CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761173Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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

Date of This Review:	February 1, 2021
Responsible OND Division:	Division of Non-Malignant Hematology (DNH)
Application Type and Number:	BLA 761173
Product Name and Strength:	Stimufend (pegfilgrastim-fpgk) injection, 6 mg/0.6 mL
Product Type:	Combination Product (Drug-Biologic)
Applicant/Sponsor Name:	Fresenius Kabi USA, LLC (Fresenius)
FDA Received Date:	March 27, 2020
OSE RCM #:	2020-1630
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Fresenius for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761173.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On March 27, 2020, Fresenius submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Fresenius also provided findings from an external study conducted by (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Fresenius:

Table 1. Suffixes submitted by Fresenius***

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

[a] Request for Nonproprietary Naming BLA 761173. Lake Zurich (IL): Fresenius Kabi USA, LLC; 2020 Mar 27. Available from: \\CDSESUB1\evsprod\bla761173\0001\m1\us\112-other-corr\request-for-nonproprietary-naming.pdf

(b) (4)

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

2.1 pegfilgrastim-(b) (4)

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

(b) (4) Thus, we find that the suffix (b) (4) is not devoid of meaning. Therefore, the proposed suffix is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

2.2 pegfilgrastim-fpgk

Fresenius's second proposed suffix, -fpgk, is comprised of 4 distinct letters. Although we note that the suffix includes the first letters of the Applicant's first and second names, Fresenius Kabi (i.e. 'f' and k'), we find that the order of the letters presented in the suffix, and the composition -fpgk in and of itself does not readily connote the Applicant's name. We determined that the proposed suffix -fpgk, 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.

[a] See Section VI which describes that any suffixes should be devoid of meaning in 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'S ANALYSIS

These findings were shared with OPDP, OTBB, ORP, OPPQ, and OBP. Per an email correspondence dated January 13, 2021 and January 24, 2021, OPDP and OTBB 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 February 1, 2021.

4 CONCLUSION

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

4.1 Recommendations for Fresenius Kabi USA, LLC

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

We also note that your first proposed suffix is unacceptable for the following reasons:

1. pegfilgrastim (b) (4)

   We find your first proposed suffix, (b) (4), unacceptable. (b) (4) Thus, we find that the suffix (b) (4) is not devoid of meaning and is therefore is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

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

We acknowledge that our evaluation differs from that of the external study performed by [redacted] We disagree with [redacted] statement that “None of the 10 suffixes were linked to a specific meaning and none had similarities or connotations with the licensee "Fresenius Kabi" for the reasons described above.

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
02/01/2021 06:05:54 PM

DANIELLE M HARRIS
02/01/2021 06:16:38 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)

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Date of This Review:	June 17, 2020
Application Type and Number:	BLA 761173
Product Name and Strength:	Stimufend (pegfilgrastim-xxxx)* Injection 6 mg/0.6 mL
Total Product Strength:	6 mg/0.6 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Fresenius Kabi USA, LLC (Fresenius Kabi)
Panorama #:	2020-38806394
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

*Stimufend has been developed as a proposed biosimilar to US-licensed Neulasta (pegfilgrastim). Since the nonproprietary name for Stimufend has not yet been determined “pegfilgrastim-xxxx” is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Stimufend, 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. Fresenius Kabi previously submitted an external name study, conducted by [redacted] (b) (4), for this proposed proprietary name under the IND.

1.1 REGULATORY HISTORY

Fresenius Kabi previously submitted the proposed proprietary name, Stimufend*** on December 21, 2017 under IND 113717. We found the name, Stimufend*** conditionally acceptable on June 19, 2018.[a] Thus, Fresenius Kabi resubmitted the name, Stimufend, for review under BLA 761173 on March 27, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 27, 2020.

- Intended Pronunciation: STIM-yu-fend
- 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
  - Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy
  - Use weight-based dosing for pediatric patients weighing less than 45 kg
- How Supplied: Clear, colorless, preservative-free solution supplied in a pre-filled single-dose syringe for manual use containing 6 mg pegfilgrastim-xxxx, supplied with a 27-gauge, 1/2-inch needle with a Safe'n'Sound® passive Needle Guard.
- Storage: Store refrigerated between 36°F to 46°F (2°C to 8°C) in the carton to protect from light. Do not shake. Discard syringes stored at room temperature for more than 72 hours. Do not freeze. Discard syringe if frozen.
- Reference Product: Neulasta (BLA 125031)

[a] Rahimi, L. Proprietary Name Review for Stimufend (IND 113717). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JUN 19. Panorama No. 2017-19922820.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Stimufend 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 Stimufend.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 29, 2020 e-mail, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Stimufend at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-seven practitioners participated in DMEPA's prescription studies for Stimufend. The responses did not overlap with any currently marketed products; however, participants in the voice study misinterpreted Stimufend as "Stimuvent" (n=1) and "Simuvent" (n=1). These misinterpretations look and sound similar to the currently marketed product, Stimudent (actually Stim-U-Dent). We previously evaluated this name pair in Appendix C of our review of the proposed proprietary name, Stimufend, under IND 113717.[c] We note that Stim-U-Dent is not a drug product; rather, it is an over-the-counter dental stick used to remove plaque. As such, there is minimal risk of confusion between the two products despite the similarity of the names.

Additionally, one participant in the voice study misinterpreted Stimufend as "Jenuven" which is similar to the currently marketed products, Januvia (NDA 021995) and Jantoven (ANDA

[b] USAN stem search conducted on March 31, 2020.

[c] Rahimi, L. Proprietary Name Review for Stimufend (IND 113717). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JUN 19. Panorama No. 2017-19922820.

040416). Despite the misinterpretation in the FDA name simulation study, we find that the name pairs, Stimufend and Januvia, and Stimufend and Jantoven, have minimal potential for confusion based on our evaluations as described below.

Stimufend and Januvia

Orthographically, the length of the names differ as Stimufend contains nine letters whereas Januvia contains seven letters. The name pair begins with different letters (J *versus* S) and the prefixes ('Stim' vs. 'Jan') and suffixes ('fend' vs. 'via') look different. Phonetically, Januvia has four syllables whereas Stimufend has three syllables. Further, the name pair has notable differences when spoken ('jah-NEW-vee-ah' *versus* 'STIM-yu-fend'). FDA's Phonetic and Orthographic Computer Analysis (POCA) program[d] calculates a combined orthographic and phonetic score of 25%, suggesting that there is a low similarity between these names.

Stimufend and Januvia differ in terms of strength (6 mg/0.6 mL *versus* 25 mg, 50 mg, and 100 mg) and the strength and/or dose must be included on a prescription/medication order for Januvia, unlike Stimufend. Furthermore, the products have different frequencies of administration (once per chemotherapy cycle *versus* once daily). The products also differ in dosage forms (injection *versus* tablet) and routes 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.

Stimufend and Jantoven

Orthographically, the name pair begins with different letters (J *versus* S) and Stimufend contains three upstroke letters (t, f, and d) in the 2nd, 6th, and 9th positions, while Jantoven contains only one upstroke letter (t) in the 4th position. Phonetically, the first two syllables of the name pair have notable differences when spoken ('JAN-to-' *versus* 'STIM-yu-'). FDA's POCA program[e] calculates a combined orthographic and phonetic score of 40%, suggesting that there is a low similarity between these names.

The frequency of administration for Jantoven is individualized and is often once daily or multiple days per week, unlike Stimufend which is administered once per chemotherapy cycle. Furthermore, the products have different dosage forms (injection *versus* tablet) and routes 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.

[d] POCA analysis of this name pair conducted on June 2, 2020 in version 4.3.

[e] POCA analysis of this name pair conducted on June 2, 2020 in version 4.3.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 132 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified three (3) names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	3
Low similarity name pair: combined match percentage score ≤54%	2

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

Our analysis of the 5 names contained in Table 1 determined none of the names will pose a risk for confusion with Stimufend 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) via e-mail on June 5, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Non-Malignant Hematology (DNH) on June 16, 2020, they stated no additional concerns with the proposed proprietary name, Stimufend.

[f] POCA search conducted on March 31, 2020 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Stimufend, is acceptable.

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

3.1 COMMENTS TO FRESENIUS KABI USA, LLC

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

If any of the proposed product characteristics as stated in your submission, received on March 27, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).

- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[h]. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

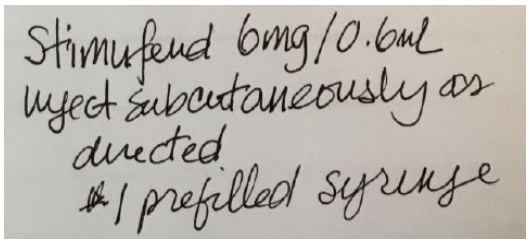
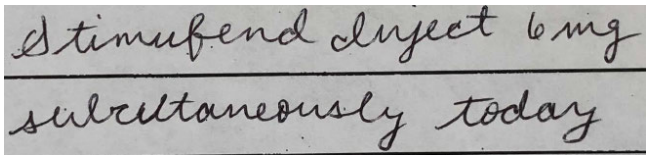
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Stimufend Study (Conducted on May 15, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Stimufend 6 mg/0.6 mL Inject subcutaneously as directed Dispense 1 prefilled syringe
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Stimufend	

FDA Prescription Simulation Responses (Aggregate Report) as of May 29, 2020

208 People Received Study
87 People Responded

Study Name: Stimufend

Total	22	17	28	20	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
JENUVEN	0	0	1	0	1
PHILMUPHEN	0	0	1	0	1
SIMUFEN	0	0	5	0	5
SIMUFEND	0	0	1	0	1
SIMUFIN	0	0	1	0	1
SIMUPHEN	0	0	1	0	1
SIMUPHEND	0	0	1	0	1
SIMUVEN	0	0	3	0	3
SIMUVENT	0	0	1	0	1
STAMUFEN	0	0	1	0	1

STAMUSCIN 6MG/.6ML	0	0	1	0	1
STANUPEN	0	0	1	0	1
STEMUFEN	0	0	1	0	1
STEMUFIN	0	0	1	0	1
STIMIFEUD	1	0	0	0	1
STIMIFUED	1	0	0	0	1
STIMUFEN	0	0	2	0	2
STIMUFEND	11	17	1	18	47
STIMUFEND INJECT	0	0	0	1	1
STIMUFEND INJECTION	0	0	0	1	1
STIMUFEUD	8	0	0	0	8
STIMUFEUR	1	0	0	0	1
STIMUFIN	0	0	1	0	1
STIMUPEN	0	0	1	0	1
STIMUPHEN	0	0	1	0	1
STIMUVEN	0	0	1	0	1
STIMUVENT	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%) – 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 – 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:** Stimufend **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.	Scot-Tussin DM	66	This name pair has sufficient orthographic and phonetic differences.
2.	Safetussin PM	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 (%)
3.	Jantoven	40
4.	Januvia	25

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
5.	(b) (4) ***	64	(b) (4)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[i] – N/A

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

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/s/

STEPHANIE L DEGRAW
06/17/2020 12:55:14 PM

HINA S MEHTA
06/17/2020 03:04:01 PM