CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761039Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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:	October 3, 2018
Responsible OND Division:	Division of Hematology Products (DHP)
Application Type and Number:	BLA 761039
Product Name and Strength:	Udenyca (pegfilgrastim-cbqv) Injection 6 mg/0.6 mL
Product Type:	Drug-device Combination Product
Applicant/Sponsor Name:	Coherus Biosciences, Inc.
FDA Received Date:	May 3, 2018
OSE RCM #:	2018-921
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum is to reassess the four-letter suffix, -cbqv for BLA 761039, which was found conditionally acceptable on March 8, 2017[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name BLA 761039.

1.1 Regulatory History

Coherus previously submitted a list of 3 suffixes, in their order for preference for BLA 761039 on August 9, 2016. FDA found the proposed suffix, -cbqv, conditionally acceptable for BLA 761039 on March 8, 2017. However, BLA 761039 received a Complete Response (CR) letter on June 9, 2017[b]. Thus, Coherus submitted a Class 2 Resubmission on May 3, 2018.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On May 3, 2018, Coherus submitted a list of two suffixes, in their order of preference, to be used in the nonproprietary name of their product[c]. Coherus also provided findings from an external study conducted by [(b) (4)])[d], evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Coherus:

Table 1. Suffixes submitted by Coherus***	
1.	-cbqv
2.	-[(b) (4)]

We reviewed Coherus' proposed suffixes in order of preference listed by Coherus, along with the supporting data they submitted, using the principles described in the applicable guidance.[e] We note the first proposed suffix was previously evaluated and found conditionally acceptable during the previous review cycle.

2.1 pegfilgrastim-cbqv

We reassessed the proposed four-letter suffix, -cbqv, using the principles described in the applicable guidance[f]. Coherus also provided findings from an external study conduct by [(b) (4)]

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[a] Garrison, N. Nonproprietary Name Suffix Memorandum for pegfilgrastim-cbqv (BLA 761039). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAR 08. RCM No.: 2016-1833.

[b] Farrell, A. Complete Response (BLA 761039). Silver Spring (MD): FDA, CDER, OND, Division of Hematology Products (US); 2017 JUN 09.

[c] Request for Proprosed Suffixes Review (BLA 761036). Redwood City (CA): Coherus BioSciences, Inc; 2018 MAY 08. Available from: \\cdsesub1\evsprod\bla761039\0056\m1\us\1182-rqst-suffx-prop-name.pdf

[d] [(b) (4)] Data Summary for Proposed Suffixes Report. Miami (FL): [(b) (4)] Inc.; 2016 SEP 12. Available from: \\cdsesub1\evsprod\bla761039\0009\m1\us\118-proprietary-names\[(b) (4)]data-propsd-suffx-rpt.pdf

[e] 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

[f] 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:

(b) (4))[g], evaluating the proposed four-letter suffix in conjunction with the nonproprietary name, which was analyzed in a previous review of the nonproprietary name[h]. This suffix was determined to include some letters that represent common medical abbreviations[i] ('bq' for Becquerel). The Applicant did not identify any abbreviations or acronyms for this proposed suffix in the external study. We considered whether the inclusion of this abbreviation 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 -cbqv, 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. Therefore, we find the proposed suffix -cbqv acceptable for this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated October 2, 2018, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Hematology Products (DHP) via e-mail on October 3, 2018.

4 CONCLUSION

We find Coherus' proposed suffix -cbqv acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to pegfilgrastim-cbqv.

4.1 Recommendations for Coherus Biosciences, Inc.

We find the nonproprietary name, pegfilgrastim-cbqv, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, pegfilgrastim-cbqv will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. 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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http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

[g] Data Summary For Proposed Suffixes: -cbqv, (b) (4) 2016 SEP 12. Available from: Application 761039 - Sequence 0009 - (b) (4) Data Summary for Proposed Suffixes Report

[h] Garrison, N. Nonproprietary Name Suffix Memorandum for pegfilgrastim-cbqv (BLA 761039). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAR 08. RCM No.: 2016-1833.

[i] Neil M Davis, *Medical Abbreviations: 30,000 Conveniences at the Expense of Communication and Safety*. Pennsylvania, 2009.

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/

NICOLE B GARRISON
10/03/2018

DANIELLE M HARRIS
10/03/2018

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)

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Date of This Review:	July 25, 2018
Application Type and Number:	BLA 761039
Product Name and Strength:	Udenyca ("CHS-1701")* Injection 6 mg/0.6 mL
Total Product Strength:	6 mg/0.6 mL
Product Type:	Drug-device Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Coherus BioSciences Inc.
Panorama #:	2018-22794706
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 "CHS-1701", which was the name Coherus BioSciences Inc. used to refer to this product during development. The proper name for CHS-1701 has not yet been conditionally accepted. We therefore continue to refer to the proposed product as "CHS-1701" throughout this review in place of the proper name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Udenyca, 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 submitted an external name study, conducted by (b) (4) for this product, which was analyzed in a previous review of the proprietary name.[a]

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Udenyca on October 29, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Udenyca acceptable under IND 115573 on March 9, 2016.[a] Subsequently, the Applicant submitted the name, Udenyca with the marketing application on August 9, 2016. DMEPA found the name acceptable on October 6, 2016; however, the Division of Hematology Products (DHP) issued a Complete Response (CR) for the application on June 9, 2017.[b] The Applicant re-submitted the application, and the proposed proprietary name, Udenyca, for review on May 3, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 3, 2018.

- Intended Pronunciation: yoo den' i kah
- Active Ingredient: CHS-1701*
- Indication of Use: To decrease the incidence of infection, as manifested by neutropenia, in patients 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

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[a] Whaley, E. Proprietary Name Review for Udenyca (IND 115573). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 MAR 09. Panorama No. 2015-1877840.

[b] Garrison, N. Proprietary Name Review for Udenyca (BLA 761039). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 OCT 06. Panorama No. 2016-9553701.

* In this document, we refer to the proposed biosimilar product by the descriptor "CHS-1701", which was the name Coherus BioSciences Inc. used to refer to this product during development. The proper name for CHS-1701 has not yet been conditionally accepted. We therefore continue to refer to the proposed product as "CHS-1701" throughout this review in place of the proper name for this product.

- Dose and Frequency: 6 mg subcutaneously once per chemotherapy cycle. Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
  Dosing of Udenyca for pediatric patients weighing less than 45 kg

Body Weight	Udenyca Dose	Volume to Administer
Less than 10 kg*	See below*	See below*
10 to 20 kg	1.5 mg	0.15 mL
21 to 30 kg	2.5 mg	0.25 mL
31 to44 kg	4 mg	0.4 mL

*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of Udenyca

- How Supplied: Supplied as a preservative-free solution containing 6 mg (0.6 mL) of pegfilgrastim (10 mg/mL) in a single-dose syringe with a 29 gauge, ½ inch needle with an UltraSafe® (b) (4) Needle Guard. Provided in a dispensing pack containing one syringe.
- Storage: Store in the refrigerator at 2º to 8ºC (36º to 46ºF), but not in the freezer
- Reference Listed Drug/Reference Product: Neulasta, BLA 125031

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[c].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Udenyca in their submission. We note that the proposed name includes the letter string 'Ud-, which is a commonly used abbreviation on prescription directions for 'as directed'. Although we typically

[c] USAN stem search conducted on June 14, 2018.

discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the letter string at the beginning of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Udenyca does not contain any additional 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 23, 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

Fifty-three (n=53) 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[d] identified 58 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 23 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. 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%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	20
Low similarity name pair: combined match percentage score ≤54%	2

[d] POCA search conducted on June 7, 2018 in version 4.2.

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

Our analysis of the 23 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 July 19, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on July 24, 2018, they stated no additional concerns with the proposed proprietary name, Udenyca.

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, Udenyca, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on May 3, 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. [e]

[e] 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[f]. 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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[f] 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. Udenyca Study (Conducted on June 1, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Udenyca 25mg subQ x 1 dose Outpatient Prescription: Udenyca 6mg subQ x 1 dose #1 syringe	Udenyca Inject 6 mg subcutaneously x 1 dose # 1 syringe

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

307 People Received Study

53 People Responded

Study Name: Udenyca

Total	17	18	18	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
EUDENICA	0	1	0	1
EUDENTICA	0	1	0	1
UCLENYCA	1	0	0	1
UDANYCA	1	0	0	1
UDEMYCA	2	0	0	2
UDENEKA	0	1	0	1
UDENICA	0	10	0	10
UDENIKA	0	2	0	2
UDENTICA	0	1	0	1

UDENYCA	8	0	17	24
UDENZCA	1	0	0	1
UDINYCA	1	0	0	1
UDMYCA	1	0	0	1
ULENYCA	1	0	0	1
UNDENYCA	0	0	1	1
VDEMYCA	1	0	0	1
YUDENECA	0	1	0	1
YUDENEKA	0	1	0	1

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

No.	**Proposed name:** Udenyca **Established name:** "CHS 1701"* **Dosage form:** Injection **Strength(s):** 6 mg/0.6 mL **Usual Dose:** - Adult and pediatric patients ≥ 45 kg: 6 mg once per chemotherapy cycle. - Pediatric patients weighing less than 45 kg a. Less than 10 kg: 0.1 mg/kg subcutaneously b. 10 to 20 kg: 1.5 mg subcutaneously c. 21 to 30 kg: 2.5 mg subcutaneously d. 31 to 44 kg: 4 mg subcutaneously	**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.	(b) (4) ***	70	Proposed proprietary name for NDA 209483 found acceptable by DMEPA (OSE# 2017-14860290). The Applicant decided to withdraw the name (b) (4) for business reasons and submitted the proposed name, Impoyz. NDA 209483 approved under the proprietary name Impoyz.

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.	Adzenys	62

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:** Udenyca **Established name:** "CHS 1701"* **Dosage form:** Injection **Strength(s):** 6 mg/0.6 mL **Usual Dose:** - Adult and pediatric patients ≥ 45 kg: 6 mg once per chemotherapy cycle. - Pediatric patients weighing less than 45 kg e. Less than 10 kg: 0.1 mg/kg subcutaneously f. 10 to 20 kg: 1.5 mg subcutaneously g. 21 to 30 kg: 2.5 mg subcutaneously h. 31 to 44 kg: 4 mg subcutaneously	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)***	58	This name pair has sufficient orthographic and phonetic differences.
2.	U-Gencin	55	This name pair has sufficient orthographic and phonetic differences. Strength: 6 mg/0.6 mL vs. 10 mg/mL and 40 mg/mL

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

No.	Name	POCA Score (%)
	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.	Undecane	63	This product is not a drug. It is an ingredient found in allspice.
2.	(b) (4)***	63	Proposed proprietary name for (b) (4) found to be unacceptable (OSE # (b) (4)). Application withdrawn by the Applicant.

No.	Name	POCA Score (%)	Failure preventions
3.	(b) (4) ***	60	Proposed proprietary name for IND (b) (4) and IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) and OSE# (b) (4)). IND is pending and no new names have been submitted.
4.	Uvadex	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	Adeno-Jec	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Undecylenate	48	Name identified in RxNorm database, however it is listed in combination with zinc undecylenate and undecyclenic acid. The product, if marketed, is an over the counter (OTC) antifungal applied topically and the collective differences are expected to sufficiently avoid any confusion or errors with the two products.
7.	Uad Caine	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Dynapen	58
2.	Acanya	56
3.	Andec	56
4.	(b) (4) ***	56
5.	Benzyl Pca	56
6.	Dynabac	56
7.	Dynacin	56
8.	Eucardic	56
9.	(b) (4) ***	56
10.	(b) (4) ***	56
11.	Ny-Tannic	56
12.	Dynafed	55

[g] 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/

NICOLE B GARRISON
07/25/2018

HINA S MEHTA
07/26/2018

MEMORANDUM
NONPROPRIETARY NAME SUFFIX

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:	March 8, 2017
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	BLA 761039
Product Name and Strength:	Udenyca (pegfilgrastim-cbqv) Injection 6 mg/0.6 mL
Total Product Strength:	6 mg/0.6 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Coherus Biosciences, Inc.
Panorama #:	2016-1833
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
OMEPRM Deputy Director (Acting):	Lubna Merchant, MS, PharmD

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the suffixes proposed by Coherus Biosciences for the nonproprietary name and communicates our recommendation for the nonproprietary name.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

FDA has determined that the use of a distinguishing suffix in the nonproprietary name for Coherus Biosciences' Udenyca product is necessary to distinguish this proposed product from Neulasta (pegfilgrastim). As explained in FDA's Guidance for Industry, Nonproprietary Naming of Biological Products, FDA expects that a nonproprietary name for Udenyca include a distinguishing suffix that will facilitate safe use and optimal pharmacovigilance. We reviewed Coherus Biosciences' proposed suffixes against the criteria described in the guidance.

On August 9, 2016, Coherus Biosciences submitted a list of suffixes, in their order of preference, to be used in the nonproprietary name of their product. We note that the Applicant submitted three suffixes. We conducted our review in the order of the preference listed by the Applicant. The Applicant also provided for our consideration findings from an external study conducted by (b) (4) evaluating the proposed four letter suffixes in conjunction with the nonproprietary name.

1. pegfilgrastim- (b) (4)

(b) (4)

2. pegfilgrastim-cbqv

We reviewed the second alterative, -cbqv provided by Coherus Biosciences. This suffix was determined to include some letters that represent common medical abbreviations[b] ('bq' for Becquerel). The Applicant did not identify any abbreviations or acronyms for this proposed suffix in the external study. We considered whether the inclusion of this abbreviation 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 also determined that Coherus's suffix –cbqv 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, and does not make promotional representations with respect to safety or efficacy of this product. Overall, we agree with the Applicant's determination.

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[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

[b] Neil M Davis, *Medical Abbreviations: 30,000 Conveniences at the Expense of Communication and Safety*. Pennsylvania, 2009.

3 CONCLUSIONS

We find that Coherus Biosciences proposed suffix "-cbqv" acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to pegfilgrastim-cbqv.

3.1 RECOMMENDATIONS FOR COHERUS BIOSCIENCES

1. We find your proposed nonproprietary name, pegfilgrastim-(b) (4) unacceptable (b) (4) [redacted].[c]

2. We find the nonproprietary name, pegfilgrastim-cbqv, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, pegfilgrastim-cbqv will be the proper name designated in the license and you should revise your proposed labels and labeling accordingly. 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 proposal unacceptable upon our re-evaluation, we would inform you of our finding.

[c] 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

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/s/

NICOLE B GARRISON
03/08/2017

LUBNA A MERCHANT
03/08/2017

PROPRIETARY NAME MEMORANDUM

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:	October 6, 2016
Application Type and Number:	BLA 761039
Product Name and Strength:	Udenyca ("CHS-1701")* Injection 6 mg/0.6 mL
Total Product Strength:	6 mg/0.6 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Coherus Biosciences, Inc.
Panorama #:	2016-9553701
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader (Acting):	Hina Mehta, PharmD

*For purposes of this review, we generally refer to Coherus Biosciences' proposed product by the Coherus Biosciences' descriptor "CHS1701." FDA has not yet designated a nonproprietary name for Coherus Biosciences' proposed biosimilar product that includes a distinguishing suffix (see Draft Guidance on Nonproprietary Naming of Biological Products).

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Udenyca, which was found conditionally acceptable under IND 115573 on March 9, 2016.[a] The Applicant submitted an external name study, conducted by (b) (4) for this product, which was analyzed during the last review of the proprietary name.

We note that there is a change in dosing for patients weighing less than 45 kg listed in the "Dosage and Administration" section of the Prescribing Information (PI) for BLA 761039. All other product characteristics remain the same. Table 1 below summarizes the change.

Table 1. Comparison of Dosage and Administration between IND and BLA

<table>
<tr><th></th><th>IND 115573</th><th>BLA 761039</th></tr>
<tr><td>Dosage and Administration in Pediatric Patients Weighing less than 45 kg</td><td>N/A</td><td>The Udenyca prefilled syringe is not designed to allow for direct administration of doses less than 0.6 mL (6 mg). The syringe does not bear graduation marks, which are necessary to accurately measure doses of Udenyca less than 0.6 mL (0.6 mg) for direct administration to patients. Thus, the direct administration to patients requiring dosing of less than 0.6 mL (6 mg) is not recommended due to the potential for dosing errors.

Dosing of Udenyca for pediatric patients weighing less than 45 kg

<table>
<tr><th>Body Weight</th><th>Udenyca Dose</th><th>Volume to Administer</th></tr>
<tr><td>Less than 10 kg*</td><td>See below*</td><td>See below*</td></tr>
<tr><td>10-20 kg</td><td>1.5 mg</td><td>0.15 mL</td></tr>
<tr><td>21-30 kg</td><td>2.5 mg</td><td>0.25 mL</td></tr>
<tr><td>31-44 kg</td><td>4 mg</td><td>0.4 mL</td></tr>
</table>
*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of Udenyca</td></tr>
</table>

[a] Whaley, E. Proprietary Name Review for Udenyca (IND 115573). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 MAR 09. Panorama No. 2015-1877840.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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 proposed proprietary name. Since our last review, we identified two new names in POCA and determined they will not pose a risk for confusion as described in Appendix A. Although we note a change in the dosage and administration since our last review, we previously evaluated identified names taking into account that the proposed product will include dosing and administration instructions for patients weighing less than 45 kg to mimic the listed drug, US-licensed Neulasta. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 15, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable from promotional and safety perspective.

If you have any questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 9, 2016 submission 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.

APPENDICES

Appendix A: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4) ***	56, Phonetic 70
2.	Adzenys XR ODT	52

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/s/

NICOLE B GARRISON
10/06/2016

HINA S MEHTA
10/06/2016