CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761304Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 13, 2023
Application Type and Number:	BLA 761304
Product Name and Strength:	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection, (b) (4) mg and 11,200 units/5.6 mL (180 mg and 2,000 units/mL)
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	argenx BV (argenx BV)
PNR ID #:	2023-1044724996
DMEPA 2 Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyvgart Hytrulo, 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. argenx BV did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

argenx BV previously submitted the proposed proprietary name, Vyvgart (b) (4) *** on October 14, 2022. However, on January 27, 2023, under IND 152843 and BLA 761304, we found the name, Vyvgart (b) (4) *** unacceptable due to the following concerns: the modifier "(b) (4)" may be interpreted on a medication order (b) (4) .[a]

Thus, argenx BV submitted the name, Vyvgart Hytrulo, for review on February 9, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the prescribing information and proprietary name submissions for Vyvgart (b) (4) received under BLA 761304 on February 9, 2023, and FDALabel[b] (for the approved product, Vyvgart).

Table 1. Relevant Product Information for Vyvgart and Vyvgart Hytrulo

Product Name	**Vyvgart (current)**	**Vyvgart Hytrulo (proposed)**
Initial Approval Date	12/17/2021	N/A
Application Number	BLA 761195	BLA 761304
Intended Pronunciation	viv' gart	viv' gart hye troo' loe
Nonproprietary name	efgartigimod alfa-fcab	efgartigimod alfa and hyaluronidase-qvfc
Indication	Treatment of generalized Myasthenia Gravis (gMG)	
Route of Administration	Intravenous infusion	Subcutaneous
Dosage Form	Injection	
Strength	400 mg/20 mL (20 mg/mL)	(b) (4) mg and 11,200 units/5.6 mL (180 mg and 2,000 units/mL)

[a] Morris, C. Proprietary Name Review for Vyvgart (b) (4) (IND 152843; BLA 761304). Silver Spring (MD): FDA, CDER, OSE, DMEPA2 (US); 2023 JAN 27. PNR ID No. 2022-1044724509; 2022-1044724807.

[b] Vyvgart [Prescribing Information]. FDALabel. U.S. Food and Drug Administration. April 2022. [cited 2023 FEB 28]. Available from: http://fdalabel.fda.gov/fdalabel-r/services/spl/set-ids/8aefc8e3-26d6-4ff6-aab9-a7542927e084/spl-doc?hl=vyvgart.

Dose and Frequency	10 mg/kg once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1,200 mg.	5.6 mL ((b) (4) mg/11,200 units) once weekly for 4 weeks
How Supplied	Carton containing one 20 mL single-dose vial	Carton containing one 5.6 mL single-dose vial
Storage	Refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Do not freeze.	Refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Unopened vials may be stored for up to 3 days at room temperature before administration or returned to refrigeration. Do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vyvgart Hytrulo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Vyvgart Hytrulo.

2.2 SAFETY ASSESSMENT

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

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

This proprietary name is comprised of multiple words consisting of the marketed root name, Vyvgart, and the modifier, Hytrulo.

argenx BV indicated in their submission that the root name "Vyvgart" is derived from the currently marketed efgartigimod product, and the modifier "Hytrulo" evokes hyaluronidase.

[c] USAN stem search conducted on February 28, 2023.

We note the proposed modifier "Hytrulo" contains the letter pair "tr", which is an abbreviation meaning "time-released". Although we typically discourage the inclusion of medication abbreviations in proprietary names, we determined that the location of the letter string, "-tr-", positioned in the middle of the modifier is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Vyvgart Hytrulo does not contain any additional components (i.e., route of administration, dosage form, etc.) that can contribute to medication error.

We evaluated the appropriateness of using the same root name for this product and the proposed modifier "Hytrulo" in Section 2.2.5 below.

2.2.3 Comments from Other Review Disciplines at Initial Review

On February 24, 2023, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Vyvgart Hytrulo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-two practitioners participated in DMEPA's prescription studies for Vyvgart Hytrulo.

One CPOE participant erroneously selected the name Vyvanse from a "dynamic begins" pick list. Vyvanse is a marketed product indicated for the treatment of attention deficit hyperactivity disorder (ADHD) available as 10 mg, 20 mg, 40 mg, 50 mg, 60 mg, and 70 mg oral capsules that are administered once daily. In this case, the participant typed "vyva" in the search field; therefore, the correct name, Vyvgart Hytrulo, did not populate the pick list. In fact, the only name to populate the pick list was "Vyvanse". We also note the participant took 24 seconds to submit their response, suggesting the participant knew the correct name was not listed, however the simulation software does not allow the participant to go back to the previous page at this time. Therefore, we determined the participant selected the only answer that was available to select. Additionally, we previously evaluated the root name, Vyvgart, and Vyvanse, and found there were sufficient orthographic, phonetic and product characteristic differences between the name pair[d]. We continue to agree with that determination and we are unaware of any safety signals with this name pair on the market. Furthermore, the proposed name Vyvgart Hytrulo contains a modifier, which if included, provides additional differentiation.

The remaining study 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 Analysis of the Root Name "Vyvgart" and the Proposed Modifier "Hytrulo"

The proposed proprietary name is comprised of two parts: the root name 'Vyvgart' and the modifier 'Hytrulo'. The root name, Vyvgart, is the proprietary name for a marketed intravenous formulation of efgartigimod alfa injection (approved on December 17, 2021 under BLA 761195). argenx BV has now developed a co-formulation of efgartigimod alfa and hyaluronidase for

[d] Morris, C. Proprietary Name Review for Vyvgart (IND 132953). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUL 07. Panorama No. 2020-37743981.

subcutaneous injection. argenx BV proposes the modifier, Hytrulo, to evoke the hyaluronidase component of the co-formulation. We note the addition of a modifier may help differentiate the proposed subcutaneous co-formulated product from the currently marketed product, Vyvgart, which is administered as an intravenous infusion. We also note that Vyvgart and Vyvgart Hytrulo share a therapeutic active ingredient (that is, efgartigimod alfa), dosage form, and indication, but differ in strength, dose, route of administration, and how supplied. See Table 1 for a comparison of product characteristics between Vyvgart and Vyvgart Hytrulo.

Given the Applicant's proposal to use 'Vyvgart' as the root name with the addition of a modifier, we considered the following (addressed respectively below): (1) use of the same root name, (2) whether use of modifier is sufficient to adequately distinguish the products, and (3) whether the proposed modifier 'Hytrulo' is appropriate.

1. Use of the same root name, Vyvgart

Our routine postmarketing surveillance has not identified any signals attributed to name confusion involving Vyvgart and both products share a therapeutic active ingredient (that is, efgartigimod alfa). Thus, we do not object to the use of the root name, Vyvgart, for this product.

2. Whether the use of a modifier is sufficient to distinguish the products

The use of a modifier to differentiate product characteristics between products, such as route of administration, is a common naming practice within a family brand. Modifiers can assist in differentiating products and may help to prevent potential selection errors when used; however, omission and oversight of modifiers is cited in literature as a common cause of medication errors[e]. Postmarket experience shows that family branding may result in medication errors if the modifier is omitted and the product characteristics are similar or overlap.

We considered the risk of name confusion between Vyvgart Hytrulo and Vyvgart if the modifier is omitted or overlooked. For example, if the proposed modifier is omitted or overlooked on a prescription or medication order for "Vyvgart Hytrulo 5.6 mL subcutaneously once weekly", this may result in 5.6 mL of the intravenous formulation of Vyvgart being dispensed and administered subcutaneously once weekly. This error would result in the patient receiving a nearly 10-fold underdose as 5.6 mL of the intravenous formulation of Vyvgart which contains 112 mg of efgartigimod alfa instead of the intended 5.6 mL of the subcutaneous formulation of Vyvgart which contains (b) (4) mg of efgartigimod alfa. Further, the addition of recombinant human hyaluronidase to therapeutic biologic products provides for increased dispersion and absorption, allowing for a larger volume (10 mL) to be injected subcutaneously with limited swelling or pain. Therefore, if 5.6 mL of the intravenous formulation (without hyaluronidase) is inadvertently administered subcutaneously, efgartigimod alfa would be very slowly absorbed, which may potentiate the underdose as the peak concentration would not be achieved, and the patient may experience swelling and pain. However, the products differ in strength and concentration ((b) (4) mg and 11,200 units/5.6 mL (180 mg and 2,000 units/mL) vs. 400 mg/20 mL (20 mg/mL)) and dose (5.6 mL ((b) (4) mg/11,200 units) vs. 10 mg/kg or 1,200 mg in patients weighing 1,200 kg or more), which may help minimize the risk of confusion between these two dosage forms if this information is included on a prescription order An alternative to using a

[e] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

modifier to distinguish this product from the currently marketed products is to use a different root name. However, marketing the new product under a unique proprietary name also carries a risk of medication errors, such as therapeutic duplication and overdoses.

Although the proposed naming strategy is not devoid of risk because modifiers may be omitted, in this case, we agree that using a modifier may assist in differentiating the current and proposed products. Furthermore, label and labeling mitigations can help minimize the residual risk of product selection or wrong route of administration errors.

3. Whether the use of the modifier "Hytrulo" is appropriate.

We considered whether 'Hytrulo' itself is a suitable modifier from a safety perspective. argenx BV indicated that "Hytrulo evokes the hyaluronidase component of the co-formulation". The proposed modifier, Hytrulo, is a novel modifier, with no known precedent in the United States marketplace. However, it is reasonable to expect that, like any novel modifier, awareness among healthcare practitioners will increase with market uptake of the product. Additionally, we determined that the modifier does not contain any components such as USAN stem, route of administration, or dosage form that is misleading or can contribute to medication error. Thus, it appears to provide adequate differentiation between the currently marketed Vyvgart (single-ingredient product, weight-based dosing, and intravenous administration) and the proposed drug product (multiple-ingredient product, fixed dosing of 5.6 mL, and subcutaneous administration). Thus, we do not object to the modifier 'Hytrulo'.

In summary, we find the use of the root name, Vyvgart, acceptable for the proposed product. Additionally, we find that the addition of the modifier "Hytrulo" to the root name Vyvgart may assist in differentiating the proposed single ingredient, intravenously administered product from the proposed multi-ingredient, subcutaneously administered product. Therefore, based on the totality of information considered above, we do not object to the proposed name, Vyvgart Hytrulo, for the proposed product.

2.2.6 Communication of DMEPA's Determination

On March 13, 2023, DMEPA 2 communicated our determination to the Division of Neurology 1 (DN 1).

3 CONCLUSION

The proposed proprietary name, Vyvgart Hytrulo, is conditionally acceptable.

If you have any questions or need clarifications, please contact Lopa Thambi, OSE project manager, at 301-796-5354.

3.1 COMMENTS TO ARGENX BV

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

If any of the proposed product characteristics as stated in your submission, received on February 9, 2023, 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.

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. 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.

c. 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vyvgart Hytrulo Study (Conducted on February 16, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: Vyvgart Hytrulo (b) (4) mg/11,200 units SQ once weekly Outpatient Prescription: Vyvgart Hytrulo Prepare 1 vial as directed, then administer 5.6 ml SQ once weekly. #1 vial	Vyvgart Hytrulo Prepare one vial as directed, then administer 5.6 mL subcutaneously once weekly #1 vial
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vyvgart Hytrulo	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name:
Vyvgart Hytrulo

As of Date 3/6/2023

257 People Received Study

92 People Responded

Total	24	23	21	24	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
LIVGART	0	0	1	0	1
RIVGART HITRULO	0	0	1	0	1
VIVGART HYDRULA	0	0	1	0	1
VIVGART HYPOLOW	0	0	1	0	1
VIVGART HYTOOLO	0	0	1	0	1
VIVGART HYTRULO	1	0	11	0	12
VIVGART HYTRULOW	0	0	1	0	1
VIVGART ITRULO	0	0	1	0	1
VIVGUARD HYTRULO	0	0	1	0	1
VYGART HYTRULO	0	0	0	1	1
VYUGART HYTRULO	1	0	0	2	3
VYUQORT HYTRULO	0	0	0	1	1
VYVANSE	0	1	0	0	1
VYVGARD HYTRULA	1	0	0	0	1
VYVGARD HYTRULO	1	0	0	0	1
VYVGART HYTRUDO	0	0	0	2	2
VYVGART HYTRULA	5	0	0	0	5
VYVGART HYTRULE	2	0	0	0	2
VYVGART HYTRULO	11	22	2	13	48
VYVGART HYTRULS	1	0	0	0	1
VYVQART HYTRULE	0	0	0	1	1
VYVQART HYTRULO	1	0	0	4	5

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/s/

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SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	2/9/2023
Responsible OND Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	IND 152843 BLA 761304
Product Name and Strength:	(efgartigimod alfa and hyaluronidase-qvfc) injection (b) (4) mg/11,200 units per 5.6 mL (180 mg/2,000 units per mL)
Product Type:	Multiple Ingredient Product
Applicant/Sponsor Name:	argenx BV (argenx)
FDA Received Date:	August 5, 2022 (IND) September 20, 2022 (BLA)
Nexus NPNS ID #:	2022-119 (IND) 2022-133 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by argenx for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761304.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On September 20, 2022, argenx submitted a list of 10 suffixes to their IND 152843, in their order of preference, to be used in the nonproprietary name of their product[a]. argenx also provided findings from an external study conducted by (b) (4)[b], evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Subsequently, argenx referenced their suffix submission to IND 152843 in their BLA 761304 submission[c]. Table 1 presents a list of suffixes submitted by argenx:

Table 1. Suffixes submitted by argenx***

1.	qvfc
(b) (4)	

[a] Cover Letter (IND 152843). Zwijnaarde (Belgium): argenx BV; 2022 Aug 05. Available from: \\CDSESUB1\EVSPROD\ind152843\0052\m1\us\12-cover-letter\efg-usa-cover-letter-152843-0052-05aug2022.pdf

[b] Data Summary of Proposed Suffixes (IND 152843). (b) (4) 2022 Jul 25. Available from: \\CDSESUB1\EVSPROD\ind152843\0052\m1\us\118-prop-names\efg-proposed-suffixes-bla-mg-sc.pdf

[c] Cover letter (BLA 761304). Zwijnaarde (Belgium): argenx BV; 2022 Sep 20. Available from: \\CDSESUB1\EVSPROD\bla761304\0001\m1\us\12-cover-letter\efg-usa-cover-letter-761304-0001-20sep2022.pdf

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

2.1 efgartigimod alfa and hyaluronidase-qvfc

argenx's first proposed suffix, -qvfc, is comprised of 4 distinct letters.

We determined that the proposed suffix -qvfc, 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.

We acknowledge that the proposed product is composed of two active ingredients, 'efgartigimod alfa' and 'hyaluronidase'. Since the product contains two active ingredients, the core name for this product is the core names of the two components, efgartigimod alfa and hyaluronidase. We considered the placement of the suffix within the nonproprietary name (i.e., after the efgartigimod alfa component of the core name vs. after the hyaluronidase component of the core name). We are concerned that placement of the suffix after the efgartigimod alfa component could result in misinterpretation of the nonproprietary name. Since efgartigimod alfa and hyaluronidase are available as individual components, the nonproprietary name, efgartigimod alfa-xxxx and hyaluronidase, could be misinterpreted as an order for the individual components versus the proposed fixed-combination product, which may lead to confusion and medication error. Thus, in this case, we determined that the suffix should be attached at the end of the core name of the product (efgartigimod alfa and hyaluronidase) with a hyphen, consistent with recommendations provided in the applicable guidance[a]. This placement would also ensure visibility of the suffix within the nonproprietary name. Thus, we determined efgartigimod alfa and hyaluronidase-qvfc will be the proper name designated in the license.

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

APPEARS THIS WAY ON ORIGINAL

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On February 8, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Neurology 1 (DN 1) on February 9, 2023.

4 CONCLUSION

We find argenx's proposed suffix -qvfc acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to efgartigimod alfa and hyaluronidase-qvfc. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for argenx BV

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

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

/s/

CARLOS M MENA-GRILLASCA
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DANIELLE M HARRIS
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