CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761184Orig1s000

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:	March 22, 2023
Application Type and Number:	BLA 761184
Product Name and Strength:	Ngenla (somatrogon-xxxx)[a] injection, 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer Ireland Pharmaceuticals (Pfizer)
PNR ID #:	2023-1044725003
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director	Mishale Mistry, PharmD, MPH

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, (b) (4) is used throughout this review.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ngenla, which was found unacceptable under BLA 761184 on January 25, 2023.[b] The proposed proprietary name, Ngenla, was found to be vulnerable to medication errors due to confusion with another product, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Ngenla, was dependent upon which underlying application was approved first.

Furthermore, DMEPA 1 evaluated the status of the underlying application of the conflicting name, (b) (4)***. We determined that (b) (4)*** was no longer a potential conflict with Ngenla because the Applicant for (b) (4)*** would proceed with another proprietary name for their product.

Thus, Pfizer resubmitted the proposed proprietary name, Ngenla, for review.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 1 evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA 1 searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 2, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Based upon our safety assessment of the proposed proprietary name, Ngenla, the application goal date for BLA 761184, and the information regarding the Applicant for (b) (4)*** proceeding with an alternate proprietary name for review, we find Ngenla conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S 1 DETERMINATION

DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE) via e-mail on March 22, 2023.

3 CONCLUSIONS

We conclude that the proposed proprietary name, Ngenla, is conditionally acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO FULL APPLICANT/SPONSOR NAME

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

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[b] Rahbani P. Proprietary Name Review for Ngenla*** (BLA 761184). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2023 Jan 25. PNR ID#: 2022-1044724855.

If any of the proposed product characteristics as stated in your submission, received on February 17, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN 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/

PEGGY M RAHBANI
03/22/2023 03:07:08 PM

MADHURI R PATEL
03/22/2023 05:08:48 PM

MISHALE P MISTRY
03/22/2023 07:39:58 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	3/1/2023
Responsible OND Division:	Division of General Endocrinology (DGE)
Application Type and Number:	BLA 761184
Product Name and Strength:	(somatrogon-ghla) injection 24 mg/1.2 mL (10 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Pfizer Ireland Pharmaceuticals (Pfizer)
Nexus NPNS ID #:	2022-144
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -ghla, for BLA 761184, which was found conditionally acceptable on July 15, 2021[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761184.

1.1 Regulatory History

We found the proposed four-letter suffix, -ghla, conditionally acceptable for BLA 761184 on July 15, 2021[a]. However, BLA 761184 received a Complete Response (CR) letter on January 21, 2022[b]. Thus, Pfizer submitted a Class 2 Resubmission on November 22, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

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

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

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On March 1, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of General Endocrinology (DGE) on March 1, 2023.

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[a] Mena-Grillasca, C.M. Nonproprietary Name Suffix Review for somatrogon-ghla (BLA 761184). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jul 15. Nexus NPNS ID No.: 2020-33.

[b] Yanoff, L.B. Complete Response (BLA 761184). Silver Spring (MD): FDA, CDER, OND, OCHEN (US); 2022 Jan 21.

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

4 CONCLUSION

We find the suffix -ghla acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to somatrogon-ghla. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Pfizer Ireland Pharmaceuticals

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

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

/s/

CARLOS M MENA-GRILLASCA
03/01/2023 05:50:01 PM

MISHALE P MISTRY
03/03/2023 09:30:33 AM

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:	January 25, 2023
Application Type and Number:	BLA 761184
Product Name and Strength:	Ngenla (somatrogon-xxxx)[a] injection, 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer Ireland Pharmaceuticals (Pfizer)
PNR ID #:	2022-1044724855
DMEPA 1 Safety Evaluator:	Peggy Rahbani, PharmD, BCPS
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, somatrogon-xxxx, is used throughout this review.

Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 1
2.1 Misbranding Assessment 1
2.2 Safety Assessment 1
3 CONCLUSION 1
3.1 Comments to the Applicant/Sponsor 1
4 REFERENCES 1
APPENDICES 1

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Pfizer previously submitted the proposed proprietary name, [(b) (4)]*** on October 28, 2016. We found the name, [(b) (4)]*** acceptable on March 28, 2017[b] under the IND 132494. However, on October 20, 2020, Pfizer submitted a request to withdraw the conditionally acceptable proprietary name [(b) (4)]***.

Subsequently, Pfizer submitted the name, Ngenla***, for review on October 30, 2020. We found the proposed proprietary name Ngenla*** conditionally acceptable on January 25, 2021[c] under the BLA 761184.

However, BLA 761184 received a Complete Response (CR) on January 21, 2022. Thus Pfizer responded to the CR and resubmitted the proposed proprietary name, Ngenla, for review under BLA 761184 on November 22, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 22, 2022.

- Intended Pronunciation: en JEN-lah
- Nonproprietary Name: somatrogon-xxxx
- Indication of Use: [(b) (4)]
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
- Dose and Frequency: 0.66 mg/kg once weekly
- How Supplied: Single patient-use disposable prefilled pen

[b] Vee, S. Proprietary Name Review for [(b) (4)]*** (IND 132494). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Mar 28. Panorama No. 2016-11034690.

[c] Fanari M. Proprietary Name Review for Ngenla*** (BLA 761184). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 25. Panorama No. 2020-43710010.

NGENLA (somatrogon) prefilled pen is available in the following packages

	[redacted] Prefilled Pen NDC: 0069-0505-02	[redacted] Prefilled Pen NDC: 0069-0520-02
Somatrogon solution concentration	20 mg/mL	50 mg/mL
[redacted]		
Color scheme	Lilac pen cap, injection button and label	Blue pen cap, injection button and label
Dose increments	0.2 mg/ 0.01 mL	0.5 mg/ 0.01 mL
Maximum dose	12 mg (0.6 mL)	30 mg (0.6 mL)

- Storage:

[redacted]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Ngenla would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and

the Division of General Endocrinology (DGE) concurred with the findings of OPDP's assessment for Ngenla.

2.2 SAFETY ASSESSMENT

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

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

Pfizer did not provide a derivation or intended meaning for the proposed proprietary name, Ngenla, in their submission. This proprietary name is comprised of a single word. We note the proposed name contains the letters 'la', which is a commonly used medical abbreviation for 'long-acting', that may be used on a prescription or medication order. Since the letter pair 'la' is included as a suffix, we considered whether the proposed name Ngenla could be interpreted as "Ngen la", with 'la' as a modifier or misinterpreted as 'Ngen long-acting formulation'. We note the letter pair 'la' is not included on ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations. The letter pair 'la' is not separated from the name, capitalized, or bolded to make the letter pair more prominent in the name. Additionally, we did not identify any names that would pose a risk for confusion even if the 'la' were to be separated from the remainder of the name.[e] Therefore, we determined it is unlikely that the 'la' suffix would lead to confusion in this instance.

Beyond this abbreviation, we note that Ngenla does not contain any additional 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 December 27, 2022, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Ngenla at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA's prescription studies for Ngenla. One participant in the Computerized Physician Order Entry (CPOE) study selected the proprietary name "Angelica Anomala Whole Extract" instead of Ngenla. However, we note that the participant entered an incorrect sequence of letters, 'ang' instead of 'nge,' when searching for the study name. As a result, the CPOE generated a pick list that did not contain Ngenla as a choice. The participant proceeded to incorrectly select "Angelica Anomala Whole Extract" after 116 seconds of pausing. Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. The name

[d] USAN stem search conducted on January 5, 2023.

[e] POCA search for 'Ngen' conducted on January 18, 2023 in version 5.2.

"Angelica Anomala Whole Extract" could not be found in commonly used drug databases and therefore, the name is unlikely to lead to potential name confusion (see Appendix G).

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 118 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 13 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 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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	12
Low similarity name pair: combined match percentage score ≤54%	0

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

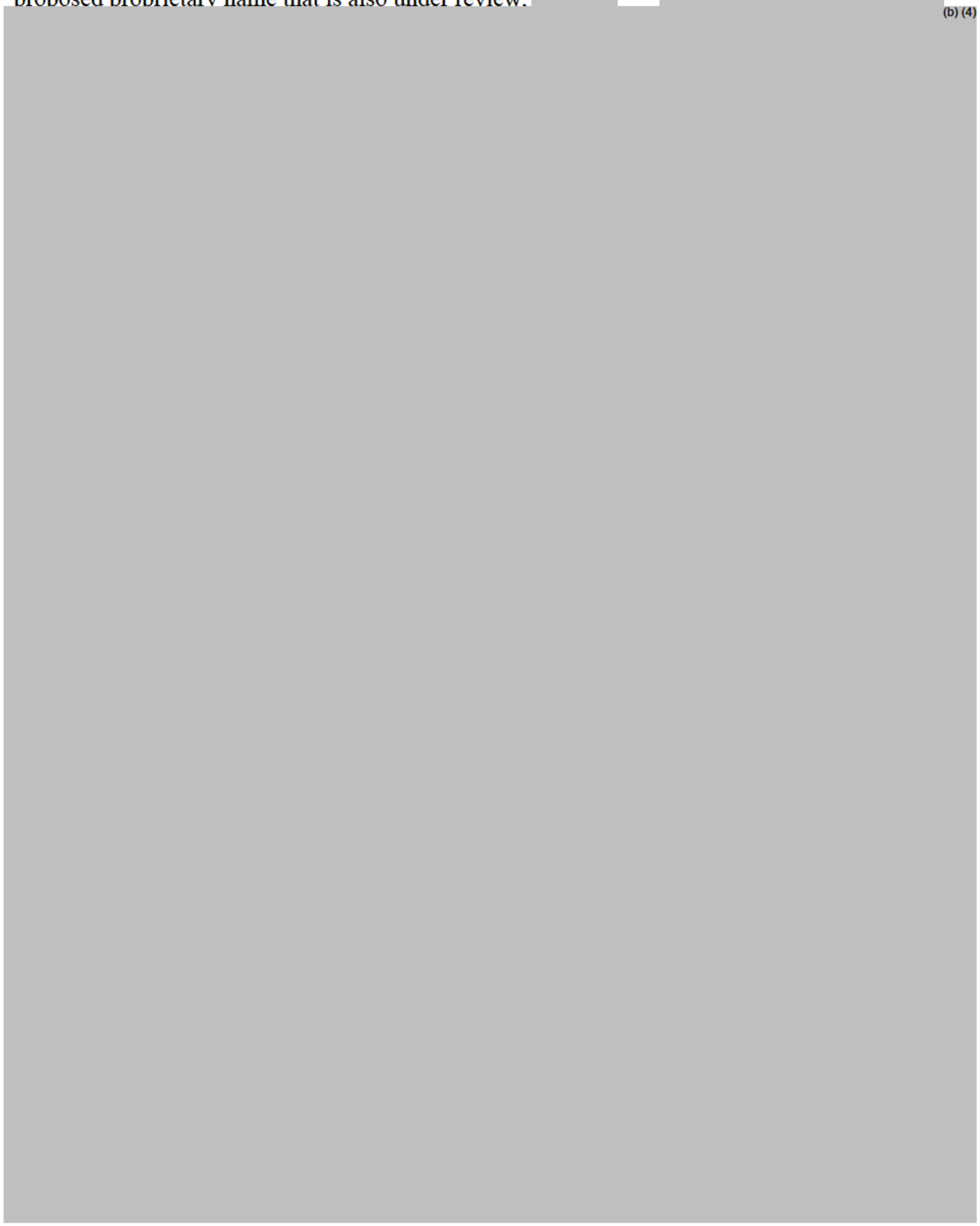
We determined 12 of the 13 names will not pose a risk for confusion with Ngenla as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4) *** which is a proposed proprietary name for another product that is also under review. The rationale for the risk of confusion is described below.

[f] POCA search conducted on January 5, 2023 in version 5.2.

Ngenla vs. (b) (4)***

The proposed proprietary name, Ngenla, may be confused with the name of other pending proposed proprietary name that is also under review. (b) (4)*** (b) (4)

(b) (4)



(b) (4)

We note that this decision differs from our previous decision regarding the acceptability of the proposed proprietary name, Ngenla. However, when Ngenla was previously evaluated, the proposed proprietary name, (b) (4)***, was not yet submitted for review by the Agency.

2.2.8 Communication of DMEPA's Determination

On January 25, 2023, DMEPA 1 communicated our determination to the Division of General Endocrinology (DGE).

3 CONCLUSION

The proposed proprietary name, Ngenla, is not acceptable from a safety perspective. The proposed proprietary name, Ngenla, is vulnerable to name confusion with (b) (4)***. Therefore, the decision to deny the name will be communicated to Pfizer via letter (See Section 3.1).

If you have further questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO PFIZER

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

The proposed proprietary name, Ngenla, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Ngenla, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Ngenla, you will be requested to submit another name.

[i] Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

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. [j]

***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.

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

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[k]. We evaluate all moderately similar names retrieved from

[k] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary

POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name 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.

Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of	**Y/N**	Do the syllables have different phonologic processes, such

	upstroke/downstroke letters present in the names?		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.

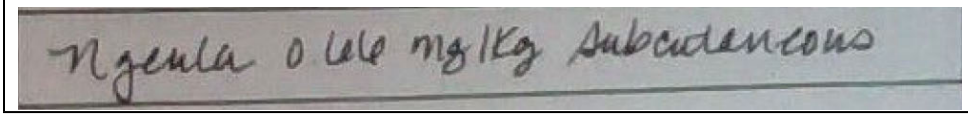
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

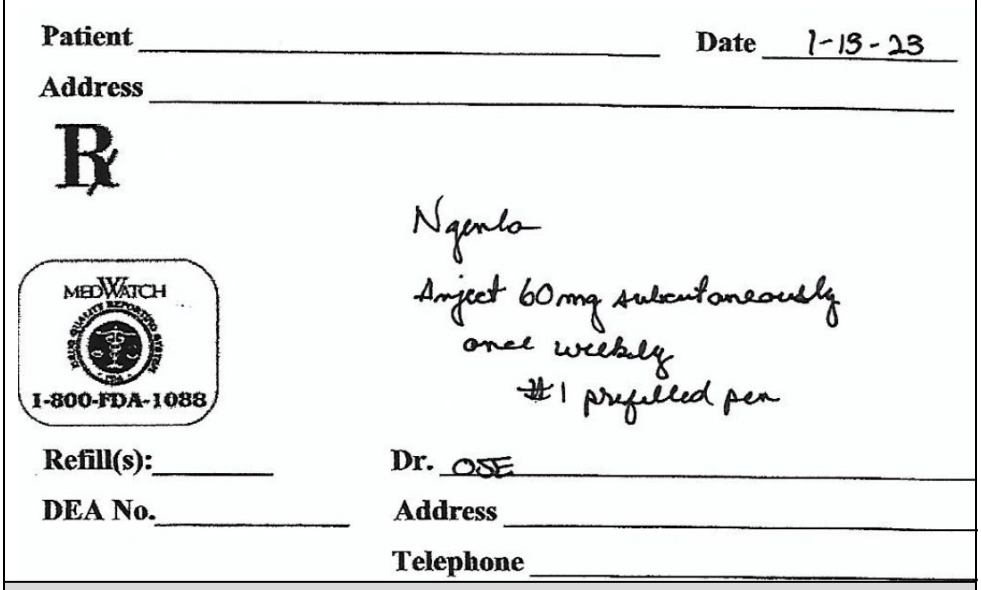
Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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.

<u>Appendix B:</u> Prescription Simulation Samples and Results

<u>Figure 1. Ngenla Study (Conducted on study date)</u>

Handwritten Medication Order/Prescription	**Verbal Prescription**
<u>Medication Order</u>: 	Ngenla Inject 60 mg subcutaneously

Outpatient Prescription:  Patient _____ Date 1-13-23 Address _____ ℞ Ngenla Inject 60mg subcutaneously once weekly #1 prefilled pen MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. OSE DEA No._____ Address _____ Telephone _____	once weekly
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Ngenla	

FDA Prescription Simulation Responses (Aggregate Report)
Study Name: Ngenla
As of Date 1/24/2023

259 People Received Study
93 People Responded

Study Name: Ngenla

Total	25	26	22	20	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
ANGELICA ANOMALA WHOLE EXTRACT	0	1	0	0	1
EMGEMLA	0	0	1	0	1
EMJEMLA	0	0	1	0	1
EMJENWA	0	0	1	0	1
ENGEMLA	0	0	2	0	2
ENGENLA	0	0	3	0	3
ENGEVLA	0	0	1	0	1
ENJEMLA	0	0	1	0	1

ENJEMNA	0	0	1	0	1
ENJENEMA	0	0	1	0	1
ENJENLA	0	0	6	0	6
ENJYMLA	0	0	1	0	1
INJEMA	0	0	1	0	1
INJENLA	0	0	1	0	1
NGENIA	1	0	0	0	1
NGENLA	12	25	0	6	43
NGENLO	0	0	0	14	14
NGENTA	1	0	0	0	1
NGEULA	10	0	0	0	10
NJEMA	0	0	1	0	1
NREULA	1	0	0	0	1

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

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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.	Ngenla	100	Name subject of this review

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

No.	Name	POCA Score (%)
1.	(b) (4)***	62

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:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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) ***	66	(b) (4)
2.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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**
3.	(b) (4) ***	63	This name pair has sufficient orthographic and phonetic differences.
4.	Margenza	60	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	60	Proposed proprietary name for ANDA 207685/S-001 and ANDA 209452/S-001 found unacceptable by DMEPA (OSE# 2021-1044724145). Subsequently, ANDAs 207685/S-01 and 209452/S-01 were approved under the proprietary name Javygtor.
2.	Zenalpha	60	Veterinary product.
3.	(b) (4) ***	56	IND (b) (4) Name found in CBER Proposed Name List. Name withdrawn in CBER memorandum dated November 13, 2015. BLA 125586 was approved under the name Andexxa.
4.	Anti Cle	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Angelica Anomala Whole Extract	25	Name identified in FDA Name Simulation Studies. 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[1]. N/A

[1] 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/

PEGGY M RAHBANI
01/25/2023 04:56:17 PM
Ngenla PNR

MISHALE P MISTRY on behalf of MADHURI R PATEL
01/25/2023 04:57:17 PM

MISHALE P MISTRY
01/25/2023 04:57:34 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Mitigation Assessment & Medication Error Surveillance (DMAMES)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	7/15/2021
Responsible OND Division:	Division of General Endocrinology (DGE)
Application Type and Number:	BLA 761184
Product Name and Strength:	Ngenla (somatrogon-ghla) injection, 24 mg/1.2 mL and 60 mg/1.2 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Pfizer Ireland Pharmaceuticals (Pfizer)
FDA Received Date:	October 20, 2020
Nexus NPNS ID #:	2020-33
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Pfizer for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761184.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 20, 2020, Pfizer submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Pfizer also provided findings from an external study conducted by (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Pfizer:

Table 1. Suffixes submitted by Pfizer***

1.	(b) (4)
2.	
3.	
4.	
5.	ghla
6.	(b) (4)
7.	
8.	
9.	
10.	

[a] Request for Nonproprietary Naming BLA 761184. Ringaskiddy (Ireland): Pfizer Ireland Pharmaceuticals; 2020 Oct 22. Available from: \\CDSESUB1\evsprod\bla761184\0001\m1\us\req-nonproprietary-naming.pdf

[b] Data Summary for Proposed Suffixes. (b) (4) 2020 Jun 23. Available from: \\CDSESUB1\evsprod\bla761184\0001\m1\us\proposed-suffixes.pdf

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

2.1 somatrogon-(b) (4)

Pfizer's first proposed suffix, (b) (4) (b) (4)

However, we note that the proposed suffix (b) (4) (b) (4) (b) (4) is not devoid of meaning, and is inconsistent with the principles describe in the Nonproprietary Naming of Biological Product guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) and submitted by the Applicant. However, the external study did not evaluate the potential suffix (b) (4)

2.2 somatrogon-(b) (4)

Pfizer's second proposed suffix, (b) (4)

We note that the proposed suffix (b) (4) (b) (4) (b) (4) is therefore inconsistent with the principles outlined in section VI of the guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) and submitted by the Applicant. However, the external study did not evaluate the potential suffix (b) (4)

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[a] See (b) (4) Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2.3 somatrogon-(b) (4)

Pfizer's third proposed suffix, (b) (4)

We note that the proposed suffix (b) (4) (b) (4) (b) (4) is not devoid of meaning, and is inconsistent with the principles describe in the Nonproprietary Naming of Biological Product guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) and submitted by the Applicant. However, the external study did not evaluate the potential suffix (b) (4)

2.4 somatrogon-(b) (4)

Pfizer's fourth proposed suffix, (b) (4) (b) (4) (b) (4) is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) and submitted by the Applicant. However, the external study did not evaluate the suffix (b) (4) (b) (4)

[a] See (b) (4) Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

2.5 somatrogon-ghla

Pfizer's fifth proposed suffix, -ghla, is comprised of 4 distinct letters. We note that the letters 'gh' and 'la' in the suffix represent the medical abbreviations for 'growth hormone' and 'long acting', respectively. We considered whether the inclusion of the letters 'gh' and 'la' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. On July 13, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of General Endocrinology (DGE) on July 15, 2021.

4 CONCLUSION

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

4.1 Recommendations for Pfizer Ireland Pharmaceuticals

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

We also note that the first 4 proposed suffixes are unacceptable for the following reasons:

1. somatrogon-(b) (4)

We find your first proposed suffix, (b) (4) unacceptable. The proposed suffix, -(b) (4) is inconsistent with the principles describe in the Nonproprietary Naming of Biological Product guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) However, the external study did not evaluate the potential suffix (b) (4)

2. somatrogon-(b) (4)

We find your second proposed suffix, (b) (4) unacceptable. The proposed suffix, (b) (4) is therefore inconsistent with the principles outlined in section VI of the guidance[a].

We acknowledge that our evaluation differs from that of the external study that you submitted, performed (b) (4) However, the external study did not evaluate the potential suffix (b) (4)

3. somatrogon-(b) (4)

We find your third proposed suffix, (b) (4) unacceptable. The proposed suffix, -(b) (4) is

[a] See (b) (4) Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

inconsistent with the principles describe in the Nonproprietary Naming of Biological Product guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) However, the external study did not evaluate the potential suffix (b) (4)

4. somatrogon-(b) (4)

We find your third proposed suffix, (b) (4) unacceptable. We note that the suffix (b) (4) (b) (4) is therefore inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

We acknowledge that our evaluation differs from that of the external study performed (b) (4) (b) (4) However, the external study did not evaluate the suffix (b) (4) (b) (4) (b) (4)

[a] See (b) (4) Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/s/

CARLOS M MENA-GRILLASCA
07/15/2021 12:33:17 PM

LUBNA A MERCHANT
07/15/2021 12:33:17 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:	January 25, 2021
Application Type and Number:	BLA 761184
Product Name and Strength:	Ngenla (somatrogon-xxxx)[a] injection, 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer Ireland Pharmaceuticals (Pfizer)
Panorama #:	2020-43710010
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

[a] Since the nonproprietary name for this BLA has not yet been determined, the nonproprietary name placeholder, somatrogon-xxxx, is used throughout this review.

Contents

1 INTRODUCTION 1
1.1 Regulatory History 1
1.2 Product Information 1
2 RESULTS 1
2.1 Misbranding Assessment 1
2.2 Safety Assessment 2
3 CONCLUSION 5
3.1 Comments to the Applicant/Sponsor 5
4 REFERENCES 7
APPENDICES 8

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Pfizer previously submitted the proposed proprietary name, [(b) (4)]*** on October 28, 2016. We found the name, [(b) (4)]*** acceptable on March 28, 2017[b] under the IND 132494. However, on October 20, 2020, Pfizer submitted a request to withdraw the conditionally acceptable proprietary name [(b) (4)]***.

Thus, Pfizer submitted the name, Ngenla, for review on October 30, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 30, 2020.

- Intended Pronunciation: en JEN-lah
- Nonproprietary Name: somatrogon-xxxx
- Indication of Use: [(b) (4)]
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL)
- Dose and Frequency: 0.66 mg/kg once weekly
- Storage: [(b) (4)]

[b] Vee, S. Proprietary Name Review for [(b) (4)] (IND 132494). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Mar 28. Panorama No. 2016-11034690.

[redacted] (b) (4)

- How Supplied: Single patient-use disposable prefilled pen

NGENLA (somatrogon) prefilled pen is available in the following packages

	[redacted] (b) (4) **Prefilled Pen** **NDC: 0069-0505-02**	[redacted] (b) (4) **Prefilled Pen** **NDC: 0069-0520-02**
Somatrogon solution concentration	20 mg/mL	50 mg/mL
[redacted] (b) (4)		
Color scheme	Lilac pen cap, injection button and label	Blue pen cap, injection button and label
Dose increments	0.2 mg/ 0.01 mL	0.5 mg/ 0.01 mL
Maximum dose	12 mg (0.6 mL)	30 mg (0.6 mL)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

Pfizer did not provide a derivation or intended meaning for the proposed proprietary name, Ngenla, in their submission. This proprietary name is comprised of a single word. We note that Ngenla ends with the letter string '-la', an abbreviation for the modifier 'long acting'. We considered whether there are any currently marketed proprietary names that begin with the letters 'Ngen' and note that this letter string does not overlap with any currently marketed products; therefore, the letter string does not pose a risk for confusion with any other currently marketed products. Beyond this abbreviation, we note that Ngenla does not contain any additional 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, November 18, 2020 e-mail, the Division of General Endocrinology (DGE) did not forward any comments or concerns relating to Ngenla at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-nine practitioners participated in DMEPA's prescription studies for Ngenla. One participant in the verbal study misinterpreted Ngenla as Angela, which is similar to the currently marketed product Angeliq. One participant's CPOE response overlapped with the currently marketed product, Hysingla and one participant's CPOE response overlapped with currently marketed product, Gleolan.

Ngenla versus Angela

One participant in the verbal study misinterpreted Ngenla as 'Angela'. We note the marketed product Angeliq is similar in spelling and pronunciation to Angela and was identified in our POCA search. We considered the differences between the products characteristics of this name pair and determined the risk of medication error between Ngenla and Angeliq is adequately minimized (see appendix E).

Ngenla versus Hysingla

One participant identified Hysingla in the CPOE study. Hysingla (hydrocodone) is an opiod agonist indicated for the management of severe pain. However, it appears that the participant entered an incorrect sequence of letters, 'ngl' instead of 'nge' when searching for the study name. As a result, the CPOE generated a pick list that did not contain Ngenla as a choice. The participant proceeded to incorrectly select Hysingla as their response. This name pair has sufficient phonetic and orthographic differences, with a combined POCA score of 50%, suggesting low similarity between Ngenla and Hysingla (see Appendix F). Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed

[c] USAN stem search conducted on November 5, 2020.

given the goal of the simulated study. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized.

Ngenla versus Gleolan

One participant identified Gleolan in the CPOE study. Gleolan (aminolevulinic acid) is an optical imaging agent in patients with glioma. However, it appears that the participant entered an incorrect sequence of letters, 'gle' instead of 'nge' when searching for the study name. As a result, the CPOE generated a pick list that did not contain Ngenla as a choice. The participant proceeded to incorrectly select Gleolan as their response. This name pair has sufficient phonetic and orthographic differences, with a combined POCA score of 55%, suggesting moderate similarity between Ngenla and Gleolan (see Appendix D). Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized.

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 107 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the 107 names retrieved from our POCA search and 2 names from the FDA name 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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	67
Low similarity name pair: combined match percentage score ≤54%	39

[d] POCA search conducted on November 5, 2020 in version 4.3.

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

Our analysis of the 109 names contained in Table 1 determined none of the names will pose a risk for confusion with Ngenla 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 General Endocrinology (DGE) via e-mail on January 25, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of General Endocrinology (DGE) on January 25, 2021, they stated no additional concerns with the proposed proprietary name, Ngenla.

3 CONCLUSION

The proposed proprietary name, Ngenla, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO PFIZER IRELAND PHARMACEUTICALS

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

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. 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[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

[f] 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.

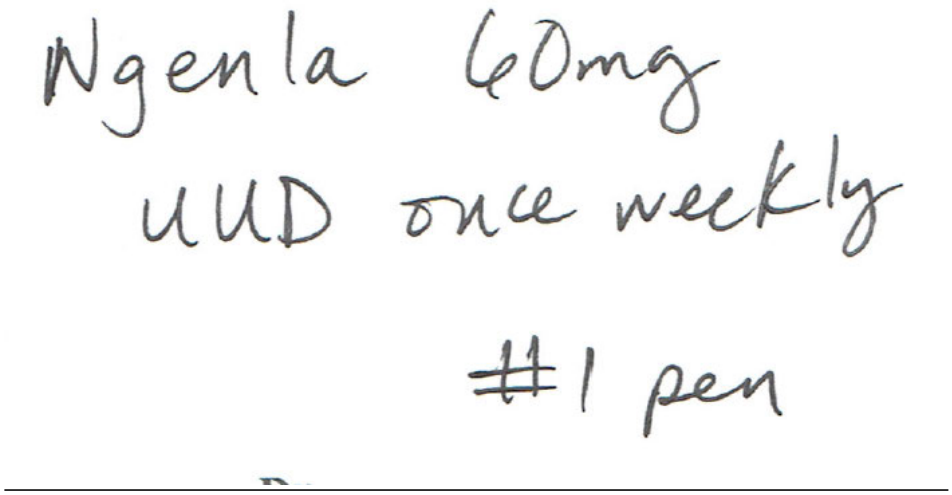
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Ngenla Study (Conducted on November 27, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Ngenla 60 mg Pen Use as directed once weekly #1
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Ngenla	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Ngenla

As of Date 12/11/2020

209 People Received Study

79 People Responded

Study Name: Ngenla

Total	18	21	12	28	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ANGELA	0	0	2	0	2
ANGEMLA	0	0	1	0	1
ANGENUA	0	0	1	0	1
ANGENWA	0	0	1	0	1
EMJENLA	0	0	1	0	1
ENGENRA	0	0	2	0	2
ENGENUA	0	0	1	0	1
ENJENYA	0	0	1	0	1
ENJIWA	0	0	1	0	1
GLEOLAN	0	1	0	0	1
HYSINGLA	0	1	0	0	1
INGENUA	0	0	1	0	1
NGENLA	18	19	0	6	43
NGENLA 0.66MG/KG	0	0	0	1	1
NGUELA	0	0	0	1	1
NSENLA	0	0	0	17	17
NSEULA	0	0	0	2	2
NSEVLA	0	0	0	1	1

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

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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.	Defen-La	72	Orthographically, the first letter of this name pair (‘D’ vs ‘N’) differ and the second (‘e’ vs ‘g’) and third letters (‘f’ vs ‘e’’) provide some differences. Phonetically, the onset sounds of the 1st syllables (‘De’ vs. ‘en’) and 2nd syllable (‘fen’ vs. ‘JEN’) of the names sound different. The following differences in product characteristics may also help to minimize the risk of errors: • The dose of Defen-La is 600 mg/60 mg or 1 tablet vs. Ngenla is a single patient use pen with a recommended dose 0.66 mg/kg. The products do not overlap in usual dose and a prescription order for both products will have a dose on the order. • If route of administration (oral vs. subcutaneous), frequency of administration (twice daily vs. once weekly), and dosage form (tablet vs. injection) are included on the medication order/prescription, there is no overlap between the products. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
2.	Gen Lax	71	Orthographically, the first letter of this name pair (‘G’ vs ‘N’) differ and provide some differences.

			Phonetically, the onset sound of the 1st syllables (‘Gen’ vs. ‘en’) and 2nd syllable (‘lax’ vs. ‘JEN’) of the names sound different. Ngenla has an additional syllable compared to Gen Lax. The following differences in product characteristics may also help to mitigate the risk of errors: • Strength: There is no numerical overlap in strength (176 mg/5 mL vs. 24 mg syringe or 60 mg syringe) and the prescription order for Ngenla will need to specify the strength. • Route and Frequency of Administration/Dosage Form: Gen Lax is an oral syrup given orally once daily vs. Ngenla is a single patient use pen injection administered once weekly subcutaneously. If route and frequency of administration and dosage form are included on the medication order/prescription, there is no overlap between the products. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
3.	Gentle	70	Name identified in RxNorm database. Unable to identify product characteristics in commonly used drug databases. Name was only found in combination with additional words.

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

No.	Name	POCA Score (%)
1.	Genora	63
2.	Genora 1/50	63
3.	Gen-Lanta	62
4.	Penlac	62

No.	Name	POCA Score (%)
5.	Natelle	60
6.	Entex La	60
7.	Angidol	58
8.	Eugenol	58
9.	(b) (4)***	58
10.	Genexa	57
11.	Lenzagel	56
12.	Endal	56
13.	Gen-Alox	56
14.	Invega	55
15.	Gleolan	55

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:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	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.	Gynogen LA 20	68	This name pair has sufficient orthographic and phonetic differences.
2.	Clinagen La 40	65	This name pair has sufficient orthographic and phonetic differences.
3.	Namenda	64	This name pair has sufficient orthographic and phonetic differences.
4.	Jenloga	64	This name pair has sufficient orthographic and phonetic differences.
5.	Gentlax	62	This name pair has sufficient orthographic and phonetic differences.
6.	Humigen La	62	This name pair has sufficient orthographic and phonetic differences.
7.	Angeliq	62	Orthographically, the names begin with different letters (‘A’ vs. ‘N’) and the endings provide some differences (‘iq’ vs. ‘a’). Phonetically, the last syllables sound different (liq vs. la).

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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**
			The following differences in product characteristics may also help to mitigate the risk of errors: • Dose: There is no overlap in dose (0.25 mg/0.5 mg or 0.5 mg/1 mg or 1 tablet vs. 0.66 mg/kg). • Strength: There is no numerical overlap in strength (0.25 mg/0.5 mg or 0.5 mg/1 mg vs. 24 mg and 60 mg) and the prescription order for both Angeliq and Ngenla*** will need to specify the strength. • Route and Frequency of Administration/Dosage Form: Angeliq is a tablet taken orally once daily vs. Ngenla is a single patient use pen injection given subcutaneously once weekly. If route and frequency of administration and dosage form are included on the medication order/prescription, there is no overlap between the products. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
8.	Xenleta	62	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences.
10.	Nesina	61	This name pair has sufficient orthographic and phonetic differences.
11.	Ninlaro	61	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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**
12.	Generlac	61	This name pair has sufficient orthographic and phonetic differences.
13.	Gentlax S	59	This name pair has sufficient orthographic and phonetic differences.
14.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
15.	Nevanac	58	This name pair has sufficient orthographic and phonetic differences.
16.	Gentex La	58	This name pair has sufficient orthographic and phonetic differences.
17.	Genasal	58	This name pair has sufficient orthographic and phonetic differences.
18.	Gentak	58	This name pair has sufficient orthographic and phonetic differences.
19.	(b) (4) ***	58	(b) (4)

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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**
			(b) (4)
20.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.
21.	Inderal La	57	This name pair has sufficient orthographic and phonetic differences.
22.	Inderal-La	57	This name pair has sufficient orthographic and phonetic differences.
23.	Genteal	56	This name pair has sufficient orthographic and phonetic differences.
24.	Renagel	56	This name pair has sufficient orthographic and phonetic differences.
25.	Gilenya	56	This name pair has sufficient orthographic and phonetic differences.
26.	Reglan	56	This name pair has sufficient orthographic and phonetic differences.
27.	Gengraf	56	This name pair has sufficient orthographic and phonetic differences.
28.	Gentran 40	56	This name pair has sufficient orthographic and phonetic differences.
29.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
30.	Gentran 70	56	This name pair has sufficient orthographic and phonetic differences.
31.	Nucala	55	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Ngenla **Established name:** somatrogon-xxxx **Dosage form:** injection **Strength(s):** 24 mg/1.2 mL (20 mg/mL) and 60 mg/1.2 mL (50 mg/mL) **Usual Dose:** 0.66 mg/kg once weekly	**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**
32.	Gleolan	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Acnigel	54
2.	10 Benzagel	54
3.	5 Benzagel	54
4.	Benzagel	54
5.	Donnagel	54
6.	Senna-Gen	54
7.	Nelova	53
8.	(b) (4)***	53
9.	Gentlelax	52
10.	Dentagel	52
11.	Genallerate	50
12.	Gelatin	50
13.	Hysingla	50
14.	Gen-Lanta Ii	50
15.	Geranial	50
16.	Anemagen	49
17.	Kengreal	49
18.	Galenamet	44

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)***	64	Proposed proprietary name for IND (b) (4) found to be unacceptable by OPDP (OSE 2020-42549235 dated October 19, 2020). Alternative proprietary name has not been submitted to date.

No.	Name	POCA Score (%)	Failure preventions
2.	Beegentle	63	Name identified in RxNorm database. Unable to identify product characteristics in commonly used drug databases.
3.	Genesa	62	Brand discontinued with no generic equivalents available. NDA 020420 withdrawn FR effective 09/17/2001.
4.	Elantan La	62	International product formally marketed in numerous international countries.
5.	Nonanal	60	Name identified in RxNorm database. Unable to identify product characteristics in commonly used drug databases.
6.	Norel La	60	Discontinued product with no available generics. Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
7.	Ambenyl	60	Brand discontinued with no generic equivalents available. NDA 009319 withdrawn FR effective 12/7/2007.
8.	Nasal La	58	Name identified in RxNorm database. Unable to identify product characteristics in commonly used drug databases.
9.	Acnegel	56	International product formally marketed in the UK.
10.	Genasan	56	Name identified in RxNorm database. Unable to identify product characteristics in commonly used drug databases.
11.	Phen-Lax	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents available.
12.	Profen La	56	Discontinued product with no available generics. Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
13.	(b) (4)***	60	Proposed proprietary name for IND (b) (4) found to be unacceptable (OSE 2019-33401165 dated 1/16/2020). Alternative proprietary name (b) (4)*** was found to be acceptable for this IND (OSE 2020-38568930 dated 10/3/2020).
14.	(b) (4)***	58	Proposed proprietary name withdrawn by applicant on August 20, 2020 for IND (b) (4). An alternative proposed proprietary name has not been submitted to date.
15.	Enomine La	57	Discontinued product with no available generics. Product withdrawn from the market due to safety concerns. Product contained phenylpropanolamine.
16.	Antrenyl	56	International product marketed in India.

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 (%)
1.	Renvela	62
2.	Bonjela	60
3.	De-Sone La	60
4.	(b) (4)***	60
5.	(b) (4)***	59
6.	Fintepla	58
7.	(b) (4)***	58
8.	Mavenclad	58
9.	(b) (4)***	57
10.	Decanal	57
11.	Onzetra	57
12.	Albenza	56
13.	Banex-La	56
14.	Benza	56
15.	Dynex La	56
16.	Ephensin-La	56
17.	Melanol	56
18.	Phenavent La	56
19.	Uni-Cenna	56
20.	Dexone La	55
21.	Ganda	55
22.	Lantex-La	55
23.	Maggel	55
24.	Makena	55
25.	Zensa	55

[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

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/s/

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