1	0	1
INNIVEB	0	0	1	0	1
INVOSAB	0	0	1	0	1
INVOTAB	0	0	1	0	1

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

No.	**Proposed name:** Inmazeb **Established name:** atolivimab, maftivimab, and odesivimab-ebgn **Dosage form:** Injection **Strength(s):** (b) (4) **Usual Dose:** (b) (4) (b) (4) single intravenous infusion	**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.**
	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

No.	Name	POCA Score (%)
1.	Ambifed	61
2.	Nymalize	58
3.	Innofem	56

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:** Inmazeb **Established name:** atolivimab, maftivimab, and odesivimab-ebgn **Dosage form:** Injection **Strength(s):** (b) (4) **Usual Dose:** (b) (4) (b) (4) single intravenous infusion	**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.	Imatinib	60	This name pair has sufficient orthographic and phonetic differences.
2.	Invanz	60	This name pair has sufficient orthographic and phonetic differences.
3.	Ed-Mycin	57	This name pair has sufficient orthographic and phonetic differences.
4.	Embeline E	56	This name pair has sufficient orthographic and phonetic differences.
5.	Imipenem	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Inmazeb **Established name:** atolivimab, maftivimab, and odesivimab-ebgn **Dosage form:** Injection **Strength(s):** (b) (4) **Usual Dose:** (b) (4) single intravenous infusion (b) (4)	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**
6.	Inomax	56	This name pair has sufficient orthographic and phonetic differences.
7.	Iomazenil	56	This name pair has sufficient orthographic and phonetic differences.
8.	Ormazine	56	This name pair has sufficient orthographic and phonetic differences.
9.	Embeline	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Indocin	54
2.	Primazine	54
3.	Inderal	52
4.	Endocet	51
5.	Imfinzi	50
6.	Indapamide	49
7.	Marezine	49
8.	Infliximab	48
9.	Innovar	46
10.	Insulin	46
11.	Indomethacin	45
12.	Erwinaze	44
13.	Innohep	44
14.	Clonazepam	42
15.	Marzia	42
16.	Duoneb	40
17.	Imatinib mesylate	37
18.	Ibsrela	34
19.	Ervebo	32
20.	Imdur	32
21.	Eraxis	28

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.	Demazin	64	Discontinued product per RedBook with no generic equivalents available.
2.	Endafed	62	Discontinued product per RedBook with no generic equivalents available.
3.	Metazem	61	International product formerly marketed in Hong Kong, Ireland, United Kingdom, Singapore, and Thailand.
4.	Q-mazine	61	International product formerly marketed in United Kingdom.
5.	Embelin	60	Name identified in RxNorm database. We are unable to identify the name, Embelin, in commonly used drug databases. We note that this name is close in spelling to the name Embeline, which we assessed in Appendix E.
6.	Kentiazem	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	(b) (4)***	60	(b) (4)
8.	Almazine	59	International product formerly marketed in United Kingdom.
9.	(b) (4)***	59	(b) (4)
10.	Immuzim	58	Veterinary product.
11.	Alenaze-D	57	Discontinued product per RedBook with no generic equivalents available.
12.	Imagent	57	Brand discontinued with no generic equivalents available. NDA 020091 Withdrawn FR Effective December 7, 2007.

No.	Name	POCA Score (%)	Failure preventions
13.	Indocid	57	International product marketed in France, Canada, India, Australia, Brazil, United Kingdom, Mexico, Switzerland, Greece, Italy, South Africa, Singapore, Venezuela, Hong Kong, Belgium, Thailand, Denmark, Finland, Ireland, Malaysia, Netherlands, Norway, New Zealand, and Turkey.
14.	Ismelin	57	Discontinued product per RedBook with no generic equivalents available.
15.	Anased	56	International product previously marketed in United Kingdom.
16.	Ibumetin	56	International product previously marketed in Austria, Denmark, United Kingdom, Norway, Sweden, and Netherlands
17.	Epimaz	55	International product formerly marketed in United Kingdom.
18.	Emadine	55	Discontinued per RedBook with no generic equivalents available.
19.	Cinaziere	49	International product formerly marketed in United Kingdom.

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.	Anemagen	62
2.	Asmaven	62
3.	Adizem	60
4.	Dimaphen	60
5.	Omni-Med	60
6.	Ampi-Tab	59
7.	Fentazin	59
8.	Minidiab	59
9.	Rimafen	59
10.	Antiben	58
11.	Anzemet	58
12.	Minizide	58
13.	Mintab	58

[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

No.	Name	POCA Score (%)
14.	Nemacide	58
15.	Rinade-B.I.D.	58
16.	Zinacef	58
17.	Ambien	56
18.	Ambisome	56
19.	Ambophen	56
20.	Anabasum	56
21.	Angiozem	56
22.	Bionafem	56
23.	Cinnamate	56
24.	End-Zit	56
25.	Enemeez	56
26.	Fenbuzip	56
27.	Vimizim	56
28.	Amabelz	55
29.	Na-Zone	55
30.	Xenazine	55
31.	Zimovane	55

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/s/

VALERIE S VAUGHAN
08/26/2020 10:25:49 AM

SEVAN H KOLEJIAN
08/26/2020 10:33:46 AM

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:	April 20, 2020
Responsible OND Division:	Division of Antivirals (DAV)
Application Type and Number:	BLA 761169
Product Name and Strength:	(atoltivimab, maftivimab, and odesivimab-ebgn)[a] injection, (b) (4)
Product Type:	Multiple Ingredient Product
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
FDA Received Date:	February 25, 2020
OSE RCM #:	2020-265
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

[a] Proprietary Name has not been designated.

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Regeneron for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761169.

1.1 Regulatory History

Regeneron 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 February 25, 2020, Regeneron submitted a list of 2 suffixes, in their order of preference, to be used in the nonproprietary name of their product[b]. Table 1 presents a list of suffixes submitted by Regeneron:

Table 1. Suffixes submitted by Regeneron***	
1.	ebgn
2.	(b) (4)

We reviewed Regeneron's proposed suffixes in order of preference listed by Regeneron, using the principles described in the applicable guidance.[c]

2.1 atoltivimab, maftivimab, and odesivimab-ebgn

Regeneron's first proposed suffix, -ebgn, is comprised of four distinct letters.

We determined that the proposed suffix -ebgn, 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.

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[a] Harris, D. General Advice Letter for BLA 761169. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Feb 13.

[b] Request for Review of Suffixes for Proper Name BLA 761169. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2020 Feb 25. Available from: \\cdsesub1\evsprod\bla761169\0004\m1\us\112-other-corr\req-rev-suffix-proper-name.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 March 18, 2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Antivirals (DAV) via e-mail on March 26, 2020.

4 CONCLUSION

We find Regeneron's proposed suffix -ebgn acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to atoltivimab, maftivimab, and odesivimab (b) (4) DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendations for Regeneron Pharmaceuticals, Inc.

We find the nonproprietary name, atoltivimab, maftivimab, and odesivimab-ebgn, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, atoltivimab, maftivimab, and odesivimab-ebgn 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
04/20/2020 02:12:47 PM

DANIELLE M HARRIS
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