CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761377Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 15, 2025
Application Type and Number:	BLA 761377
Product Name, Dosage Form, and Strength:	Eydenzelt (aflibercept-boav) injection, 2 mg/0.05 mL
Product Type:	Combination Product (Drug-Biologic)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
PNR ID #:	2025-1044726666
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Eydenzelt, which was found conditionally acceptable under BLA 761377 on December 11, 2024.[a] Thus, Celltrion submitted the proposed proprietary name, Eydenzelt, under BLA 761377 for re-review on August 22, 2025.[b] We note that all product characteristics remain the same.

2 REGULATORY HISTORY

Celltrion submitted the proposed proprietary name, Eydenzelt, under IND 147335 and BLA 761377 on April 19, 2022, and July 3, 2023, respectively. We found the name conditionally acceptable on September 5, 2023.[c] However, BLA 761377 was issued a Complete Response Letter on June 27, 2024.

Subsequently, as part of their Class 2 resubmission Celltrion submitted the proposed proprietary name, Eydenzelt, under BLA 761377 for re-review on September 30, 2024. We found the name conditionally acceptable on December 11, 2024.[d] However, BLA 761377 was issued a Complete Response Letter on March 26, 2025.

Thus, Celltrion submitted the name, Eydenzelt, for re-review on August 22, 2025, as part of their Class 2 resubmission of BLA 761377.

3 DISCUSSION

3.1 MISBRANDING ASSESSMENT

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

3.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Eydenzelt, 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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN

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[a] Getahun, S. Proprietary Name Review for Eydenzelt (BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 DEC 11. PNR ID No. 2024-1044726012.

[b] Cover Letter (BLA 761377 Eydenzelt). Incheon (Republic of Korea): Celltrion, Inc.; 2025 AUG 22. Available from: \\CDSESUB1\EVSPROD\bla761377\0050\m1\us\cover-letter.pdf

[c] Birkemeier, D. Proprietary Name Review for Eydenzelt (IND 147335 and BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 SEP 05. PNR ID No. 2022-1044724550 and 2023-1044725221.

[d] Getahun, S. Proprietary Name Review for Eydenzelt (BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 DEC 11. PNR ID No. 2024-1044726012.

stems as of the last USAN updates. The August 22, 2025, search of USAN stems did not find any USAN stems in the proposed proprietary name, Eydenzelt.

3.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On September 15, 2025, DMEPA 1 communicated our determination to the Division of Ophthalmology (DO).

4 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, Eydenzelt, is conditionally acceptable.

4.1 COMMENTS TO CELLTRION, INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 22, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

5 REFERENCE

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

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/s/

SOFANIT N GETAHUN
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VALERIE S VAUGHAN
09/15/2025 05:24:42 PM

IDALIA E RYCHLIK
09/16/2025 04:10:43 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME
Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)
*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	August 6, 2025
Responsible OND Division:	Division of Ophthalmology (DO)
Application Type and Number:	BLA 761377
Product Name and Strength:	Eydenzelt (aflibercept-boav) injection, 2 mg/0.05 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
FDA Received Date:	April 18, 2025
Nexus NPNS ID #:	2025-326
DMEPA 2 Biologics Suffix Specialist:	Carlos Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 Purpose of Review

This review is to reassess our evaluation of the four-letter suffix –boav for BLA 761377, which was found conditionally acceptable on March 25, 2024,[a] and January 30, 2025,[b] for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761377.

2 Regulatory History

- The proposed suffix -boav was found conditionally acceptable for BLA 761377 on March 25, 2024.[a]
- BLA 761377 received a Complete Response (CR) letter on June 27, 2024.[c]
- Celltrion submitted a Class 2 Resubmission on September 26, 2024.
- Upon re-review the proposed suffix -boav was found conditionally acceptable on January 30, 2025.[b]
- BLA 761377 received a Complete Response (CR) letter on March 26, 2025.[d]
- Celltrion submitted a Class 2 Resubmission on April 18, 2025.

3 Assessment of the Nonproprietary Name

We reassessed the previously conditionally acceptable suffix -boav, using the principles described in the Nonproprietary Naming of Biological Products guidance.[e]

We determined that the proposed suffix -boav, is not too similar to any other product's 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 lead be misinterpreted, and does not make misrepresentations with respect to safety and efficacy of the product.

4 Communication of DMEPA 1 Analysis

These findings were shared with OPDP. On July 16, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Ophthalmology (DO) on August 6, 2025.

5 Conclusion

We find the suffix –boav acceptable and recommend the nonproprietary name aflibercept-boav be used throughout the draft labels and labeling.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for aflibercept-boav (BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 25. Nexus ID.: 2023-180.
[b] Mena-Grillasca, C. Nonproprietary Name Suffix Review for aflibercept-boav (BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 Jan 30. Nexus ID.: 2024-288.
[c] Boyd, W. Complete Response (CR) Letter (BLA 761377). Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2024 Jun 27.
[d] Boyd, W. Complete Response (CR) Letter (BLA 761377). Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2025 Mar 26.
[e] 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
08/06/2025 06:45:13 PM

MISHALE P MISTRY
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SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	1/30/2025
Responsible OND Division:	Division of Ophthalmology (DO)
Application Type and Number:	BLA 761377
Product Name and Strength:	Eydenzelt (aflibercept-boav) injection 2 mg/0.05 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
Nexus NPNS ID #:	2024-288
DMEPA 1 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -boav, for BLA 761377, which was found conditionally acceptable on March 25, 2024[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761377.

1.1 Regulatory History

FDA found the proposed four-letter suffix, -boav, conditionally acceptable for BLA 761377 on March 25, 2024. However, BLA 761377 received a Complete Response (CR) letter on June 27, 2024[b]. Thus, Celltrion submitted a Class 2 Resubmission on September 26, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

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

We determined that the proposed suffix -boav, 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.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On January 8, 2025, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Ophthalmology (DO) on January 30, 2025.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for aflibercept-boav (BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 25. Nexus NPNS No.: 2023-180.

[b] Boyd W.M., Complete Response (BLA 761377). Silver Spring (MD): FDA, CDER, OND, DO (US); 2024 Jun 27.

[c] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find the suffix -boav acceptable and recommend the nonproprietary name aflibercept-boav be used throughout the draft labels and labeling.

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/s/

CARLOS M MENA-GRILLASCA
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MISHALE P MISTRY
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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	December 11, 2024
Application Type and Number:	BLA 761377
Product Name, Dosage Form, and Strength:	Eydenzelt (aflibercept-boav) injection, 2 mg/0.05 mL
Product Type:	Combination Product (Drug-Biologic)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
PNR ID #:	2024-1044726012
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD, BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

Table of Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Celltrion previously submitted the proposed proprietary name, Eydenzelt, under IND 147335 and BLA 761377 on April 19, 2022, and July 3, 2023, respectively. We found the name conditionally acceptable on September 5, 2023.[a] However, BLA 761377 was issued a Complete Response Letter on June 27, 2024.

Thus, Celltrion submitted the name, Eydenzelt, for review on September 26, 2024, as part of their Class 2 resubmission of BLA 761377.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 30, 2024[b],and the prescribing information received on September 26, 2024[c].

Table 1. Relevant Product Information for Eydenzelt	
Intended pronunciation:	I-den-zelt
Nonproprietary name:	aflibercept-boav
Indication:	Treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR)
Dosage Form:	injection
Strength:	2 mg/0.05 mL
Route of administration:	Intravitreal injection

[a] Birkemeier, D. Proprietary Name Review for Eydenzelt (IND 147335 and BLA 761377). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 SEP 05. PNR ID No. 2022-1044724550 and 2023-1044725168.

[b] Cover Letter (Eydenzelt). Incheon (Republic of Korea): Celltrion, Inc.; 2024 SEP 30. Available from: \\CDSESUB1\EVSPROD\bla761377\0039\m1\us\cover-letter.pdf

[c] Proposed prescribing information for Eydenzelt. Incheon (Republic of Korea): Celltrion, Inc.; 2024 SEP 26. Available from: \\CDSESUB1\EVSPROD\bla761377\0038\m1\us\draft-labeling-text.docx

<table>
<tr><th colspan="2">Table 1. Relevant Product Information for Eydenzelt</th></tr>
<tr><td>Dose and frequency:</td><td>AMD: 2 mg intravitreally every 4 weeks for the first 12 weeks, followed by 2 mg intravitreally once every 8 weeks

RVO: 2 mg intravitreally every 4 weeks

DME and DR: 2 mg intravitreally every 4 weeks for the first five injections, followed by 2 mg intravitreally every 8 weeks</td></tr>
<tr><td>How Supplied:</td><td>
<table>
<tr><th>NDC Number</th><th>Carton Type</th><th>Carton Contents</th></tr>
<tr><td>72606-026-01</td><td>Prefilled Syringe</td><td>one blister pack containing one EYDENZELT 2 mg (0.05 mL of a 40 mg/mL solution) sterile, single-dose pre-filled syringe

one Prescribing Information</td></tr>
<tr><td>72606-026-02</td><td>Vial kit with injection components</td><td>one EYDENZELT 2 mg (0.05 mL of a 40 mg/mL solution) single-dose glass vial

one 18-gauge × ½-inch, 5-micron, filter needle for withdrawal of the vial contents

one 30 gauge × ½ inch injection needle for intravitreal injection

one 1-mL syringe for administration one Prescribing Information</td></tr>
</table>
</td></tr>
<tr><td>Storage:</td><td>Refrigerate at 2°C to 8ºC (36°F to 46ºF). Do not freeze. Do not use beyond the date stamped on the carton and container label. Store in the original carton until time of use to protect from light. Do not open sealed blister pack until time of use.</td></tr>
</table>

Table 1. Relevant Product Information for Eydenzelt	
Reference Product:	Eydenzelt (aflibercept-boav) is a proposed [redacted] (b) (4) to US-licensed Reference Product, Eylea (aflibercept) BLA 125387

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Eydenzelt would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Eydenzelt. The Division of Ophthalmology (DO) did not comment on the findings of OPDP's assessment for Eydenzelt.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Ophthalmology (DO) did not forward any comments or concerns relating to Eydenzelt at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-nine (99) practitioners participated in DMEPA's prescription studies for Eydenzelt.

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.

[d] USAN stem search conducted on October 16, 2024.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[e] identified 53 names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed, and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two (2) names not previously analyzed. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides 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 2. 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%	2
Low similarity name pair: combined match percentage score ≤54%	0

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 2 names contained in Table 2 determined none of the names will pose a risk for confusion with Eydenzelt as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On December 11, 2024, DMEPA 1 communicated our determination to the Division of Ophthalmology (DO).

3 CONCLUSION

The proposed proprietary name, Eydenzelt, is conditionally acceptable.

3.1 COMMENTS TO CELLTRION, INC.

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

[e] POCA search conducted on October 16, 2024, in version 5.9.

If any of the proposed product characteristics as stated in your submission, received on September 30, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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]

*Table 3. 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.

[f] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. 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 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, Cerner RxNorm, Purple Book, 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 4-6) 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 4).
- 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[9]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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-

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

concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

Additionally, other review disciplines opinions such as OPQ 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 Safety Evaluator 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 4. 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>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">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</td></tr>
<tr><td>Step 2</td><td colspan="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.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

Table 6. 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. Eydenzelt Study (Conducted on 10/18/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order: Eydenzelt 2mg intravitreal injection once	Eydenzelt Bring to Clinic. Dispense #1 Vial
Outpatient Prescription: Eydenzelt Bring to clinic Dispense #1 vial Dr. OdE	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Eydenzelt	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Eydenzelt People Received Study: 187 People Responded: 99					
Total	22	27	22	28	99
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
EYDENGELT	1	0	0	0	1
EYDENMZELL	1	0	0	0	1
EYDENZELT	17	16	0	28	61
EYDENZELT 2MG	1	0	0	0	1
EYDONZELT	0	10	0	0	10
EYEDENZELY	0	1	0	0	1
EYOLENZELT	2	0	0	0	2
IDELZET	0	0	1	0	1
IDENZELT	0	0	15	0	15
IDENZELZ	0	0	1	0	1
IDENZILT	0	0	1	0	1
IDENZULT	0	0	1	0	1
IDINZELT	0	0	3	0	3

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Eydenzelt Pronunciation: I-den-zelt Established name: aflibercept-boav Dosage form: injection Strength(s): 2 mg/0.05 mL Dosage: 2 mg every 4 weeks	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.	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.	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: Eydenzelt Pronunciation: I-den-zelt Established name: aflibercept-boav Dosage form: injection Strength(s): 2 mg/0.05 mL Dosage: 2 mg every 4 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.	Lenmeldy	56	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.	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
1.	N/A		

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.	Danziten***	55

[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/

SOFANIT N GETAHUN
12/11/2024 08:46:13 AM

VALERIE S VAUGHAN
12/11/2024 09:31:28 AM

IDALIA E RYCHLIK
12/11/2024 10:01:26 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	3/25/2024
Responsible OND Division:	Division of Ophthalmology (DO)
Application Type and Number:	BLA 761377
Product Name and Strength:	Eydenzelt (aflibercept-boav) injection, 2 mg/0.05 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Celltrion, Inc. (Celltrion)
FDA Received Date:	June 29, 2023
Nexus NPNS ID #:	2023-180
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Celltrion for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761377.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 29, 2023, Celltrion submitted a list of 5 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Celltrion also provided findings from their evaluation of the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Celltrion:

Table 1. Suffixes submitted by Celltrion***

1.	boav
2.	(b) (4)
3.	
4.	
5.	

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

2.1 aflibercept-boav

Celltrion's first proposed suffix, -boav, is comprised of 4 distinct letters.

We determined that the proposed suffix -boav, 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

[a] Nonproprietary Name Review Request and Supporting Analysis BLA 761377. Incheon (Republic of Korea): Celltrion, Inc.; 2023 Jun 29. Available from: \\CDSESUB1\EVSPROD\bla761377\0001\m1\us\nonproprietary-name.pdf

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

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 DMEPA 1 ANALYSIS

These findings were shared with OPDP. On March 13, 2024, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Ophthalmology (DO) on March 25, 2024.

4 CONCLUSION

We find Celltrion's proposed suffix -boav acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to aflibercept-boav. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Celltrion, Inc.

We find the nonproprietary name, aflibercept-boav, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, aflibercept-boav will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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

/s/

CARLOS M MENA-GRILLASCA
03/25/2024 12:05:22 PM

MISHALE P MISTRY
03/25/2024 01:38:34 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 5, 2023
Application Type and Number:	IND 147335 BLA 761377
Product Name and Strength:	Eydenzelt (aflibercept-xxxx) injection, 2 mg/0.05 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Celltrion Inc. (Celltrion)
PNR ID #:	2022-1044724550 (IND 147335) 2023-1044725168 (BLA 761377)
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Celltrion submitted the proposed proprietary name, Eydenzelt, under IND 147335 on April 19, 2022. Subsequently, Celltrion submitted the proposed proprietary name, Eydenzelt, under BLA 761377 on July 3, 2023. This review evaluates the proposed proprietary name, Eydenzelt, under both IND 147335 and BLA 761377.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 19, 2022, under IND 147335 and on July 3, 2023, under BLA 761377.

- Intended Pronunciation: I-den-zelt
- Nonproprietary Name: aflibercept-xxxx
- Indication of Use:
    - Neovascular (Wet) Age-related Macular Degeneration (AMD)
    - Macular Edema Following Retinal Vein Occlusion (RVO)
    - Diabetic Macular Edema (DME)
    - Diabetic Retinopathy (DR)
- Route of Administration: intravitreal injection
- Dosage Form: injection
- Strength: 2 mg/0.05 mL
- Dose and Frequency:
    - AMD: 2 mg intravitreally every 4 weeks for the first 12 weeks, followed by 2 mg intravitreally once every 8 weeks
    - RVO: 2 mg intravitreally every 4 weeks
    - DME and DR: 2 mg intravitreally every 4 weeks for the first five injections, followed by 2 mg intravitreally every 8 weeks
- How Supplied:
    - One prefilled syringe
    - One vial kit containing one 18-gauage x 1½-inch, 5 micron, filter needle, one 30-gauage x ½-inch injection needle, and one 1 mL syringe
- Storage: Refrigerate at 2°C to 8ºC (36°F to 46ºF). Do not freeze.

- Eydenzelt (aflibercept-xxxx) is a proposed [redacted] (b) (4) to US-licensed Eylea (aflibercept), BLA 125387.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 25, 2023, the Division of Ophthalmology (DO) did not forward any comments or concerns relating to Eydenzelt at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-two practitioners participated in DMEPA's prescription studies for Eydenzelt. 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.

[a] USAN stem search conducted on July 3, 2023.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 51 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. 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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	47
Low similarity name pair: combined match percentage score ≤54%	3

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

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

2.2.8 Communication of DMEPA's Determination

On August 30, 2023, DMEPA 1 communicated our determination to the Division of Ophthalmology (DO).

3 CONCLUSION

The proposed proprietary name, Eydenzelt, is conditionally acceptable.

If you have any questions or need clarifications, please contact Celia Williams, OSE project manager, at 301-796-0525.

3.1 COMMENTS TO CELLTRION INC.

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

If any of the proposed product characteristics as stated in your submission, received on July 3, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

[b] POCA search conducted on July 5, 2023 in version 5.2.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, 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[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign 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

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

with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

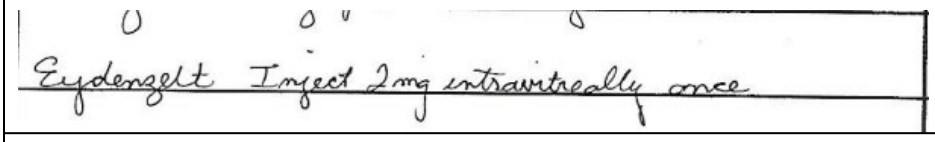
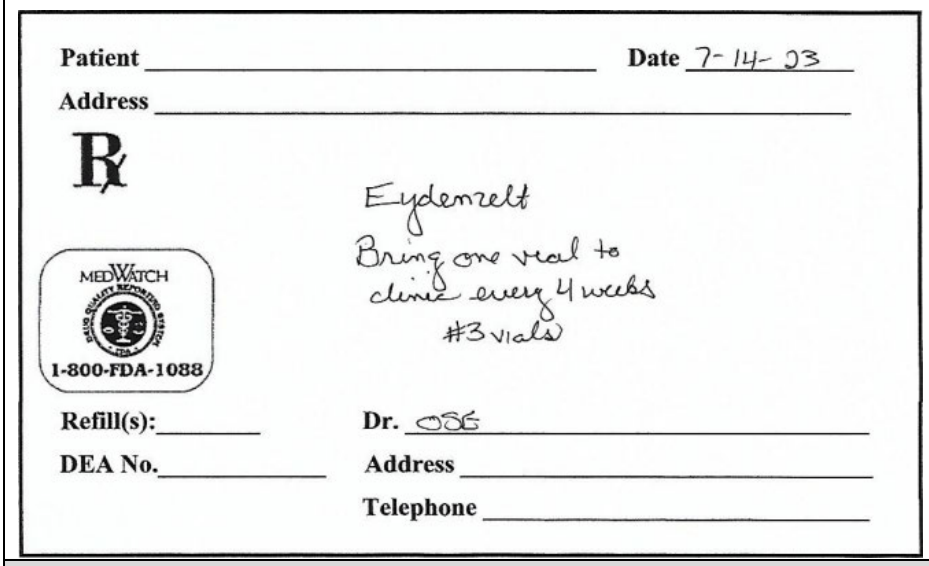
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Eydenzelt Study (Conducted on July 14, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Eydenzelt Bring 1 vial to clinic every 4 weeks Dispense 3 vials
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Eydenzelt	

FDA Prescription Simulation Responses (<u>Aggregate Report)</u>

Study Name: Eydenzelt					
Conducted on July 14, 2023					
253 People Received Study					
72 People Responded					
Total	**16**	**19**	**15**	**22**	**72**
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
EYDEMZELT	0	3	0	0	3
EYDENSELT	1	0	0	0	1
EYDENZELT	14	16	0	22	52
EYDENZELT INJECT	1	0	0	0	1
EYEDENZELT	0	0	1	0	1
IDENSELT	0	0	2	0	2
IDENZEL	0	0	1	0	1
IDENZELT	0	0	10	0	10
INDENZELT	0	0	1	0	1

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

No.	**Proposed name:** Eydenzelt **Established name:** aflibercept-xxxx **Dosage form:** injection **Strength(s):** 2 mg/0.05 mL **Usual Dose:** 2 mg every 4 or 8 weeks	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.	Eydenzelt	100	This name is the subject of this review.

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.	Banzel	58

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:** Eydenzelt **Established name:** aflibercept-xxxx **Dosage form:** injection **Strength(s):** 2 mg/0.05 mL **Usual Dose:** 2 mg every 4 or 8 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.	Osenvelt***	68	This name pair has sufficient orthographic and phonetic differences
2.	Benzodent	59	This name pair has sufficient orthographic and phonetic differences.
3.	Dentagel	58	This name pair has sufficient orthographic and phonetic differences.
4.	Dibenzyline	58	This name pair has sufficient orthographic and phonetic differences.
5.	End-Zit	58	This name pair has sufficient orthographic and phonetic differences.
6.	10 Benzagel	56	This name pair has sufficient orthographic and phonetic differences.
7.	5 Benzagel	56	This name pair has sufficient orthographic and phonetic differences.
8.	Benzagel	56	This name pair has sufficient orthographic and phonetic differences.
9.	Benzo-Jel	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Eydenzelt **Established name:** aflibercept-xxxx **Dosage form:** injection **Strength(s):** 2 mg/0.05 mL **Usual Dose:** 2 mg every 4 or 8 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**
10.	Denta 5000 Plus	56	This name pair has sufficient orthographic and phonetic differences.
11.	Ethedent	56	This name pair has sufficient orthographic and phonetic differences.
12.	Eye-Lert	56	This name pair has sufficient orthographic and phonetic differences.
13.	Benzaclin	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.	Medent	53

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.	Feldene Melt	68	International product marketed in the United Kingdom.
2.	Medent Ld	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Benziq Ls	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	Clenz-Lyte	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Ethylbenzene	60	Product is not a drug. It is an organic compound.
6.	Mepenzolate	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Benzyl Pca	59	Product is not a drug. It is an ingredient found in cosmetics.
8.	Eyepentolate	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
9.	Ed-In-Sol	58	Name identified in RxNorm database. Product is deactivated and there are no generics available.
10.	(b) (4)***	58	Proposed proprietary name found conditionally acceptable under IND (b) (4) (Panorama #: (b) (4) (b) (4) However, IND (b) (4) was withdrawn by the Sponsor on (b) (4)
11.	Benz-All	57	Product is not a drug. It is a germicidal product used for sterilization.
12.	Ethyl Benzoate	57	Product is not a drug. It is a simple ester of benzoic acid formed by the condensation of benzoic acid and ethanol.
13.	Benzoate	56	Product is not a drug. It is a food preservative and pickling agent.
14.	Feldene P	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Benzene	55	Product is not a drug. It is a compounding agent or homeopathic.
16.	Dibenzyl Ether	55	Product is not a drug. It is a benzyl ether derived from benzyl alcohol.
17.	Extendryl G	55	Name identified in RxNorm database. Product is deactivated and there are no generics available.
18.	Pipenzolate	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Hyteneze	54	International product formerly marketed in the United Kingdom
20.	Ethylene	48	Product is not a drug. It is an organic compound.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[e]

No.	Name	POCA Score (%)
1.	Rendells	58
2.	Danyelza	57
3.	Deconsal Ct	57
4.	Merbentyl	57
5.	Adynovate	56
6.	Deconsal C	56

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

No.	Name	POCA Score (%)
7.	Dexilant	56
8.	Tedizolid	56
9.	Tencet	56
10.	Yondelis	56
11.	Zynrelef	56
12.	Diatensec	55
13.	Doptelet	55
14.	Hydone Tablet	55
15.	(b) (4) ***	55

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/s/

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