

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761212Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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

Date of This Review:	September 11, 2025
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761212
Product Name and Strength:	Armlupeg (pegfilgrastim-unne) injection, 6 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Lupin Limited (Biotech Division) (Lupin)
FDA Received Date:	May 30, 2025
Nexus NPNS ID #:	2025-331
DMEPA 2 Biologics Suffix Specialist:	Carlos Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 Purpose of Review

This review is to reassess our evaluation of the four-letter suffix –unne for BLA 761212, which was found conditionally acceptable on February 7, 2022^a and August 6, 2024^b, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761212.

2 Regulatory History

- The proposed suffix -unne was found conditionally acceptable on February 7, 2022.^a
- BLA 761212 received a Complete Response (CR) letter on February 1, 2024.^c
- Lupin submitted a Class 2 Resubmission on May 14, 2024.
- The proposed suffix -unne was found conditionally acceptable on August 6, 2024.
- BLA 761212 receive a Complete Response (CR) letter on November 14, 2024.^d
- Lupin submitted a Class 2 Resubmission on May 30, 2025.

3 Assessment of the Nonproprietary Name

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

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

4 Communication of DMEPA 2 Analysis

These findings were shared with OPDP. On September 4, 2025, OPDP did not identify any promotional concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on September 11, 2025.

5 Conclusion

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

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for pegfilgrastim-unne (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 Feb 07. Nexus ID.: 2021-21.

^b Mena-Grillasca, C. Nonproprietary Name Suffix Review for pegfilgrastim-unne (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Aug 06. Nexus ID.: 2024-253.

^c Farrell, A.T. Complete Response (BLA 761212). Silver Spring (MD): FDA, CDER, OND, Division of Non-Malignant Hematology (DNH) (US); 2024 Feb 01.

^d Farrell, A.T. Complete Response (BLA 761212). Silver Spring (MD): FDA, CDER, OND. Division of Non-Malignant Hematology (DNH) (US); 2024 Nov 14.

^e Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf>

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
09/11/2025 02:58:19 PM

CHI-MING TU
09/11/2025 03:10:18 PM

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:	August 5, 2025
Application Type and Number:	BLA 761212
Product Name, Dosage Form, and Strength:	Armlupeg (pegfilgrastim-unne) ^a Injection, 6 mg/0.6 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Lupin Limited (Biotech Division) (Lupin)
PNR ID #:	2025-1044726500
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

^a The non-proprietary name suffix “unne” was found conditionally acceptable on February 7, 2022 and August 6, 2024 and is currently under re-evaluation.

Table of Contents

1	Introduction.....	3
1.1	Regulatory History	3
1.2	Product Information.....	3
2	Discussion	6
2.1	Misbranding Assessment	6
2.2	Safety Assessment	6
2.2.1	United States Adopted Names (USAN) Search	7
2.2.2	Components of the Proposed Proprietary Name	7
2.2.3	Comments from Other Review Disciplines at Initial Review.....	7
2.2.4	FDA Prescription Simulation Studies	7
2.2.5	Phonetic and Orthographic Computer Analysis (POCA) Search Results	8
2.2.6	Names Retrieved for Review Organized by Name Pair Similarity.....	8
2.2.7	Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities	9
2.2.8	Communication of DMEPA's Determination	9
3	Conclusion	9
3.1	Comments to Lupin Limited (Biotech Division).....	9
4	References	10
5	Appendices	11

1 INTRODUCTION

This review evaluates the proposed proprietary name, Armlupeg, 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. Lupin submitted an external name study, conducted by (b) (4),^b for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761212 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Lupin previously submitted the proposed proprietary name, Armlupeg, under BLA 761212 on April 2, 2021, and we found the name conditionally acceptable on June 22, 2021.^c However, this Application received a Complete Response letter^d on February 1, 2024 for product quality and facility inspection issues.

Lupin resubmitted the proposed proprietary name, Armlupeg, for review on May 14, 2024 as part of the Class 2 Resubmission for BLA 761212. At that time, we noted an additional indication and recommended dosage was added to the proposed Prescribing Information since the previous review cycle. We found the name conditionally acceptable on August 5, 2024.^e However, the Application received a Complete Response letter^f on November 14, 2024 for facility inspection issues.

Thus, Lupin submitted the proposed proprietary name, Armlupeg, for review on May 30, 2025 under BLA 761212.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission^g and the prescribing information^h received on May 30, 2025.

Table 1. Relevant Product Information for Armlupeg	
Intended pronunciation:	arm' loo peg
Nonproprietary name:	pegfilgrastim-unne

(b) (4)

^c DeGraw, S. Proprietary Name Review for Armlupeg (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 22. PNR ID No. 2021-1044723907.

^d Thompson, C. Complete Response Letter for BLA 761212. Silver Spring (MD): FDA, CDER, DCN (US); 2024 FEB 01. BLA 761212. Available from: <https://dartrts.fda.gov/dartrts/faces/ViewDocument?documentId=090140af8072200d>.

^e Kundreskas, J. Proprietary Name Review for Armlupeg*** (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 05. PNR ID No. 2024-1044725788.

^f Thompson, C. Complete Response Letter for BLA 761212. Silver Spring (MD): FDA, CDER, DCN (US); 2024 NOV 14. BLA 761212. Available from: <https://dartrts.fda.gov/dartrts/faces/ViewDocument?documentId=090140af8077fe06>.

^g Request for Proprietary Name Review for BLA 761212. Pune (India): Lupin Limited (Biotech Division); 2025 MAY 30. Available from: <\\CDSESUB1\EVSPROD\bla761212\0054\m1\us\118-proprietary-name.pdf>.

^h Proposed prescribing information for Armlupeg. Pune (India): Lupin Limited (Biotech Division); 2025 MAY 30. Available from: <\\CDSESUB1\EVSPROD\bla761212\0054\m1\us\bla-761212-uspi-clean.pdf>.

Table 1. Relevant Product Information for Armlupeg	
Indication:	• Patients with Cancer Receiving Myelosuppressive Chemotherapy: Armlupeg is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Armlupeg is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: Armlupeg is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
Dosage Form:	Injection
Strength:	6 mg/0.6 mL
Route of administration:	Subcutaneous

Table 1. Relevant Product Information for Armlupeg

Dose and frequency:

- Patients with Cancer Receiving Myelosuppressive Chemotherapy: The recommended dosage of Armlupeg is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. (b) (4)
Do not administer Armlupeg between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
- Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: The recommended dose of Armlupeg is two doses, 6 mg each, administered subcutaneously one week apart. (b) (4)
Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose.

The Armlupeg prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Armlupeg less than 0.6 mL (6 mg) for direct administration to patients. (b) (4)

(b) (4)

Table 1. Relevant Product Information for Armlupeg	
How Supplied:	Armlupeg (pegfilgrastim-unne) injection is a clear, colorless solution supplied in a prefilled single-dose syringe for manual use containing 6 mg pegfilgrastim-unne, supplied with a 27-gauge, 1/2-inch needle with an UltraSafe® Plus Passive™ Needle Guard. The needle cap of the prefilled syringe contains dry natural rubber (a derivative of latex). Armlupeg is provided in a (b) (4) containing one sterile 6 mg/0.6 mL prefilled syringe (NDC 70748-273-01). Armlupeg prefilled syringe does not bear graduation marks and is intended only to deliver the entire contents of the syringe (6 mg/0.6 mL) for direct administration. (b) (4) (b) (4)
Storage:	Store refrigerated between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not shake. Discard syringes stored at room temperature for more than 48 hours. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard syringe if frozen more than once.
Reference Product:	Armlupeg (pegfilgrastim-unne) is a proposed biosimilar to US-licensed Reference Product, Neulasta (pegfilgrastim) BLA 125031

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Armlupeg would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Armlupeg. The Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Armlupeg.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.ⁱ

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Lupin did not provide a derivation or intended meaning for the proposed proprietary name, Armlupeg, in their submission. This proprietary name is comprised of a single word that contains the letter strings “ML” and “PE”, which are the medical abbreviation for “milliliter” and the modifier “phenylephrine”, respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the location of these letter strings embedded within the infix of the proposed name means they are unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription and lead to confusion. Therefore, in this case we do not object to the proposed proprietary name based on the inclusion of these medical abbreviations.

The proposed proprietary name, Armlupeg, incorporates the letter string “lup”, which is a part of the Sponsor’s name, Lupin Limited. Our Guidance for Industry Best Practices in Developing Proprietary Names for Human Prescription Drug Products recommends sponsors avoid proprietary names that incorporate the sponsor’s name, or some part of the sponsor’s name, across multiple products (e.g., “ABCName1,” “ABCName2,” “ABCName3”).^j This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. The practice can be problematic when products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists. We note that the letter string “lup” is present in existing drug nomenclature across multiple sponsors (e.g., Lupkynis, Lupron Depot, and Lupron Depot-PED). We acknowledge that Lupin Limited currently does not market any products in the US that incorporate all or part of the sponsor’s name at this time. Because this is the first instance where Lupin Limited proposed a proprietary name containing the letter string “lup”, we do not object to the inclusion of “lup” in the proposed name.

Armlupeg does not contain any other components that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Armlupeg at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Seventy-three (73) practitioners participated in FDA’s prescription simulation studies for Armlupeg.

ⁱ USAN stem search conducted on June 4, 2025.

^j Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products. 2020. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry>.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name “Aralast, Aralast NP” from the static pick list. The participant did not type in any sequence of letters and was presented with a software generated static pick list of 25 names that included “Aralast, Aralast NP” as the first name on the list and “Armlupeg” as the tenth name on the list. The participant incorrectly selected “Aralast, Aralast NP” after 21 seconds in order to proceed with the FDA prescription simulation study.

We further evaluated these name pair Armlupeg vs. Aralast NP. The name pair has sufficient orthographic and phonetic differences. We considered whether additional product characteristics would help differentiate the products during an electronic prescribing scenario. We note that the strength (6 mg/0.6 mL vs. 0.5 gram and 1 gram), dosage form (injection vs. for injection), and route of administration (subcutaneous vs. intravenous infusion) differ between Armlupeg and Aralast NP.

Based on these factors, we determined the risk of medication errors between Armlupeg and Aralast NP is adequately minimized. We placed the name Aralast NP in Appendix E.

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^k identified 13 names with a combined phonetic and orthographic score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed, and we agree with the findings from our previous reviews for the names evaluated previously. Therefore, we identified two names not previously analyzed. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search, and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2

^k POCA search conducted on June 4, 2025 in version 5.12.8.

Low similarity name pair: combined match percentage score $\leq 54\%$	1
--	---

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

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

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On August 5, 2025, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Armlupeg, is conditionally acceptable.

3.1 COMMENTS TO LUPIN LIMITED (BIOTECH DIVISION)

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

If any of the proposed product characteristics as stated in your submission, received on May 30, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

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

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

Drugs@FDA

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

RxNorm

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

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

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

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. **Misbranding Assessment:** For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

¹ National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>. Last accessed 10/05/2020.

Table 3. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Tables 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category that cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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^m. 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.

- o Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.
- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

^m 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

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

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

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq$ 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		
-----	---	--	--

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: - Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. - Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. - Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? - Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. - Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) - Do the names have different number of syllables? - Do the names have different syllabic stresses? - Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	
--	---	--

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Armlupeg Study (Conducted on 6/10/2025)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Armlupeg, inject (b) (4) subcutaneously, once</i> <u>Outpatient Prescription:</u> <i>Armlupeg inject 6 mg SQ today, repeat dose in 1 week #2</i> CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Armlupeg	Armlupeg Inject 6 mg subcutaneously today and repeat dose in one week Dispense 2

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Armlupeg					
People Received Study: 160					
People Responded: 73					
Total	20	22	11	20	73
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ARALAST, ARALAST NP	0	0	0	1	1
AREMUTEG	0	0	1	0	1
ARINLUPEG	0	1	0	0	1
ARMIPEG	0	0	1	0	1
ARMLAPEG	0	2	0	0	2
ARMLUPEG	12	18	7	19	56
ARMLUPEQ	6	1	0	0	7
ARMLUPEQ INJECT	1	0	0	0	1
ARMUPEG	0	0	1	0	1
ARMUPLEG	1	0	0	0	1
ARMUTEG	0	0	1	0	1

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

No.	Proposed name: Armlupeg Pronunciation: arm' loo peg Established name: pegfilgrastim-unne Dosage form: Injection Strength(s): 6 mg/0.6 mL Dosage: 6 mg, (b) (4) subcutaneously once per chemotherapy cycle or as 2 total doses one week apart.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	N/A		

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

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

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Armlupeg Pronunciation: arm' loo peg Established name: pegfilgrastim-unne Dosage form: Injection Strength(s): 6 mg/0.6 mL Dosage: 6 mg, (b) (4) subcutaneously once per chemotherapy cycle or as 2 total doses one week apart.	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) ***	62	(b) (4)

No.	Proposed name: Armlupeg Pronunciation: arm' loo peg Established name: pegfilgrastim-unne Dosage form: Injection Strength(s): 6 mg/0.6 mL Dosage: 6 mg, (b) (4) subcutaneously once per chemotherapy cycle or as 2 total doses one week apart.	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)
2.	Aralast NP	43%	See FMEA in Section 2.2.4.

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

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

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

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

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusionⁿ.

No.	Name	POCA Score (%)
1.	(b) (4) ***	64

ⁿ 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/

JODY K KUNDRESKAS
08/05/2025 09:08:29 AM

NICOLE F IVERSON
08/05/2025 11:37:05 AM

HINA S MEHTA
08/06/2025 12:06:27 PM

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)

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

Date of This Review:	8/6/2024
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761212
Product Name and Strength:	Armlupeg (pegfilgrastim-unne) injection, 6 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Lupin Limited (Biotech Division) (Lupin)
Nexus NPNS ID #:	2024-253
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -unne, for BLA 761212, which was found conditionally acceptable on February 7, 2022^a, for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761212.

1.1 Regulatory History

We found the proposed four-letter suffix, -unne, acceptable for BLA 761212 on February 7, 2022^a. However, BLA 761212 received a Complete Response (CR) letter on February 1, 2024^b. Thus, Lupin submitted a Class 2 Resubmission on May 14, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously proposed four-letter suffix, -unne, using the principles described in the applicable guidance^c.

We determined that the proposed suffix -unne, 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 2 ANALYSIS

These findings were shared with OPDP. On August 1, 2024, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on August 6, 2024.

^a Mena-Grillasca, C. Nonproprietary Name Suffix Review for pegfilgrastim-unne (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2022 Feb 07. Nexus No.: 2021-21.

^b Farrell, A.T. Complete Response (BLA 761212). Silver Spring (MD): FDA, CDER, OND, DNH (US); 2024 Feb 01.

^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 -unne acceptable and recommend the nonproprietary name pegfilgrastim-unne be used throughout the draft labels and labeling.

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
08/06/2024 03:08:19 PM

CHI-MING TU
08/06/2024 08:10:50 PM

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:	August 5, 2024
Application Type and Number:	BLA 761212
Product Name, Dosage Form, and Strength:	Armlupeg (pegfilgrastim-unne) ^a Injection, 6 mg/0.6 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Lupin Limited (Biotech Division) (Lupin)
PNR ID #:	2024-1044725788
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

^a The non-proprietary name suffix “unne” was found conditionally acceptable on April 2, 2021 and is currently under re-evaluation.

Table of Contents

1	INTRODUCTION	3
1.1	REGULATORY HISTORY	3
1.2	PRODUCT INFORMATION	3
2	Discussion	6
2.1	MISBRANDING ASSESSMENT	6
2.2	SAFETY ASSESSMENT	6
2.2.1	United States Adopted Names (USAN) Search	7
2.2.2	Components of the Proposed Proprietary Name	7
2.2.3	Comments from Other Review Disciplines at Initial Review	7
2.2.4	FDA Prescription Simulation Studies	7
2.2.5	Phonetic and Orthographic Computer Analysis (POCA) Search Results	8
2.2.6	Names Retrieved for Review Organized by Name Pair Similarity	10
2.2.7	Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities	10
2.2.8	Communication of DMEPA's Determination	10
3	CONCLUSION	10
3.1	Comments to Lupin Limited (Biotech Division)	10
4	REFERENCES	12
5	APPENDICES	13

1 INTRODUCTION

This review evaluates the proposed proprietary name, Armlupeg, 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. Lupin submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761212 (see Section 1.1 below).

We note, Lupin stated that they are proposing an additional indication for adults to increase survival in patients acutely exposed to myelosuppressive doses of radiation as the Orphan Drug Exclusivity for that indication is now expired. Thus, there is a change in dose to include weight-based dosing for pediatrics and frequency to include 2 doses one week apart. All other product characteristics remain the same.

1.1 REGULATORY HISTORY

Lupin previously submitted the proposed proprietary name, Armlupeg, under BLA 761212 on April 2, 2021, and we found the name conditionally acceptable on June 22, 2021.^c However, this Application received a Complete Response letter^d on February 1, 2024 for product quality and facility inspection issues

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 14, 2024^e and the prescribing information received on May 14, 2024^f.

Table 1. Relevant Product Information for Armlupeg	
Intended pronunciation:	arm' loo peg
Nonproprietary name:	pegfilgrastim-unne

^c DeGraw, S. Proprietary Name Review for Armlupeg (BLA 761212). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 22. PNR ID No. 2021-1044723907.

^d Thompson, C. Complete Response Letter for BLA 761212. Silver Spring (MD): FDA, CDER, DCN (US); 2024 FEB 01. BLA 761212.

^e Proprietary Name (Armlupeg BLA 761212). Pune (India): Lupin Limited (Biotech Division); 2024 MAY 14. Available from: <\\CDSESUB1\EVSPROD\bla761212\0041\m1\us\118-proprietary-name.pdf>.

^f Proposed prescribing information for Armlupeg. Pune (India): Lupin Limited (Biotech Division); 2024 May 14. Available from: <\\CDSESUB1\EVSPROD\bla761212\0041\m1\us\bla-761212-uspi-clean.pdf>.

Table 1. Relevant Product Information for Armlupeg	
Indication:	• Patients with Cancer Receiving Myelosuppressive Chemotherapy: Armlupeg is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Armlupeg is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. • Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: Armlupeg is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
Dosage Form:	Injection
Strength:	6 mg/0.6 mL
Route of administration:	Subcutaneous

Table 1. Relevant Product Information for Armlupeg

Dose and frequency:	Patients with Cancer Receiving Myelosuppressive Chemotherapy: The recommended dosage of Armlupeg is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. (b) (4) Do not administer Armlupeg between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: The recommended dose of Armlupeg is two doses, 6 mg each, administered subcutaneously one week apart. (b) (4) . Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose. The Armlupeg prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Armlupeg less than 0.6 mL (6 mg) for direct administration to patients. (b) (4)
-----------------------------------	--

Table 1. Relevant Product Information for Armlupeg	
How Supplied:	Armlupeg (pegfilgrastim-unne) injection is a clear, colorless solution supplied in a prefilled single-dose syringe for manual use containing 6 mg pegfilgrastim-unne, supplied with a 27-gauge, 1/2-inch needle with an UltraSafe® Plus Passive™ Needle Guard. The needle cap of the prefilled syringe contains dry natural rubber (a derivative of latex). Armlupeg is provided in a (b) (4) containing one sterile 6 mg/0.6 mL prefilled syringe (NDC 70748-273-01). Armlupeg prefilled syringe does not bear graduation marks and is intended only to deliver the entire contents of the syringe (6 mg/0.6 mL) for direct administration. (b) (4)
Storage:	Store refrigerated between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not shake. Discard syringes stored at room temperature for more than 48 hours. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard syringe if frozen more than once.
Reference Product:	Armlupeg (pegfilgrastim-unne) is a proposed biosimilar to US-licensed Reference Product, Neulasta (pegfilgrastim) BLA 125031

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Armlupeg would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Armlupeg. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Armlupeg.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.^g

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Lupin did not provide a derivation or intended meaning for the proposed proprietary name, Armlupeg, in their submission. This proprietary name is comprised of a single word that contains the letter strings “ML” and “PE”, which is the medical abbreviation for “milliliter” and the modifier “phenylephrine”, respectively. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we note the location of these letter strings embedded within the infix of the proposed name means they are unlikely to be separated from the surrounding letters or to be misunderstood within the context of a prescription and lead to confusion. Therefore, in this case we do not object to the proposed proprietary name based on the inclusion of these medical abbreviations.

Additionally, we note that the proposed proprietary name, Armlupeg, incorporates the letter string “lup”, which is a part of the Sponsor’s name, Lupin Limited. Our Guidance for Industry Best Practices in Developing Proprietary Names for Human Prescription Drug Products recommends sponsors avoid proprietary names that incorporate the sponsor’s name, or some part of the sponsor’s name, across multiple products (e.g., “ABCName1,” “ABCName2,” “ABCName3”).^h This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. The practice can be problematic when products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists. We note that the letter string “lup” is present in existing drug nomenclature across multiple sponsors (e.g., Lupkynis, Lupron Depot, and Lupron Depot-PED). We acknowledge that Lupin Limited currently does not market any products in the US that incorporate all or part of the sponsor’s name at this time. Because this is the first instance where Lupin Limited proposed a proprietary name containing the letter string “lup”, we do not object to the inclusion of “lup” in the proposed name.

Armlupeg does not contain any other components (i.e., a route of administration, dosage form, frequency, etc.) that can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On June 12, 2024, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Armlupeg at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Sixty-five (65) practitioners participated in DMEPA’s prescription simulation studies for Armlupeg. The responses did not overlap with any currently marketed products nor did the

^g USAN stem search conducted on July 9, 2024.

^h Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products. 2020. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry>

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 searchⁱ identified 11 names with a combined score of $\geq 55\%$ or an individual orthographic or phonetic score of $\geq 70\%$. 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 also evaluated previously identified names taking into account the change in product characteristics:

Table 2. Changes in Product Characteristics		
	Armlupeg ^j (previous BLA 761212 submission)	Armlupeg ^{k,l} (current BLA 761212 submission)
Indication	Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia	- Patients with Cancer Receiving Myelosuppressive Chemotherapy: Armlupeg is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Armlupeg is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. - Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: Armlupeg is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

ⁱ POCA search conducted on July 9, 2024 in version 5.9.

^j DeGraw, S. Proprietary Name Review for PPN (previous Application #####). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JUN 22. PNR ID No. 2021-1044723907.

^k Proprietary Name (Armlupeg BLA 761212). Pune (India): Full Applicant/Sponsor name; 2024 MAY 14. Available from: [\\CDSESUB1\EVSPROD\bla761212\0041\m1\us\118-proprietary-name.pdf](#).

^l Proposed prescribing information for PPN. Pune (India): Full Applicant/Sponsor name; 2024 May 14. Available from: [\\CDSESUB1\EVSPROD\bla761212\0041\m1\us\bla-761212-uspi-clean.pdf](#).

Dose and Frequency	6 mg administered subcutaneously once per chemotherapy cycle	Patients with Cancer Receiving Myelosuppressive Chemotherapy: The recommended dosage of Armlupeg is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. (b) (4) Do not administer Armlupeg between 14 days before and 24 hours after administration of cytotoxic chemotherapy. Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome: The recommended dose of Armlupeg is two doses, 6 mg each, administered subcutaneously one week apart. (b) (4) . Administer the first dose as soon as possible after suspected or confirmed exposure to radiation levels greater than 2 gray (Gy). Administer the second dose one week after the first dose. The Armlupeg prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Armlupeg less than 0.6 mL (6 mg) for direct administration to patients (b) (4) (b) (4)
----------------------------------	---	--

--	--	--

Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Armlupeg. Therefore, we identified one name not previously analyzed. This name is included in Table 3 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 3 provides the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 3. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	1
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the one name contained in Table 3 determined that it will not pose a risk for confusion with Armlupeg as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On August 5, 2024, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

The proposed proprietary name, Armlupeg, is conditionally acceptable.

3.1 COMMENTS TO LUPIN LIMITED (BIOTECH DIVISION)

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

If any of the proposed product characteristics as stated in your submission, received on May 14, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

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

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

Drugs@FDA

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

RxNorm

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

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

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

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. **Misbranding Assessment:** For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^m

*Table 4. 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.

^m National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors>. Last accessed 10/05/2020.

*Table 4. Prescreening Checklist for Proposed Proprietary Name	
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - o 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 namesⁿ. 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.

- o Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).
 - Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.
- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

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

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

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

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

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

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

Table 5. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is $\geq$ 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 6: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? • *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 6: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

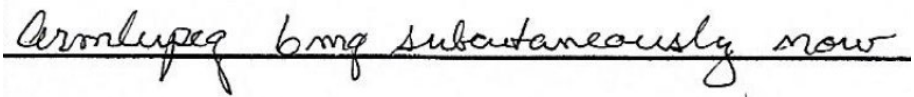
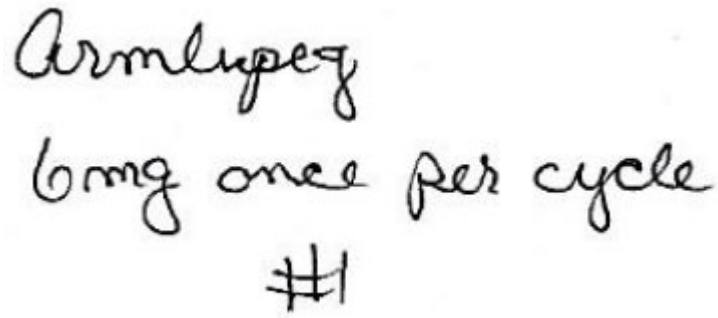
	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	
--	--	--

Table 7. Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Armlupeg Study (Conducted on 5/24/2024)

Handwritten Medication Order Prescription	Verbal Prescription
<u>Medication Order:</u> 	Armlupeg 6 mg once per cycle Dispense 1
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Armlupeg	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Armlupeg					
People Received Study: 197					
People Responded: 65					
Total	18	15	12	20	65
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ARLUPAG	0	0	1	0	1
ARLUPEG	0	0	1	0	1
ARMLUPEG	4	4	6	20	34
ARMLUPEQ	13	9	0	0	22
ARMLYPEQ	0	1	0	0	1
ARMUPEG	0	0	2	0	2
ARMYLUPEQ	0	1	0	0	1
ARONLUPEQ	1	0	0	0	1
RLUPEG	0	0	1	0	1

RMUPEG	0	0	1	0	1
--------	---	---	---	---	---

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is $\geq 70\%$)

No.	Proposed name: Armlupeg Pronunciation: arm' loo peg Established name: pegfilgrastim-unne Dosage form: Injection Strength(s): 6 mg/0.6 mL Dosage: 6 mg, (b) (4) subcutaneously once per chemotherapy cycle or as 2 total doses administered one week apart.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	N/A		

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

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

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Armlupeg Pronunciation: arm' loo peg Established name: pegfilgrastim-unne Dosage form: Injection Strength(s): 6 mg/0.6 mL Dosage: 6 mg, (b) (4) subcutaneously once per chemotherapy cycle or as 2 total doses administered one week apart.	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.	Pharmalgen	58	This name pair has sufficient orthographic and phonetic differences.

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

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

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

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

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion^o.

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

^o 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/

JODY K KUNDRESKAS
08/05/2024 04:22:09 PM

NICOLE F IVERSON
08/05/2024 04:37:48 PM

HINA S MEHTA
08/05/2024 08:55:04 PM

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)

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

Date of This Review:	2/7/2022
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761212
Product Name and Strength:	Armlupeg (pegfilgrastim-unne) injection 6 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Lupin Limited (Biotech Division) (Lupin)
FDA Received Date:	April 2, 2021
Nexus NPNS ID #:	2021-21
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 Lupin for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761212.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On April 2, 2021, Lupin submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product^a. Lupin also provided findings from an external study conducted by the (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 Lupin:

Table 1. Suffixes submitted by Lupin***		
1.	(b) (4)	
2.	(b) (4)	
3.	unne	
4.	(b) (4)	
5.	(b) (4)	
6.	(b) (4)	
7.	(b) (4)	
8.	(b) (4)	
9.	(b) (4)	
10.	(b) (4)	

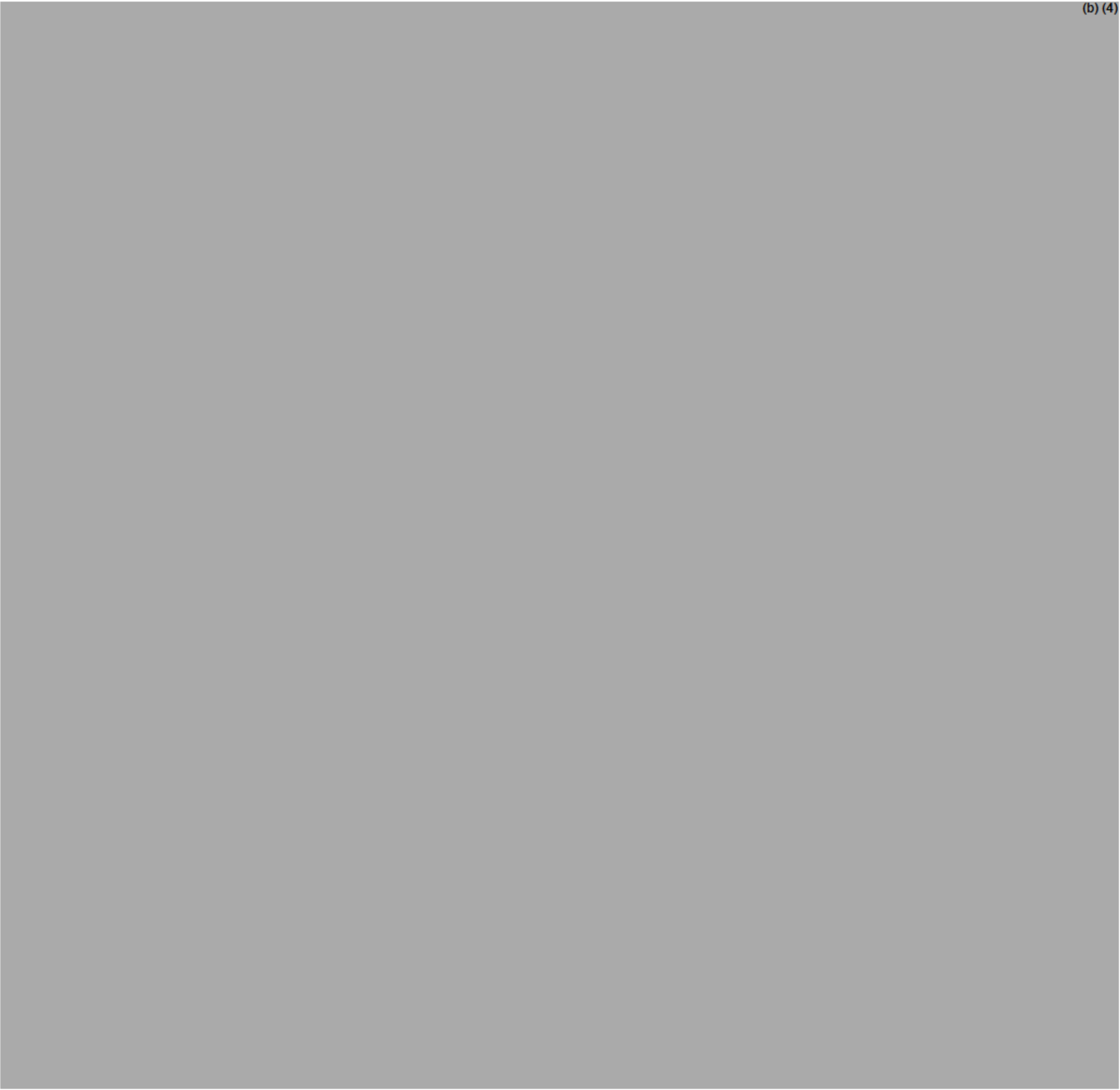
^a Suffix Data BLA 761212. Pune (India): Lupin Limited (Biotech Division); 2021 Apr 2. Available from:

[\\CDSESUB1\evsprod\bla761212\0001\m1\us\suffix-data.pdf](#)

(b) (4)

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

(b) (4)



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

2.3 pegfilgrastim-unne

Lupin's third proposed suffix, -unne, is comprised of 3 distinct letters (u, n, e).

We determined that the proposed suffix -unne, 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 2 ANALYSIS

These findings were shared with OPDP. On February 1, 2022, OPDP did not identify any concerns that would render the proposed suffix '-unne' unacceptable. In addition, on February 2, 2022, OPDP indicated that the suffix (b) (4) may misleadingly suggest that (b) (4) (b) (4) DMEPA 2 also communicated our findings to the Division of Non-Malignant Hematology (DNH) on February 7, 2022.

4 CONCLUSION

We find Lupin's proposed suffix -unne acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to pegfilgrastim-unne. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Lupin Limited (Biotech Division)

We find the nonproprietary name, pegfilgrastim-unne, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, pegfilgrastim-unne 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 finding.

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

(b) (4)

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
02/07/2022 06:17:24 PM

DANIELLE M HARRIS
02/07/2022 08:24:35 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:	June 22, 2021
Application Type and Number:	BLA 761212
Product Name and Strength:	Armlupeg (pegfilgrastim-xxxx) ^a injection, 6 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Lupin Limited (Lupin)
PNR ID #:	2021-1044723907
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

^a The nonproprietary name suffix for this BLA has not yet been determined; therefore, the placeholder, pegfilgrastim-xxxx, is used throughout this review to refer to the nonproprietary name and suffix for this product.

Contents

1	INTRODUCTION	1
1.1	Product Information	1
2	RESULTS.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment	1
3	CONCLUSION	3
3.1	Comments to Lupin Limited	4
4	REFERENCES	5
	APPENDICES	6

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 2, 2021.

- Intended Pronunciation: arm' loo peg
- Nonproprietary Name: pegfilgrastim-xxxx
- Indication of Use: decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 6 mg/0.6 mL
- Dose and Frequency: 6 mg administered subcutaneously once per chemotherapy cycle
- How Supplied: (b) (4) containing one prefilled single-dose syringe with a 27-gauge, 1/2-inch needle with an UltraSafe® Plus Passive™ Needle Guard
- Storage: store refrigerated between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not shake. Avoid freezing.
- Reference Product: Neulasta (BLA 125031)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Armlupeg would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Armlupeg.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name^b.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 19, 2021, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Armlupeg at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-five (75) practitioners participated in DMEPA's prescription studies for Armlupeg. The responses did not overlap with any currently marketed products; however, one participant in the voice study misinterpreted Armlupeg as "Onlupeg" which is a close variant of the currently approved product, Onureg (NDA 214120). Despite the misinterpretation in the FDA name simulation study, we find that the name pair, Armlupeg and Onureg, has minimal potential for confusion based on our evaluation as described below.

Orthographically, the name pair differs in length (8 letters *versus* 6 letters) and begins with different letters (A *versus* O). Further, Armlupeg has an upstroke letter 'l' in the 4th position and a downstroke letter 'p' in the 6th position which are not present in Onureg. Phonetically, the 1st syllable of the name pair (Arm- *versus* On-) and the onset of the 2nd syllable ('l' *versus* 'u') and 3rd syllable ('p' *versus* 'r') provide sufficient phonetic differences. FDA's Phonetic and Orthographic Computer Analysis (POCA) program⁴ calculates a combined orthographic and phonetic score of 40%, suggesting that there is a low similarity between these names.

Additionally, Armlupeg and Onureg differ in terms of strength (6 mg/0.6 mL *versus* 200 mg and 300 mg), dose (6 mg *versus* 300 mg), frequency of administration (once per chemotherapy cycle *versus* once daily on days 1 through 14 of a 28-day cycle), dosage form (injection *versus* tablet), and route of administration (subcutaneous *versus* oral), which can further help to differentiate the products if included on a prescription/medication order. Therefore, due to the above considerations, we do not think that the name pair is vulnerable to name confusion. This name pair is evaluated in Appendix F.

See Appendix B for the complete results from the prescription simulation studies.

^b USAN stem search conducted on April 8, 2021.

⁴ POCA analysis of this name pair conducted on May 11, 2021 in version 4.4.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^c identified 10 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	8
Low similarity name pair: combined match percentage score $\leq 54\%$	3

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

Our analysis of the 12 names contained in Table 1 determined none of the names will pose a risk for confusion with Armlupeg 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 Non-Malignant Hematology (DNH). At that time, we also requested additional information or concerns that could inform our review. On June 21, 2021, the Division of Non-Malignant Hematology (DNH) stated no additional concerns with the proposed proprietary name, Armlupeg.

3 CONCLUSION

The proposed proprietary name, Armlupeg, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

^c POCA search conducted on April 8, 2021 in version 4.4.

3.1 COMMENTS TO LUPIN LIMITED

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

If any of the proposed product characteristics as stated in your submission, received on April 2, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^d

^d 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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^e. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as 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 $\geq 55\%$ to $\leq 69\%$).

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 <u>with</u> overlapping or similar strengths or doses.

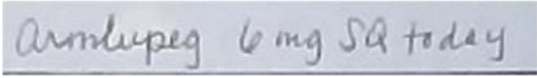
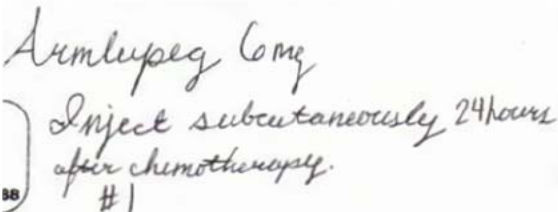
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 $\leq 54\%$).

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. Armlupeg Study (Conducted on April 23, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Armlupeg 6 mg Inject subcutaneously 24 hours after chemotherapy Dispense #1
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Armlupeg	

FDA Prescription Simulation Responses (Aggregate Report)

205 People Received Study
75 People Responded

Study Name: Armlupeg

Total	15	27	15	18	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
ARMLUPAY	0	0	2	0	2
ARMLUPE	0	0	4	0	4
ARMLUPEG	15	27	5	13	60
ARMLUPEQ	0	0	0	1	1
ARMLUPIKE	0	0	1	0	1
ARMLUTAY	0	0	1	0	1
ARNLOPA	0	0	1	0	1
AROMLUPEG	0	0	0	1	1
ARONLUPEG	0	0	0	3	3
ONLUPEG	0	0	1	0	1

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

No.	Proposed name: Armlupeg Established name: pegfilgrastim-xxxx Dosage form: injection Strength(s): 6 mg/0.6 mL Usual Dose: 6 mg once per chemotherapy cycle	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.	Armlupeg	100	Subject of this review

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Armlupeg Established name: pegfilgrastim-xxxx Dosage form: injection Strength(s): 6 mg/0.6 mL Usual Dose: 6 mg once per chemotherapy cycle	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.	Alupent	56	This name pair has sufficient orthographic and phonetic differences.
2.	Aurlumyn***	56	This name pair has sufficient orthographic and phonetic differences. The following differences in product characteristics may also help to mitigate the risk of errors: • Route of administration: Armlupeg is administered as a subcutaneous injection whereas Aurlumyn*** is administered as a continuous IV infusion; therefore, the routes of administration do not overlap. • Frequency of administration: Armlupeg is administered once per chemotherapy cycle or as 2 doses administered 1 week apart, whereas Aurlumyn*** is administered once a

No.	Proposed name: Armlupeg Established name: pegfilgrastim-xxxx Dosage form: injection Strength(s): 6 mg/0.6 mL Usual Dose: 6 mg once per chemotherapy cycle	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
			day for 5 consecutive days; therefore, the frequencies of administration do not overlap. Therefore, in this scenario, due to the above-mentioned factors and the phonetic and orthographic differences, we find this name pair acceptable.

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

No.	Name	POCA Score (%)
1.	Pramegel	46
2.	Armodafinil	42
3.	Onureg	40

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.	Arm-A-Med	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
2.	(b) (4) ***	58	Proposed proprietary name for IND 122065 found unacceptable by DMEPA (OSE# 2017-16717375 dated 01/26/2018). Subsequently, the proposed proprietary name Soanz*** was found conditionally acceptable for NDA 213218 (OSE# 2020-1044351159 dated 03/18/2021).
3.	Pharmaseb	56	Veterinary product
4.	Alupram	55	International product formerly marketed in the UK.

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

No.	Name	POCA Score (%)
1.	Permapen	60
2.	Marblen	55

^f 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/

STEPHANIE L DEGRAW
06/22/2021 10:58:30 AM

HINA S MEHTA
06/22/2021 03:50:51 PM

CHI-MING TU
06/25/2021 09:47:01 AM