CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

220018Orig1s000
220020Orig1s000

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:	February 19, 2025
Application Type and Number:	NDA 220018 NDA 220020
Product Name, Dosage Form, and Strength:	Yeztugo (lenacapavir) Injection, 463.5 mg/1.5 mL (309 mg/mL) Tablet, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Sciences, Inc. (Gilead)
PNR ID #:	2024-1044726184 2024-1044726183
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia Rychlik, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Yeztugo, which was found conditionally acceptable under IND 153858 on November 6, 2024.[a] Thus, Gilead submitted the proposed proprietary name, Yeztugo, under NDA 220018 and NDA 220020 for re-review on December 19, 2024.[b] We note that all product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yeztugo 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 Yeztugo. The Division of Antivirals (DAV) did not comment on the findings of OPDP's assessment for Yeztugo.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Yeztugo, 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 stems as of the last USAN updates. The December 23, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Yeztugo[c].

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On February 19, 2025, DMEPA 1 communicated our determination to the Division of Antivirals (DAV).

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, Yeztugo, is conditionally acceptable.

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[a] Fanari, M. Proprietary Name Review for Yeztugo (IND 153858). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Nov 6. PNR ID No. 2024-1044725845.

[b] Request for Proprietary Name Review (NDA 220018 and NDA 220020; Yeztugo). Foster City (CA): Gilead; 2024 Dec 19. Available from: \\CDSESUB1\evsprod\NDA220018\0003\m1\us\12-cover-letters and \\CDSESUB1\evsprod\NDA220020\0003\m1\us\12-cover-letters.

[c] USAN stem search conducted on 12/23/2024

3.1 COMMENTS TO GILEAD

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

If any of the proposed product characteristics as stated in your submission, received on December 19, 2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 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.

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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02/19/2025 12:45:17 PM

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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:	November 6, 2024
Application Type and Number:	IND 153858
Product Name, Dosage Form, and Strength:	Yeztugo (lenacapavir) Tablet, 300 mg Injection, 463.5 mg/1.5 mL (309 mg/mL)
Product Type:	Single Ingredient Product Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Sciences, Inc. (Gilead)
PNR ID #:	2024-1044725845
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia Rychlik, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Gilead previously submitted the proposed proprietary name, (b) (4) *** under IND 153858 on March 28, 2024. However, on May 15, 2024, we found the name, (b) (4) *** unacceptable due to misbranding concerns with the proprietary name[b].

Thus, Gilead submitted the proposed proprietary name, Yeztugo, for review on June 14, 2024 under IND 153858.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 14, 2024[c]

Table 1. Relevant Product Information for Yeztugo	
Intended pronunciation:	Yez-TOO-go
Active ingredient:	lenacapavir
Indication:	HIV-1 pre-exposure prophylaxis (PrEP) in adults and adolescents
Dosage Form:	Tablet and Injection
Strength:	Tablet: 300 mg Injection: 463.5 mg/1.5 mL (309 mg/mL)
Route of administration:	Oral and Subcutaneous
Dose and frequency:	Oral Loading Dose: 600 mg (2x 300 mg tablets) on Day 1 and 2 Maintenance Dose: 927 mg (2x 463.5 mg/1.5 mL injections) Day 1 and every 6 months

(b) (4)

[b] Fanari, M. Proprietary Name Review for Yeztugo (IND 153858). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2024 May 15. PNR ID No. 2024- 1044725704

[c] Request for Proprietary Name Review (IND 153858; Yeztugo). Foster City (CA): Gilead Sciences, Inc.; 2024 Jun 14. Available from: \\CDSESUB1\evsprod\IND153858\0123\m1\us.

Table 1. Relevant Product Information for Yeztugo	
How Supplied:	Tablet: 4 count bottles Injection: Vial kit containing 2 lenacapavir vials (463.5 mg/1.5 mL), 2 syringes, 2 withdrawal needles and 2 needles for administration (b) (4)
Storage:	Store bottle and injection in original packaging at 20°C-25°C (68°F–77°F), excursions permitted to 15°C–30°C (59°F–86°F) (see USP Controlled Room Temperature)
Reference Listed Drug:	NDA 215974- Sunlenca (lenacapavir) Tablets 300 mg NDA 215973-Sunlenca (lenacapavir) Injection 463.5 mg/1.5 mL (309 mg/mL)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Yeztugo 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 Yeztugo. The Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Yeztugo.

2.2 SAFETY ASSESSMENT

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

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

Gilead indicated in their submission that the proposed proprietary name, Yeztugo, is a combination of letters that is devoid of meaning. This proprietary name is comprised of a single that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

[d] USAN stem search conducted on October 17, 2024.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On July 11, 2024, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Yeztugo at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-one (n=91) practitioners participated in DMEPA's prescription simulation studies for Yeztugo. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[e] identified 5 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. 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 and (b) (4) external study. 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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	4
Low similarity name pair: combined match percentage score ≤54%	4

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

Our analysis of the 9 names contained in Table 2 determined none of the names will pose a risk for confusion with Yeztugo as described in Appendices C through H.

2.2.8 DISCUSSION OF DUAL PROPRIETARY NAMES

Gilead proposes the name Yeztugo, a dual proprietary name for lenacapavir. Gilead currently markets lenacapavir tablets and injection under the proprietary name Sunlenca (NDA 215974 & NDA 215973) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

[e] POCA search conducted on October 17, 2024 in version 5.9.

Table 3 compares the proposed name Yeztugo with the currently approved Sunlenca[f] and their respective product characteristics.

Table 3. Relevant Product Information for Yeztugo and Sunlenca		
Product Name	Yeztugo	Sunlenca
Application	IND 153858	NDA 215974, NDA 215973
Intended Pronunciation	Yez-TOO-go	sun-LEN-kuh
Active Ingredient	Lenacapavir	
Indication	HIV-1 pre-exposure prophylaxis (PrEP) in adults and adolescents	Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations
Route of Administration	Oral and Subcutaneous	
Dosage Form	Tablet and Injection	
Strength	300 mg Tablet and 463.5 mg/1.5 mL (309 mg/mL) injection	
Dose and Frequency	Oral Loading Dose: 600 mg (2x 300 mg tablets) on Day 1 and 2 Maintenance Dose: 927 mg (2x 463.5 mg/1.5 mL injections) Day 1 and every 6 months	Initiation with one of two options followed by once every 6-months maintenance dosing. Tablets may be taken without regard to food. <u>Initiation Option 1</u> Day 1- 927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 tablets) Day 2- 600 mg orally (2 tablets) <u>Initiation Option 2</u> Day 1-600 mg orally (2 tablets) Day 2-600 mg orally (2 tablets) Day 8-300 mg orally (1 tablet) Day 15-927 mg by subcutaneous injection (2 x 1.5 mL injections) <u>Maintenance</u>

[f] Sunlenca [Prescribing Information]. DailyMed. U.S. National Library of Medicine. July 2024. [cited 2024 Sept 19]. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e5652804-29c4-40d7-aeb2-0142ed2a7b5b

Table 3. Relevant Product Information for Yeztugo and Sunlenca		
Product Name	Yeztugo	Sunlenca
		927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/-2 weeks.
How Supplied	Tablet: 4 count and 5 count blister packs and 4 count bottles* Injection: Vial kit** containing 2 lenacapavir vials (463.5 mg/1.5 mL), 2 syringes, 2 withdrawal needles and 2 needles for administration	
Storage	Store bottle, blister packs and injection in original packaging at 20 °C – 25 °C (68 °F – 77 °F), excursions permitted to 15 °C – 30 °C (59 °F – 86 °F) (see USP Controlled Room Temperature)	

**Bottle configuration approved 7/22/2024 (NDA 215974/S06)*

(b) (6)

In the request for proprietary name review, Gilead provided the following justifications to support a new proprietary name for lenacapavir for the HIV PrEP indication:

> "A different proprietary name for LEN for PrEP will help prevent prescribing errors, such as inappropriate use of a 14-day oral lead-in, which has not been studied for PrEP; facilitate prevention-specific guidance for HIV testing prior to initiation, during re-initiation, and guidance for HIV prevention options after discontinuation; reduce the stigma associated with taking a drug that is known primarily as HIV-1 treatment; and track real world use of LEN for PrEP".

We have evaluated the risks associated with this naming strategy and do not object to the use of a dual proprietary name in this case. Further, the Division of Antivirals (DAV) did not have any objections to the dual proprietary naming strategy for lenacapavir.

2.2.9 COMMUNICATION OF DMEPA'S DETERMINATION

On November 4, 2024, DMEPA 1 communicated our determination to the Division of Antivirals (DAV).

3 CONCLUSION

The proposed proprietary name, Yeztugo, is conditionally acceptable.

3.1 COMMENTS TO GILEAD SCIENCES, INC.

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

A request for proprietary name review for Yeztugo should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on June 14, 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.[g]

*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.

[g] 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[h]. 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.

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

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 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?		

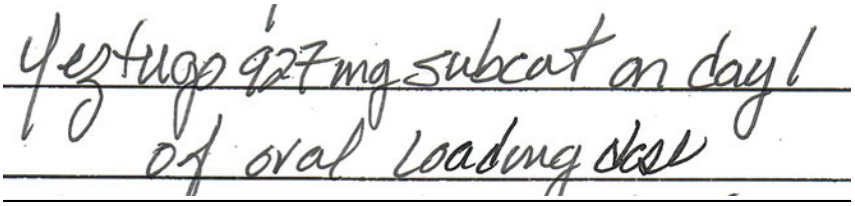
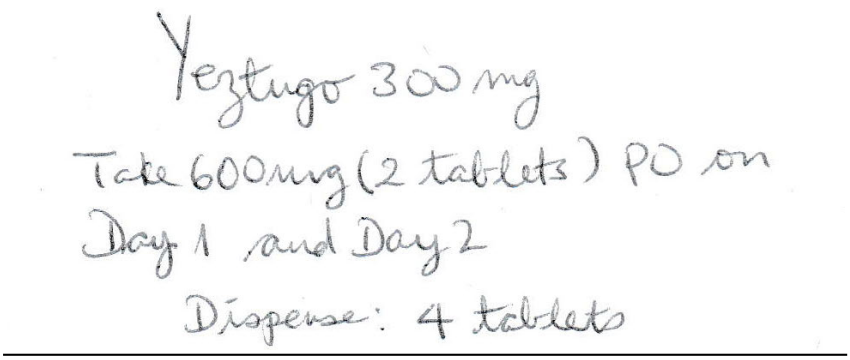
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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	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: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

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. Yeztugo Study (Conducted on 7/16/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Yeztugo 300 mg Take 600 mg (2 tablets) on Day 1 and Day 2
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Yeztugo	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Yeztugo - 2024-07-16 People Received Study: 191 People Responded:91					
Total	26	21	19	25	91
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
FEZTUGO	1	0	0	0	1
IEZTUOP	1	0	0	0	1

YASTUGO	0	0	2	0	2
YERTUGO	0	1	0	0	1
YES TO GO	0	0	1	0	1
YES-2-GO	0	0	1	0	1
YESTOGO	0	0	6	0	6
YESTUGO	0	0	9	0	9
YEZTUGO	17	20	0	25	62
YEZTUGS	2	0	0	0	2
YEZTUOP	4	0	0	0	4
YEZTUOP 927 MG	1	0	0	0	1

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

No.	Proposed name: Yeztugo Pronunciation: Yez-TOO-go Established name: lenacapavir Dosage form: tablet and injection Strength(s): 300 mg tablet and 463.5 mg/mL injection Dosage: 600 mg (2x 300 mg tablets) on Day 1 and 2, 927 mg (2x 463.5 mg/1.5 mL) on Day 1 and every 6 months thereafter	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.	Yeztugo	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-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-N/A

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Delstrigo	48
2.	Yasmin	34
3.	Yaz	26
4.	Yuperli	26

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	59	Proposed proprietary name (b) (4)

No.	Name	POCA Score (%)	Failure preventions
2.	(b) (4) ***	58	Proposed proprietary name for (b) (4)

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion[i].

No.	Name	POCA Score (%)
1.	Zynteglo	60
2.	Cyltezo	58

[i] 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

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