CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213426Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	July 12, 2021
Application Type and Number:	NDA 213426
Product Name and Strength:	Seglentis (celecoxib and tramadol) tablet, 56 mg/44 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Esteve Pharmaceuticals, S.A. (Esteve)
PNR ID #:	2021-1044723930
DMEPA 1 Safety Evaluator:	Cameron Johnson, PharmD
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Division Director (Acting):	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review re-evaluates the proposed proprietary name, Seglentis, 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. Esteve submitted an external name study, conducted by [redacted] for this proposed proprietary name. The study was evaluated in our previous review of the name.

1.1 REGULATORY HISTORY

Esteve previously submitted the proposed proprietary name, [redacted] on April 23, 2019. However, we found the name, [redacted] unacceptable [redacted]

Esteve then submitted the proposed proprietary name, [redacted] on September 20, 2019. However, we found the name, [redacted] unacceptable [redacted]

Esteve then submitted the proposed proprietary name, Seglentis, on January 23, 2020. We found the name, Seglentis, conditionally acceptable on April 2, 2020.[c] However, NDA 213426 received a Complete Response (CR) due to a facility inspection deficiency.

On April 16, 2021, Esteve submitted their response to the deficiency in the CR letter as a class 2 resubmission. In the class 2 resubmission, Esteve also resubmitted the name, Seglentis, for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 16, 2021.

- Intended Pronunciation: Seg-len-tus
- Active Ingredient: celecoxib and tramadol
- Indication of Use: the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate
- Route of Administration: oral
- Dosage Form: tablet

---

[a] Myers, Deb. Proprietary Name Review for [redacted] (IND 128177). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 SEP 03. Panorama No. 2019-30983314.

[b] Johnson, C. Proprietary Name Review for [redacted] (NDA 213426). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);. 2019 OCT 23. Panorama No. 2019-34589634.

[c] Johnson, C. Proprietary Name Review for Seglentis (NDA 213426). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);. 2020 APR 02. Panorama No. 2019-37340409.

- Strength: 56 mg/44 mg
- Dose and Frequency: 2 tablets every 12 hours as needed for pain relief
- How Supplied: bottles of 30 tablets; bottles of 90 tablets
- Storage: USP Controlled Room Temperature

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Seglentis would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Seglentis.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On May 5, 2021, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Seglentis at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-four (74) practitioners participated in DMEPA's prescription studies for Seglentis. 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. However, we note that one participant from the outpatient prescription study who interpreted the name as "Seglantis" commented that the name was "too similar to Lantus". We evaluated this name pair

[d] USAN stem search conducted on May 4, 2021.

(Seglentis vs. Lantus) for orthographic and phonetic confusion (see Appendix E) and find that there is sufficient orthographic and phonetic differences between this name pair. 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 174 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in 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 12 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	10
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 thirteen (13) names contained in Table 1 determined none of the names will pose a risk for confusion with Seglentis as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 1 communicated our findings to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP). At that time we also requested additional information or concerns that could inform our review. On July 1, 2021, the Division of Anesthesiology, Addiction

[e] POCA search conducted on May 4, 2021 in version 4.4.

Medicine, and Pain Medicine (DAAP) stated no additional concerns with the proposed proprietary name, Seglentis.

3 CONCLUSION

The proposed proprietary name, Seglentis, is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO ESTEVE PHARMACEUTICALS, S.A.

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

If any of the proposed product characteristics as stated in your submission, received on April 16, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

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

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

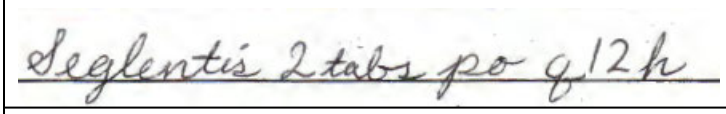
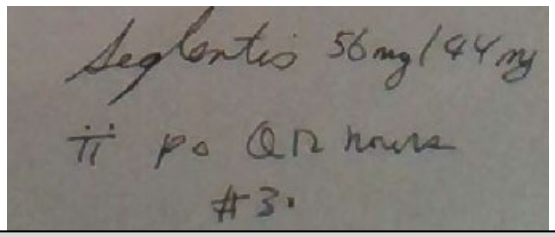
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Seglentis Study (Conducted on April 30, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Seglentis 56 mg/44 mg Take 2 tablets by mouth every 12 hours Dispense 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Seglentis	

FDA Prescription Simulation Responses (Aggregate Report)

205 People Received Study
74 People Responded

Study Name: Seglentis

Total	**19**	**18**	**22**	**15**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
SECLANTUS	0	0	1	0	1
SEGLANTES	1	0	0	0	1
SEGLANTIS	4	0	0	0	4
SEGLEMPTIS	0	0	2	0	2
SEGLENTES	0	0	1	0	1
SEGLENTIS	13	18	9	14	54
SEGLENTIX	0	0	1	0	1
SEGLETNTIS	0	0	0	1	1
SEHLENTIS	1	0	0	0	1
SENGLENTIS	0	0	2	0	2

SENGLYPTIS	0	0	1	0	1
SENLENGIZ 56MG/44MG	0	0	1	0	1
SIBLENTEZ	0	0	1	0	1
SIGLENTIS	0	0	1	0	1
SYGLENTIS	0	0	1	0	1
ZENLEFTINCE	0	0	1	0	1

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

No.	**Proposed name:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
	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:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4)***	59	This name pair has sufficient orthographic and phonetic differences.
3.	Sleep Tabs	58	This name pair has sufficient orthographic and phonetic differences.
4.	Selumetinib	56	This name pair has sufficient orthographic and phonetic differences.
5.	Scemblix***	55	This name pair has sufficient orthographic and phonetic differences.
6.	Lantus	53	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.	Nextstellis	52

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

No.	Name	POCA Score (%)	Failure preventions
1.	Gleptosil	59	Veterinary product indicated for the prevention and treatment of iron deficiency anemia in piglets.
2.	(b) (4) ***	56	(b) (4) was the (b) (4) proposed proprietary name (b) (4) (b) (4) *** submitted under NDA 213801. However, (b) (4) was withdrawn by the Applicant and the product was approved under the name Myrbetriq Granules.
3.	Telmesteine	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Peg-10 Lanolin	58
2.	Peg-70 Lanolin	58
3.	Xylimelts	56

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

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

/s/

CAMERON D CLARK
07/12/2021 11:37:44 AM

VALERIE S VAUGHAN
07/12/2021 12:37:09 PM

IRENE Z CHAN
07/12/2021 02:52:26 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 2, 2020
Application Type and Number:	NDA 213426
Product Name and Strength:	Seglentis (celecoxib and tramadol) tablet, 56 mg/ 44 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Esteve Pharmaceuticals, S.A. (Esteve)
Panorama #:	2020-37340409
DMEPA Safety Evaluator:	Cameron Johnson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Esteve previously submitted the proposed proprietary name, (b) (4) *** on April 23, 2019. However, we found the name, (b) (4) *** unacceptable (b) (4)

Esteve then submitted the proposed proprietary name, (b) (4) *** on September 20, 2019. However, we found the name, (b) (4) *** unacceptable (b) (4)

Thus, Esteve submitted the name, Seglentis, for review on January 23, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 23, 2020.

- Intended Pronunciation: Seg-len-tus
- Active Ingredient: celecoxib and tramadol
- Indication of Use: The management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 56 mg/ 44 mg
- Dose and Frequency: 2 tablets by mouth every 12 hours as needed for pain
- How Supplied: bottles of 30 and 90 tablets
- Storage: Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F)

---

[a] Myers, D. Proprietary Name Review for (b) (4) (IND 128177). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);. 2019 SEP 03. Panorama No. 2019-30983314.

[b] Johnson, C. Proprietary Name Review for (b) (4) (NDA 213426). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US);. 2019 OCT 23. Panorama No. 2019-34589634.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Seglentis would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Seglentis.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 4, 2020 e-mail, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Seglentis at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

76 practitioners participated in DMEPA's prescription studies for Seglentis. One response did sound similar to a product in the pipeline. One participant interpreted "Seglentis" as "Taglentis" in the simulated verbal prescription study which is similar to the pending proprietary name (b) (4) ***" that is also currently under review. We evaluated this name pair for phonetic confusion (see Appendix C) and found it acceptable. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 162 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.

[c] USAN stem search conducted on March 10, 2020.

[d] POCA search conducted on January 28, 2020 in version 4.3.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	4
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	152
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 168 names contained in Table 1 determined none of the names will pose a risk for confusion with Seglentis as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) via e-mail on April 1, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) on April 1, 2020, they stated no additional concerns with the proposed proprietary name, Seglentis.

3 CONCLUSION

The proposed proprietary name, Seglentis, is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO ESTEVE PHARMACEUTICALS, S.A.

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

If any of the proposed product characteristics as stated in your submission, received on January 23, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

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

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

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

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. 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.

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

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

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

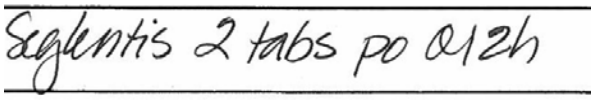
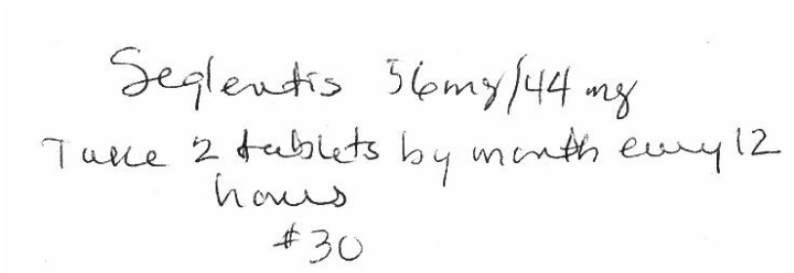
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Seglentis Study (Conducted on February 7, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Seglentis 56 mg/44 mg Take 2 tablets by mouth every 12 hours Dispense # 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Seglentis	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Seglentis
As of Date 3/10/2020

212 People Received Study
76 People Responded

Study Name: Seglentis

Total	27	14	15	20	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
GEGLEATIS	1	0	0	0	1
GLENTES	0	0	1	0	1
SAGLENTIS	0	0	3	1	4
SEGLEATIS	1	0	0	0	1
SEGLENTAS	0	0	1	0	1
SEGLENTIS	16	13	4	18	51
SEGLENTIS 56 MG/44 MG	1	0	0	0	1
SEGLENTIS 56MG/44MG	0	0	1	0	1
SEGLEUTIS	2	0	0	0	2
SEGLEVTIS	3	0	0	0	3
SEGLUROMET	0	1	0	0	1
SELENTIS	0	0	0	1	1
SEQLENTIS	2	0	0	0	2
SEQLEVTIS	1	0	0	0	1
SIGLENTIS	0	0	1	0	1
STEGLENTIS	0	0	1	0	1
SYGLENTIS	0	0	1	0	1
TAGLENTIS	0	0	1	0	1
ZAGLENTIS	0	0	1	0	1

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

No.	**Proposed name:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/ 44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	**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.	Seglentis***	100	Name is subject of this review.
2.	Semilente	72	Brand discontinued with no generic equivalents available. NDA 018382 withdrawn, FR effective 09/04/1996. NDA 017996 withdrawn, FR effective 9/25/1997.
3.	Serentil	70	Brand discontinued with no generic equivalents available. NDA 016774 withdrawn FR effective 03/26/2018. NDA 016775 withdrawn FR effective 3/26/2018. NDA 016997 withdrawn FR effective 3/26/2018.
4.	(b) (4) ***	74	(b) (4)

No.	**Proposed name:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/ 44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	**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.**
			(b) (4)

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 (%)
5.	Symlinpen 60	64
6.	Symlinpen 120	64
7.	Symlinpen	64
8.	Lucentis	65
9.	Sitagliptin	60
10.	Solfenacin	55
11.	Steglatro	57
12.	Steglujan	56
13.	Segluromet	62
14.	Skelaxin	56
15.	Ongentys***	62
16.	Isentress	58
17.	Reglan ODT	61

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:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/ 44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	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**
18.	(b) (4)***	69	This name pair has sufficient orthographic and phonetic differences.
19.	Sesquient***	57	This name pair has sufficient orthographic and phonetic differences.
20.	Salonpas	59	This name pair has sufficient orthographic and phonetic differences.
21.	Genistein	55	This name pair has sufficient orthographic and phonetic differences.
22.	Selenium	60	This name pair has sufficient orthographic and phonetic differences.
23.	Gentlax S	59	This name pair has sufficient orthographic and phonetic differences.
24.	Gent-L-Tip	59	This name pair has sufficient orthographic and phonetic differences.
25.	Libetist	62	This name pair has sufficient orthographic and phonetic differences.
26.	Augmentin Es-600	56	This name pair has sufficient orthographic and phonetic differences.
27.	Saline Mist	62	This name pair has sufficient orthographic and phonetic differences.
28.	Secretin	63	This name pair has sufficient orthographic and phonetic differences.
29.	Selzentry	62	This name pair has sufficient orthographic and phonetic differences.
30.	Semaglutide	56	This name pair has sufficient orthographic and phonetic differences.
31.	Senexon S	56	This name pair has sufficient orthographic and phonetic differences.
32.	Senna Leaves	55	This name pair has sufficient orthographic and phonetic differences.
33.	Sennalax S	56	This name pair has sufficient orthographic and phonetic differences.
34.	Sinucleanse	56	This name pair has sufficient orthographic and phonetic differences.
35.	Sleeptabs	58	This name pair has sufficient orthographic and phonetic differences.
36.	Sprintec	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/ 44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	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**
37.	Stingeze	55	This name pair has sufficient orthographic and phonetic differences.
38.	Selenos	68	This name pair has sufficient orthographic and phonetic differences.
39.	Gleostine	56	This name pair has sufficient orthographic and phonetic differences.
40.	Elestrin	56	This name pair has sufficient orthographic and phonetic differences.
41.	Elinest	57	This name pair has sufficient orthographic and phonetic differences.
42.	Gentasol	56	This name pair has sufficient orthographic and phonetic differences.
43.	S-2 Inhalant	55	This name pair has sufficient orthographic and phonetic differences.
44.	Sedalmex	56	This name pair has sufficient orthographic and phonetic differences.
45.	Selexipag	56	This name pair has sufficient orthographic and phonetic differences.
46.	Setlakin	61	This name pair has sufficient orthographic and phonetic differences.
47.	Shur-Clens	58	This name pair has sufficient orthographic and phonetic differences.
48.	Sildenafil	56	This name pair has sufficient orthographic and phonetic differences.
49.	Sinemet	58	This name pair has sufficient orthographic and phonetic differences.
50.	Sleep-Ettes	61	This name pair has sufficient orthographic and phonetic differences.
51.	Strensiq	62	This name pair has sufficient orthographic and phonetic differences.
52.	(b) (4) ***	62	This name pair has sufficient orthographic and phonetic differences.
53.	Celontin	66	This name pair has sufficient orthographic and phonetic differences.
54.	Dilantin	56	This name pair has sufficient orthographic and phonetic differences.
55.	Dilantin-125	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Seglentis **Established name:** celecoxib and tramadol **Dosage form:** tablet **Strength(s):** 56 mg/ 44 mg **Usual Dose:** 2 tablets by mouth every 12 hours as needed for pain	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**
56.	Clenpiq	56	This name pair has sufficient orthographic and phonetic differences.
57.	Cogentin	60	This name pair has sufficient orthographic and phonetic differences.
58.	Tecentriq	56	This name pair has sufficient orthographic and phonetic differences.
59.	Pegloticase	62	This name pair has sufficient orthographic and phonetic differences.
60.	(b) (4) ***	57	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 (%)
61.	Selegiline	51
62.	Genahist	50
63.	Selenomethionine Se 75	46
64.	Gel-Tin	53
65.	Synagis	50
66.	Lantus	53
67.	Glynase	54
68.	Celexa	44
69.	Synvisc	45
70.	Cephalexin	48

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
71.	(b) (4) ***	68	(b) (4)

No.	Name	POCA Score (%)	Failure preventions
72.	Gentisate	56	International product marketed in Germany and Italy.
73.	Genestin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
74.	Genesis	60	Veterinary product for the control of pruritus associated with allergic dermatitis in dogs.
75.	Lente Insulin	51	Brand discontinued with no generic equivalents available. NDA 017998 withdrawn FR effective 08/07/1997.
76.	Stilbetin	60	Brand discontinued with no generic equivalents available. NDA 004056 withdrawn FR effective 09/13/2000.
77.	Selenocysteine	54	This is not a drug. This is a proteinogenic amino acid containing selenium.
78.	Selamectin	62	Veterinary product for treatment of parasitic infections in dogs and cats.
79.	Salinex	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available
80.	Sebulex	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available
81.	Serenus	57	Veterinary product used as a horse calming supplement.
82.	Sinuvent	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
83.	Sinuvent Pe	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
84.	Solvent Red 27	58	This is not a drug. This is used to color different products.
85.	Streptase	56	This is not a drug. This is a group of crystal structures that form the mineral gypsum.
86.	Selenite	67	This is not a drug. This is a group of crystal structures that form the mineral gypsum.
87.	Selenite Ion	64	This is not a drug. This is the ion of a group of crystal structures that form the mineral gypsum.
88.	Selegilene	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. This name may represent a misspelled version of the established name, selegiline, which is evaluated in this review.
89.	Selenate Ion	63	This is not a drug. This is an ion of the compound selenate, which is an analog to sulfates.

No.	Name	POCA Score (%)	Failure preventions
90.	Semilente Insulin	56	Brand discontinued with no generic equivalents available. NDA 018382 withdrawn, FR effective 09/04/1996. NDA 017996 withdrawn, FR effective 9/25/1997.
91.	Glibenese	60	International product marketed in United Kingdom, France, Belgium and Poland.
92.	Stemetil	59	International product marketed in several countries.
93.	Salutensin	60	Brand discontinued with no generic equivalents available. NDA 12359 withdrawn FR effective 06/04/2004.
94.	Sani-Clens	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
95.	Selepen	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
96.	Serdolect	56	International product marketed in several countries.
97.	Silanetriol	56	This is not a drug. This is a latex polymer used in cosmetic products.
98.	Silicones	58	This is not a drug. This is a synthetic chemical compound used in sealants, adhesives, lubricants, medicines and other products.
99.	Slentrol	60	Veterinary product used for management of obesity in dogs.
100.	Solvent Red 4	58	This is not a drug. This is used to color different products.
101.	Stintisone	58	International product marketed in several countries.
102.	(b) (4) ***	64	Proposed proprietary name for IND 58356 found acceptable by DMEPA (OSE #2007-49). However, the Sponsor withdrew the name on February 15, 2017 and proposed the proprietary name, Nourianz. NDA 22075 approved under the proprietary name Nourianz.
103.	(b) (4) ***	58	Proposed proprietary name for IND 105453 found unacceptable by DMEPA (OSE# 2017-16225443). NDA 210656 approved under the proprietary name Daurismo.
104.	Beegentle	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Dilantin-30	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
106.	Genticin	56	International product marketed in several countries.

No.	Name	POCA Score (%)	Failure preventions
107.	Pentids 250	57	Brand discontinued with no generic equivalents available. ANDA 62155 withdrawn FR effective 11/25/1992.
108.	Pentids 800	57	Brand discontinued with no generic equivalents available. ANDA 62155 withdrawn FR effective 11/25/1992.
109.	Galenamet	55	International product marketed in United Kingdom and formerly marketed in Ireland.
110.	Pentids 200	57	Brand discontinued with no generic equivalents available. ANDA 62149 and ANDA 62155 withdrawn FR effective 11/25/1992.
111.	Pentids 400	57	Brand discontinued with no generic equivalents available. ANDA 62149 and ANDA 62155 withdrawn FR effective 11/25/1992.
112.	Plenaxis	60	Brand discontinued with no generic equivalents available. NDA 21320 withdrawn FR effective 08/19/2013.
113.	Timentin	57	Brand discontinued with no generics available. NDA 050590 withdrawn FR effective 7/21/2017.

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

No.	Name	POCA Score (%)
114.	Beclomist	57
115.	Belinostat	56
116.	Bellamine S	56
117.	Betalin S	57
118.	Cedilanid-D	56
119.	Celestone	57
120.	Cenestin	58
121.	Cetrimides	58
122.	Cholestin	56
123.	(b) (4) ***	58
124.	Clindesse	58
125.	Clindets	62
126.	Clinistat	56

[g] 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 (%)
127.	Clintabs	58
128.	Colestid	55
129.	Cycloset	56
130.	Declinax	56
131.	Depletite	56
132.	Diclegis	62
133.	E.E.S. Granules	56
134.	E-Glades	62
135.	Eliglustat	58
136.	Enlon-Plus	58
137.	Fer-Gen-Sol	56
138.	Ferretts Ips	56
139.	Gelatin	55
140.	Genatuss	56
141.	Gen-Lanta	60
142.	Gen-Lanta Ii	57
143.	Glister	58
144.	Glyset	55
145.	Green-Tussin	60
146.	Inveltys	56
147.	(b) (4) ***	58
148.	Isodettes	55
149.	Isolyte S	58
150.	Little Noses	64
151.	Lotensin	56
152.	Miglustat	56
153.	Milantex	55
154.	Peg-60 Lanolin	58
155.	Peg-75 Lanolin	58
156.	Peg-Lyte	56
157.	Penbritin-S	55
158.	Reclipsen	57
159.	Renflexis	59
160.	Tegrin Plus	66
161.	Tegsedi	56
162.	Tiglutik	59
163.	Tiglutik Kit	57
164.	Tolectin	55
165.	Tolectin 600	55
166.	Tolectin Ds	58
167.	Tolinase	55
168.	Wigrettes	58

APPEARS THIS WAY ON ORIGINAL

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/

CAMERON D JOHNSON
04/02/2020 03:12:21 PM

OTTO L TOWNSEND
04/02/2020 03:47:46 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	October 23, 2019
Application Type and Number:	NDA 213426
Product Name and Strength:	(b) (4) (celecoxib and tramadol hydrochloride) tablets, 56 mg/44 mg
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Esteve Pharmaceuticals, S.A, (Esteve)
Panorama #:	2019-34589634
DMEPA Safety Evaluator:	Cameron Johnson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

3 Pages have been Withheld in Full as B4 (CCI/TS) immediately following this page

---

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/

CAMERON D JOHNSON
10/23/2019 11:51:23 AM

OTTO L TOWNSEND
10/23/2019 12:32:39 PM