CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761080Orig1s000

PROPRIETARY NAME REVIEW(S)

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 14, 2018
Application Type and Number:	BLA 761080
Product Name and Strength:	Nivestym ("filgrastim hospira"*) Injection *Pre-filled syringe*: 300 mcg/0.5 mL, 480 mcg/0.8 mL *Vial*: 300 mcg/mL, 480 mcg/1.6 mL
Total Product Strength:	Vials: 300 mcg/mL Prefilled syringes: 600 mcg/mL
Product Type:	Single-Ingredient and Drug-device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hospira
Panorama #:	2018-21696040
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* In this document, we refer to the proposed biosimilar product by the descriptor "Filgrastim Hospira", which was the name Hospira used to refer to this product during development. The proper name, filgrastim-aafi, is conditionally accepted until such time that the application is approved.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Nivestym, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A, respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** on November 17, 2015. It was noted the proposed proprietary name, (b) (4) *** incorporated (b) (4) However, we found the name unacceptable due to the presence of United States Adopted Name (USAN) stem, (b) (4) in the name. We communicated this to the applicant in a teleconference dated February 4, 2016.

Subsequently, the Applicant submitted the name Nivestym on April 5, 2016. We found the proposed name, Nivestym acceptable under IND 109991 on July 22, 2016 in OSE# 2016-7400898[a]. However, we amended the decision regarding the acceptability of the proposed name, Nivestym due to a conflict that existed with another similar pending proposed proprietary name, (b) (4) that was under review.[b]

The Applicant submitted the name, (b) (4) for review on September 21, 2017. We found the proposed name, (b) (4) acceptable under BLA on December 13, 2017 in OSE# 2017-17678807[c]. Subsequently, the Applicant was informed by DMEPA that the conflict existing with Nivestym and the other similar pending proposed proprietary was resolved. Thus, the Applicant withdrew the name (b) (4) and submitted the name, Nivestym for review on March 16, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 16, 2018.

- Intended Pronunciation: Neye-vest-um
- Active Ingredient: "filgrastim hospira*"

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[a] Whaley, E. Proprietary Name Review for Nivestym (IND 109991). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Jul 22. Panorama No. 2016-7400898.

[b] Garrison, N. Proprietary Name Review for Nivestym (IND 109991). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Aug 01. Panorama No. 2016-7400898-1.

[c] (b) (4)

[*] In this document, we refer to the proposed biosimilar product by the descriptor "Filgrastim Hospira", which was the name Hospira used to refer to this product during development. The proper name, filgrastim-aafi, is conditionally accepted until such time that the application is approved.

- Indication of Use:
  - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
  - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
  - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
  - Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
  - (b) (4)
- Route of Administration: Subcutaneous and Intravenous
- Dosage Form: Injection
- Strength: 300 mcg/mL single dose vial (supplied as 300 mcg/mL and 480 mcg/1.6 mL) and 600 mcg/mL prefilled syringe (supplied as 300 mcg/0.5mL and 480 mcg/0.8mL)
- Dose and Frequency:

Indication	Usual Dosage	Frequency of Administration	Dosing Interval
Myelosuppressive Chemotherapy or Induction and/or Consolidation Chemotherapy	5 mcg/kg/day	Once daily subcutaneous injection or by continuous IV infusion	Every 24 hours
Bone Marrow Transplantation	10 mcg/kg/day	Once daily as an IV infusion lasting no longer than 24 hours	Every 24 hours
Autologous Peripheral Progenitor Cell Collection	10 mcg/kg/day	Once daily as a subcutaneous injection administered for at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis	Every 24 hours
Congenital Neutropenia	6 mcg/kg/day	Subcutaneous injection twice per day	Every 12 hours

Idiopathic or Cyclic Neutropenia	5 mcg/kg/day	Subcutaneous injection daily	Every 24 hours
			(b) (4)

- How Supplied:
  - 300 mcg/mL and 480 mcg/1.6 mL single-dose vials in a dispensing pack of 10 vials
  - 300 mcg/0.5 mL and 480 mcg/0.8 mL prefilled syringes in a pack of 1 and 10 prefilled syringes
- Storage: Store Nivestym at 2°C to 8°C (36°F to 46°F) in the carton to protect from light. Do not leave Nivestym in direct sunlight. Avoid freezing; if frozen, thaw in the refrigerator before administration. Discard Nivestym if frozen more than once. Avoid shaking. Transport via a pneumatic tube has not been studied.
- Reference Listed Drug/Reference Product: Neupogen (BLA 103353)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[d].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Nivestym, is consistent with the name, Nivestim***, their EU-approved Neupogen biosimilar. Nivestim*** is currently approved in over 50 countries worldwide. This proprietary name is comprised of a single word that that contains the letters 'iv', which is the abbreviation for the intravenous route of administration. Although we typically discourage the inclusion of medical abbreviations in

[d] USAN stem search conducted on May 1, 2018.

proprietary names, we determined that the location of this abbreviation in the middle of the name, and the lack of prominence of this abbreviation makes it unlikely that the letters 'iv' within the proposed proprietary name, Nivestym, could lead to confusion in this case.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 11, 2018 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Sixty-seven (67) practitioners participated in DMEPA's prescription studies. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[e] identified 97 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 39 names not previously analyzed. These names are included in Table 1 below 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 and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	36
Low similarity name pair: combined match percentage score ≤54%	0

[e] POCA search conducted on April 2, 2018 in version 4.2.

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

Our analysis of the 39 names contained in Table 1 determined none of the names will pose a risk for confusion 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 Hematology Products (DHP) via e-mail on June 11, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on June 14, 2018, they stated no additional concerns with the proposed proprietary name, Nivestym.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on March 16, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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. [f]

[f] 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[g]. 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.

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[g] 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.

   Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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.

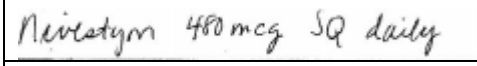
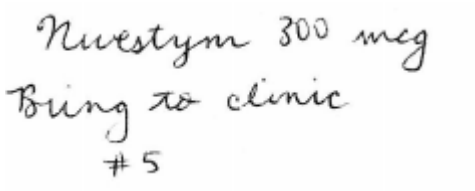
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Nivestym Study (Conducted on April 13, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Nivestym 300 mcg Bring to clinic #5
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study

67 People Responded

Study Name: Nivestym

Total	25	21	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
NIVASTEM	0	13	0	13
NIVESTEM	0	1	0	1
NIVESTGM	0	0	1	1
NIVESTRYM	2	0	0	2
NIVESTYM	8	0	13	21
NIVESTYN	0	0	6	6
NIVESTYON	0	0	1	1
NIVOSTEM	0	3	0	3
NNUESTYM	1	0	0	1

NUESTYM	7	0	0	7
NUVESTRYNN	1	0	0	1
NUVESTYM	6	0	0	6
NYVOSTEM	0	2	0	2
NYZASTEM	0	2	0	2

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

No.	**Proposed name: Nivestym** **Established name:** **"filgrastim hospira*"** **Dosage form: Injection** **Strength(s):** • **Vial:** 300 mcg/mL, 480 mcg/mL • **Prefilled syringe:** 300 mcg/0.5 mL, 480 mcg/0.8 mL **Usual Dose:** 5 mcg/kg/day or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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.	Nivestym	100	Subject of this review.
2.	(b) (4)***	78	The proposed name for BLA 761080 was found acceptable in OSE# 2017-17678807. The Applicant later withdrew the proposed name, (b) (4)*** and submitted the proposed name, Nivestym, which is the subject of this review.
3.	(b) (4)***	72	The proposed name for IND (b) (4) (b) (4)*** was found unacceptable by DMEPA in OSE# 2017-13203158. Subsequently, the Applicant submitted the proposed name, (b) (4)***, which was found unacceptable by DMEPA in OSE# 2017-17830701.

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.	Inveltys***	64

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: Nivestym** **Established name:** **"filgrastim hospira*"** **Dosage form: Injection** **Strength(s):** • **Vial:** 300 mcg/mL, 480 mcg/mL • **Prefilled syringe:** 300 mcg/0.5 mL, 480 mcg/0.8 mL **Usual Dose:** 5 mcg/kg/day or 10 mcg/kg/day. The frequency of administration and dosing interval vary depending on the indication.	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) ***	55	This name pair has sufficient orthographic and phonetic differences.

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

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	60	The proposed name for NDA 208743, (b) (4) *** was found unacceptable by DMEPA in OSE# 2016-8278936. NDA 208743 is approved under the proprietary name, Tymlos.

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

No.	Name	POCA Score (%)
1.	Mecysteine	60
2.	Timentin	60
3.	Teveten	60
4.	Myricetin	60
5.	Desitin	59
6.	Genistein	58
7.	Unitensen	58
8.	Metosyn	58
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NICOLE B GARRISON
06/14/2018

HINA S MEHTA
06/14/2018

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:	December 13, 2017
Application Type and Number:	BLA 761080
Product Name and Strength:	(b) (4) ("filgrastim hospira"*) Injection *Pre-filled syringe*: 300 mcg/0.5 mL, 480 mcg/0.8 mL *Vial*: 300 mcg/mL, 480 mcg/1.6 mL
Total Product Strength:	Vials: 300 mcg/mL Prefilled syringes: 600 mcg/mL
Product Type:	Single-Ingredient and Drug-device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hospira
Panorama #:	2017-17678807
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

* For the purposes of this review, we generally refer to Hospira's proposed product by Hospira's descriptor "filgrastim hospira." FDA has not yet designated a nonproprietary name for Hospira's proposed biosimilar that includes a distinguishing suffix (see Guidance on Nonproprietary Naming of Biological Products).

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