CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761148Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	05/25/2022
Application Type and Number:	BLA 761148
Product Name and Strength:	Rolvedon (eflapegrastim-xxxx)[a] Injection, 13.2 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc. (Spectrum)
PNR ID #:	2022-1044724484
DMAMES Safety Evaluator:	Judine Berlus, PharmD, MPH
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] The nonproprietary name for this proposed biosimilar has not been determined yet so a placeholder elfapegrastim-xxxx is used throughout this review.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Spectrum previously submitted the following proposed proprietary names:

Proposed proprietary names	FDA received date	Application Number	Date of review	DMEPA finding
(b) (4) ***b	(b) (4)			Not acceptable due to confusion with another product that is also under review. ***Specifically, due to orthographic or phonetic similarities and shared product characteristics with the proprietary name, (b) (4) ***.
(b) (4) ***c	(b) (4)			Not acceptable due to confusion with another product that is also under review. ***Specifically, due to orthographic or phonetic similarities and shared product characteristics with the proprietary name, (b) (4) ***.
Rolontis***[d]	June 3, 2016	IND 103461	October 25, 2016	Acceptable
Rolontis***[e]	October 24, 2019	BLA 761148	January 14, 2020	Acceptable

(b) (4)

[d] Rahimi, L. Proprietary Name Review for Rolontis (IND 103461). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 OCT 25. PNR ID No. 2016-8354548.

[e] Kane, D. Proprietary Name Review for Rolontis (BLA 7641148). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 14. PNR ID No. 2019-35315339.

Rolontis***[f]	n/a (Decision amendment)	BLA 761148	November 15, 2021	Not acceptable due to confusion with another product that is also under review. *** (b) (4) (b) (4) ***

Thus, Spectrum submitted the name, Rolvedon, for review on March 11, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 11, 2022.

- Intended Pronunciation: Roll veh don
- Nonproprietary Name: eflapegrastim-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 clinically significant incidence of febrile neutropenia.
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 13.2 mg/0.6 mL
- Dose and Frequency: 13.2 mg administered subcutaneously once per chemotherapy cycle, approximately 24 hours after cytotoxic chemotherapy
- How Supplied: Supplied in a pre-filled single-dose syringe with 29-gauge, ½ inch pre-attached (staked) needle with a needle guard
- Storage: Store refrigerated between 2ºC to 8°C (36ºF to 46°F) in the carton to protect from light

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

[f] Clark, C. Proprietary Name Review for Rolontis (BLA 7641148). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 NOV 15. PNR ID No. 2020-35315339-1.

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

2.2 SAFETY ASSESSMENT

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

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

Spectrum did not provide a derivation or intended meaning for the proposed proprietary name, Rolvedon, 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 can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 18, 2022, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Rolvedon at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred and three (103) practitioners participated in DMEPA's prescription studies for Rolvedon. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[h] identified 118 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

[g] USAN stem search conducted on March 21, 2022.

[h] POCA search conducted on March 21, 2022 in version 4.4.

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	107
Low similarity name pair: combined match percentage score ≤54%	10

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

Our analysis of the 118 names contained in Table 1 determined none of the names will pose a risk for confusion with Rolvedon as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On May 25, 2022, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH). At that time we also requested additional information or concerns that could inform our review. On , the Division of Non-Malignant Hematology (DNH) stated no additional concerns with the proposed proprietary name, Rolvedon.

3 CONCLUSION

The proposed proprietary name, Rolvedon, is acceptable.

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

3.1 COMMENTS TO SPECTRUM PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 11, 2022, 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. [i]

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

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

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

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

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

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

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

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

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

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

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation study 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.

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

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

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

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

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

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

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

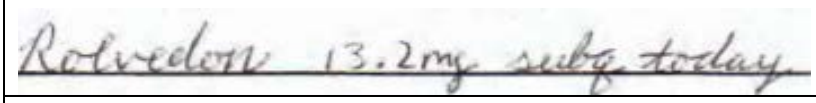
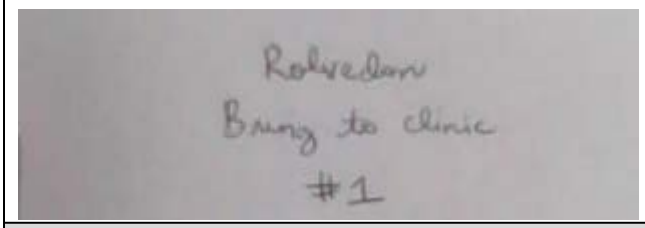
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Rolvedon Study (Conducted on March 25, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Rolvedon Bring to Clinic #1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Rolvedon	

FDA Prescription Simulation Responses (Aggregate Report)

263 People Received Study

103 People Responded

Study Name: Rolvedon

Total	24	26	28	25	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
LORVADON	0	0	1	0	1
RALVADON	0	0	1	0	1
ROLDADON	0	0	1	0	1
ROLEVEDON	0	0	0	1	1
ROLVADINE	0	0	1	0	1
ROLVADON	0	0	12	0	12
ROLVEDAN	1	0	0	0	1
ROLVEDON	23	26	3	24	76
ROLVIDON	0	0	8	0	8
ROVADAN	0	0	1	0	1

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

No.	**Proposed name:** Rolvedon **Established name:** eflapegrastim-xxxx **Dosage form:** Injection **Strength(s):** 13.2 mg/0.6 mL **Usual Dose:** 13.2 mg subcutaneously 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.	Rolvedon***	100	Name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Reltone	60
2.	Nolvadex-D	60
3.	Zolpidem	59
4.	Nolvadex	58
5.	Zoledronic	58
6.	Trazodone	57
7.	Remeron	56
8.	Robafen	56
9.	Vilazodone	56

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:** Rolvedon **Established name:** eflapegrastim-xxxx **Dosage form:** Injection **Strength(s):** 13.2 mg/0.6 mL **Usual Dose:** 13.2 mg subcutaneously 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.	Rosadan	63	Orthographically, Rolvedon contains the upstroke letter 'l' in the third position, which is absent in Rosadan. Phonetically, the 2nd syllable ('ve' vs. 'a') and 3rd syllable ('don' vs 'dan') of

No.	**Proposed name:** Rolvedon **Established name:** eflapegrastim-xxxx **Dosage form:** Injection **Strength(s):** 13.2 mg/0.6 mL **Usual Dose:** 13.2 mg subcutaneously 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**
			the name pair provides notable differences when spoken. Although both products are single strength where the strength may be omitted on a prescription, the name pair does not overlap in route of administration (subcutaneous vs. topical), frequency of administration (once per chemo cycle vs. twice daily), dosage form (injection vs. cream/gel) and dose (13.2 mg vs. apply a thin layer) thus, these product characteristic differences provide additional differentiation if included on a prescription.
2.	(b) (4) ***	63	This name pair has sufficient orthographic and phonetic differences
3.	Voluven	62	This name pair has sufficient orthographic and phonetic differences
4.	Obredon	62	Orthographically, this name pair begins with different letters (‘R’ vs. ‘O’) and the prefix (‘Rol’ vs. “’Ob’) provides some differences. Phonetically, the first (‘Rol’ vs. ‘Ob’) syllable sound different. Although, both products are single strength (13.2 mg/0.6 ml vs. 200 mg/5 ml;2.5 mg/5 ml) where the strength may be omitted, the name pair does not overlap in dose (13.2 mg vs. 10 mL). Additionally, the name pair does not overlap in other product characteristics: route of administration (subcutaneous vs. oral), frequency of

No.	**Proposed name:** Rolvedon **Established name:** eflapegrastim-xxxx **Dosage form:** Injection **Strength(s):** 13.2 mg/0.6 mL **Usual Dose:** 13.2 mg subcutaneously 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**
			administration (once per chemo cycle vs. 4- 6 times per day), dosage form (injection vs oral liquid); thus, these product characteristic differences provide additional differentiation if included on a prescription.
5.	Relador	60	Orthographically, the infixes (‘-ve-’ vs. ‘-a-’) of the name pair provide some orthographic differences. Phonetically, the second syllable (‘ve’ vs. ‘a’) and ending syllables (‘don’ vs. ‘-dor’) sound different. Although, Rolvedon and Relador are both single strength (13.2 mg/0.6 mL vs. 2.5%-2.5%) where the strength may be omitted on a prescription, the name pair does not overlap in other product characteristics: route of administration (subcutaneous vs. topical), frequency of administration (once per chemo cycle vs. one hour prior to procedure), dosage form (injection vs topical cream); thus, these product characteristic differences provide additional differentiation if included on a prescription.
6.	Relovox	60	This name pair has sufficient orthographic and phonetic differences
7.	Povidone	58	This name pair has sufficient orthographic and phonetic differences
8.	Proleukin	58	This name pair has sufficient orthographic and phonetic differences
9.	Ramelteon	57	This name pair has sufficient orthographic and phonetic differences

No.	**Proposed name:** Rolvedon **Established name:** eflapegrastim-xxxx **Dosage form:** Injection **Strength(s):** 13.2 mg/0.6 mL **Usual Dose:** 13.2 mg subcutaneously 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**
10.	(b) (4)***	57	This name pair has sufficient orthographic and phonetic differences
11.	Relafen	57	This name pair has sufficient orthographic and phonetic differences
12.	Remeven	57	This name pair has sufficient orthographic and phonetic differences
13.	Rocklatan	57	This name pair has sufficient orthographic and phonetic differences
14.	Vonvendi	56	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.	Dronedarone	54
2.	Predone	54
3.	Paroven	54
4.	(b) (4)***	54
5.	Dolene	53
6.	Predalone 50	53
7.	Diprolene	52
8.	Everone	50
9.	Levo-Dromoran	48
10.	Lavender Oil	46

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.	Folvron	66	Brand discontinued and no generic equivalents available. NDA 006012 withdrawn FR effective 06/16/2006.
2.	Boldenone	64	Per Redbook, product deactivated and there are no generics available.
3.	Oprelvekin	62	Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
4.	Redoxon	62	International Product marketed in various countries.
5.	Refolinon	62	International Product marketed in the UK, Greece, and South Africa.
6.	Solfoton	62	Per Redbook product is deactivated and there are no generics available.
7.	Rotenone	62	Product is not a drug. It is used as an ingredient in insecticides or pesticides.
8.	Roferon-A	61	BLA 103145 was revoked on 05/09/2014 with no generic equivalents available (Red book)
9.	Relcofen	61	International Product marketed in the UK.
10.	Solvent Red 27	61	Product is not a drug. It is a chemical dye.
11.	Solvent Red 4	61	Product is not a drug. It is a chemical dye.
12.	2-Pyrrolidone	60	Product is not a drug. It is an ingredient used in inkjet cartridges.
13.	Drolban	60	Brand discontinued effective 03/02/1994 and there are no generic equivalents available. NDA 012966 withdrawn FR 02/10/1997
14.	Pro-Vent	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Nerolidol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Rondec-Dm	60	Product deactivated and there are no generics available.
17.	Brolene	59	International Product marketed in the UK, Australia, Greece and Ireland.
18.	Brovex D	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Alverine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Formadon	58	Per Redbook product is deactivated and there are no generics available.
21.	Prolex D	58	Per Redbook product is deactivated and there are no generics available.
22.	Pyrrolidine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Refludan	58	Brand withdrawn FR effective 03/26/2018 and there are no generic equivalents available.

No.	Name	POCA Score (%)	Failure preventions
24.	(b) (4)***	58	Proposed Proprietary Name was found acceptable (b) (4) However, NDA (b) (4) was issued Complete Response on (b) (4). There's been no activity under this NDA since (b) (4)
25.	Regroton	58	Brand withdrawn FR effective 06/04/2004 and there are no generic equivalents available.
26.	Prolex Dm	57	Product deactivated and there are no generics available.
27.	Robenidine	57	Veterinary product.
28.	Rondamine	57	Product deactivated and there are no generics available.
29.	Solvadi	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	Solu-Medrone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Aerolone	56	Brand discontinued with no generic equivalents available. NDA 007245 withdrawn FR effective 03/02/1994.
32.	Ceradon	56	Brand discontinued on 07/25/1997 with no generic equivalents available. NDA 050601 withdrawn 07/25/1997.
33.	Replenine	56	International Product marketed in the UK, Malaysia, Singapore, Israel, Turkey, Brazil, Greece, and Mexico.
34.	Revolution	56	Veterinary Product
35.	Rolontis***	56	Proposed name denied on November 15, 2021 under BLA 761148. Applicant proposed new name that is the subject of this review.
36.	Solvent Brown 1	56	Product is not a drug. It is a chemical dye.
37.	Vendone	56	Per Redbook product is deactivated and there are no generics available.
38.	Androlone-D	55	Product deactivated and there are no generics available.
39.	Crospovidone	55	Product is not a drug. Inactive ingredient used in the pharmaceutical industry.
40.	(b) (4)***	55	Proposed proprietary name found conditionally acceptable under IND 114577 on Dec 15, 2015. Name was withdrawn on Sept 3, 2020 and product was approved under NDA under PN Lupkynis on Jan 22, 2021.

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

No.	Name	POCA Score (%)
1.	Gold Bond	62
2.	Voltaren	61
3.	Brevicon	60
4.	Dolasetron	60
5.	Dologen	60
6.	Idelvion	60
7.	Orvaten	60
8.	Propoven	60
9.	Wellferon	60
10.	Alferon N	59
11.	(b) (4) ***	59
12.	Kelferon	58
13.	Ovadine	58
14.	Pholedrine	58
15.	Poly-Vent	58
16.	Preludin	58
17.	Silvadene	58
18.	Volraman	58
19.	Bovadine	57
20.	Brulidine	57
21.	Lovenox	57
22.	Travenol	57
23.	Tri Levlen	57
24.	Atrovent	56
25.	Dermoneen	56
26.	Dolsed	56
27.	Eraldin	56
28.	Lergoban	56
29.	Lodrane D	56
30.	Povidine	56
31.	Solodyn	56
32.	Tolcylen	56
33.	Tolmetin	56
34.	Valbazen	56
35.	Zaldyon	56
36.	Dralzine	55

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

No.	Name	POCA Score (%)
37.	(b) (4) ***	55
38.	Ladropen	55
39.	Olivine	55
40.	Proflavine	55
41.	Provenge	55
42.	Triolein	55
43.	(b) (4) ***	55
44.	Vermidol	55

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JUDINE J BERLUS
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HINA S MEHTA
05/26/2022 01:44:50 PM

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SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	5/20/2022
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761148
Product Name and Strength:	Rolvedon (eflapegrastim-xnst) injection 13.2 mg/0.6 mL
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc. (Spectrum)
Nexus NPNS ID #:	2022-96
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the proposed suffix, -xnst, for BLA 761148, which was found conditionally acceptable on June 26, 2020[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761148.

1.1 Regulatory History

We found the proposed four-letter suffix, -xnst, conditionally acceptable for BLA 761148 on June 26, 2020[a]. However, BLA 761148 received a Complete Response (CR) letter on August 3, 2021[b]. Thus, Spectrum submitted a Class 2 Resubmission on March 11, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

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

Spectrum's proposed suffix, -xnst, is comprised of 4 distinct letters. We note that the letters 'ns' in the suffix represent the medical abbreviation for 'normal saline'. We considered whether the inclusion of the letters 'ns' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

We determined that the proposed suffix -xnst, 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.

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[a] Mena-Grillasca, C.. Nonproprietary Name Suffix Review for eflapegrastim-xnst (BLA 761148). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jun 26. RCM No.: 2020-178.

[b] Unger, E.F. Complete Response (BLA 761148). Silver Spring (MD): FDA, CDER, OND, Office of Cardiology, Hematology, Endocrynology, and Nephrology (US); 2021 Aug 03.

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

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On May 11, 2022, 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 May 20, 2022.

4 CONCLUSION

We find the suffix -xnst acceptable and recommend the nonproprietary name eflapegrastim-xnst be used throughout the labels and labeling.

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/s/

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DANIELLE M HARRIS
05/23/2022 07:33:16 AM

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	November 15, 2021
Application Type and Number:	BLA 761148
Product Name and Strength:	Rolontis (eflapegrastim) injection, 13.2 mg/0.6 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc.
PNR ID #:	2020-35315339-1
DMEPA 1 Safety Evaluator:	Cameron Clark, PharmD
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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11/15/2021 07:08:24 PM

VALERIE S VAUGHAN
11/15/2021 09:09:43 PM

MISHALE P MISTRY
11/16/2021 10:39:01 AM

MEMORANDUM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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)

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Date of This Review:	June 26, 2020
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761148
Product Name and Strength:	Rolontis (eflapegrastim-xnst) injection, 13.2 mg/0.6 mL
Product Type:	Combination Product (Drug-Biologic)
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc. (Spectrum)
FDA Received Date:	October 24, 2019
OSE RCM #:	2020-178
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Spectrum for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761148.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 24, 2019, Spectrum submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by Spectrum:

Table 1. Suffixes submitted by Spectrum***

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

[a] Request for Review of Suffixes for Proper Name BLA 761148. Irvine (CA): Spectrum Pharmaceuticals, Inc.; 2019 Oct 24. Available from: \\cdsesub1\evsprod\bla761148\0000\m1\us\112-other-correspondence\m1-12-4-request-comments-advice.pdf

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

2.1 eflapegrastim-xnst

Spectrum's first proposed suffix, -xnst, is comprised of 4 distinct letters. We note that the letters 'ns' in the suffix represent the medical abbreviations for 'normal saline'. We considered whether the inclusion of the letters 'ns' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated June 23, 2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Non-Malignant Hematology (DNH) via e-mail on June 26, 2020.

4 CONCLUSION

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

4.1 Recommendations for Spectrum Pharmaceuticals, Inc.

We find the nonproprietary name, eflapegrastim-xnst, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, eflapegrastim-xnst will be the proper name designated in the license. You should revise your proposed labels and labeling

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[a] See Section VI which describes that suffixes should be devoid of meaning in the Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
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LUBNA A MERCHANT on behalf of DANIELLE M HARRIS
06/29/2020 08:28:52 AM

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)

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Date of This Review:	January 14, 2020
Application Type and Number:	BLA-761148
Product Name and Strength:	Rolontis (eflapegrastim) Injection, 13.2 mg/0.6 mL
Total Product Strength:	13.2 mg/0.6ml
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Spectrum Pharmaceuticals, Inc. (Spectrum)
Panorama #:	2019-35315339
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

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