CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761175Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	February 3, 2025
Application Type and Number:	BLA 761175
Product Name, Dosage Form, and Strength:	Jobevne (bevacizumab-nwgd) Injection, 100 mg/4 mL (25 m/mL) and 400 mg/16 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2024-1044726103
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Jobevne, 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. Biocon submitted an external name study, conducted by [redacted] (b) (4), [a] for this proposed proprietary name. The submitted external name study was previously reviewed under BLA 761175 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Mylan previous submitted the proposed proprietary name, [redacted] (b) (4) under IND 122927 on October 16, 2019, and under BLA 761175 on December 27, 2019. The name was found conditionally acceptable on March 25, 2020.[b] However, we later found the name, [redacted] (b) (4) unacceptable due to [redacted] (b) (4) on August 13, 2021.[c]

Subsequently, Mylan submitted the name, Jobevne, for review on January 18, 2022. The name was found conditionally acceptable on April 12, 2022.[d] However, BLA 761175 received a complete response on February 6, 2023 due to facility inspection deficiencies.[e]

On March 9, 2023, Mylan Pharmaceutical transferred ownership of BLA 761175 to Biocon.[f]

On August 11, 2023, Biocon submitted the name, Jobevne, for review as part of the Class 2 Resubmission to the complete response letter. The name was found conditionally acceptable on November 2, 2023.[g] However, the BLA received a complete response on February 7, 2024 due to facility inspection deficiencies.[h]

[redacted] (b) (4)

[b] Stewart, J. Proprietary Name Review for [redacted] (b) (4) (IND 122927 and BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Mar 25. Panorama ID No. 2019-35135944 and 2019-36801673

[c] Thomas, S. Proprietary Name Memorandum for [redacted] (b) (4) (IND 122927 and BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 13. Panorama ID No. 2019-35135944-1 and 2019-36801673-1

[d] Thomas, S. Proprietary Name Review for Jobevne (BLA 761175), Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 APR 12. PNR ID No. 2022-1044724395.

[e] Fashoyin-Aje, L. Complete Response for MYL-14020 (BLA 761175). Silver Spring (MD): FDA, CDER, OND (US); 2023 Feb 6. Available from: https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af806b03a9.

[f] Product Correspondence. Administrative Change in Application – Acceptance of BLA Ownership. Cambridge (MA): Biocon Biologics Inc. 2023 Mar 9. Available from: \\CDSESUB1\EVSPROD\bla761175\0035\m1\us\12-cover-letters\cover-letter-0035-acceptance-of-bla-ownership-20230309.pdf.

[g] Do, N. Proprietary Name Review for Jobevne (BLA 761175), Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 Nov 1. PNR ID No. 2023-1044725285.

[h] Fashoyin-Aje, L. Complete Response for MYL-14020 (BLA 761175). Silver Spring (MD): FDA, CDER, OND (US); 2024 Feb 7. Available from: https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af80724553.

Thus, Biocon resubmitted the proposed proprietary name, Jobevne, for review on November 13, 2024 as part of the Class 2 Resubmission for BLA 761175.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 13, 2024[i] and amendment received on November 21, 2024[j] and the prescribing information received on November 13, 2024.[k]

Table 1. Relevant Product Information for Jobevne	
Intended pronunciation:	joh-BEV-nee
Nonproprietary name:	bevacizumab-nwgd

[i] 1.18 Proprietary Name (BLA 761175 (Jobevne)). Cambridge (MA): Biocon Biologics Inc; 2024 Nov 13. Available from: \\CDSESUB1\EVSPROD\bla761175\0040\m1\us\118-proprietary-names\proprietary-names-jobevne.pdf.

[j] Amendment to Request for Proprietary Name Review-Jobevne (BLA 761175). Cambridge (MA): Biocon Biologics Inc.; 2024 Nov 21. Available from: \\CDSESUB1\EVSPROD\bla761175\0040\m1\us\12-cover-letters\cover-letter-0040-amendment-to-request-for-proprietary-name.pdf.

[k] Proposed prescribing information for Jobevne. Cambridge (MA): Biocon Biologics Inc.; 2024 Nov 13. Available from: \\CDSESUB1\EVSPROD\bla761175\0039\m1\us\114-labeling\draft\labeling\draft-labeling-text-pi-biocon-clean-word.docx.

Table 1. Relevant Product Information for Jobevne	
Indication:	For the treatment of: **Metastatic Colorectal Cancer** • In combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment • In combination with fluoropyrimidine-irinotecan, or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment of patients who have progressed on a first-line bevacizumab product containing regimen Limitation of Use: not indicated for adjuvant treatment of colon cancer. **Non-Squamous Non–Small Cell Lung Cancer** • In combination with carboplatin and paclitaxel, for the first line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer **Recurrent Glioblastoma** • For the treatment of recurrent glioblastoma (GBM) in adults. **Metastatic Renal Cell Carcinoma** • In combination with interferon alfa for the treatment of metastatic renal cell carcinoma (mRCC). **Persistent, Recurrent, or Metastatic Cervical Cancer** • In combination with paclitaxel and cisplatin or paclitaxel and topotecan **Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer** • In combination with carboplatin and paclitaxel, followed by Jobevne as a single agent, for stage III or IV disease following initial surgical resection • In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens • In combination with carboplatin and paclitaxel or with carboplatin and gemcitabine, followed by Jobevne as a single agent, for platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Dosage Form:	Injection
Strength:	100 mg/4 mL (25 m/mL) and 400 mg/16 mL (25 mg/mL)
Route of administration:	Intravenous

Table 1. Relevant Product Information for Jobevne	
Dose and frequency:	Metastatic colorectal cancer • 5 mg/kg every 2 weeks with bolus-IFL • 10 mg/kg every 2 weeks with FOLFOX4 • 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks with fluoropyrimidine- irinotecan or fluoropyrimidine-oxaliplatin-based chemotherapy after progression on a first-line bevacizumab product-containing regimen First-line non–squamous non–small cell lung cancer • 15 mg/kg every 3 weeks with carboplatin and paclitaxel Recurrent glioblastoma • 10 mg/kg every 2 weeks Metastatic renal cell carcinoma • 10 mg/kg every 2 weeks with interferon alfa Persistent, recurrent, or metastatic cervical cancer • 15 mg/kg every 3 weeks with paclitaxel and cisplatin, or paclitaxel and topotecan Epithelial ovarian, fallopian tube, or primary peritoneal cancer *Stage III or IV Disease Following Initial Surgical Resection* • 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel for up to 6 cycles, followed by 15 mg/kg every 3 weeks as a single agent for a total of up to 22 cycles or until disease progression, whichever occurs earlier. *Recurrent Disease* Platinum Resistant • 10 mg/kg intravenously every 2 weeks in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan given every week. • 15 mg/kg intravenously every 3 weeks in combination with topotecan given every 3 weeks. Platinum Sensitive • 15 mg/kg intravenously every 3 weeks, in combination with carboplatin and paclitaxel for 6 to 8 cycles, followed by Jobevne 15 mg/kg every 3 weeks as a single agent until disease progression. • 15 mg/kg intravenously every 3 weeks, in combination with carboplatin and gemcitabine for 6 to 10 cycles, followed by Jobevne 15 mg/kg every 3 weeks as a single agent until disease progression.
How Supplied:	supplied in a single-dose vial within a carton in the following strengths: • 100 mg/4 mL (25 mg/mL) • 400 mg/16 mL (25 mg/mL)
Storage:	Store refrigerated at 2° to 8°C (36° to 46°F) in the original carton to protect from light. Do not freeze or shake.

Table 1. Relevant Product Information for Jobevne	
Reference Product:	Jobevne (bevacizumab-nwgd) is a proposed biosimilar to US-licensed Reference Product, Avastin (bevacizumab) BLA 125085

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Jobevne would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Jobevne. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Jobevne.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Jobevne at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-four (94) practitioners participated in DMEPA's prescription simulation studies for Jobevne. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

[l] USAN stem search conducted on January 6, 2025.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[m] identified forty-six (46) names with a combined score of ≥55% or an individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two (2) names not previously analyzed. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
Low similarity name pair: combined match percentage score ≤54%	0

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

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

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On February 3, 2025, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Jobevne, is conditionally acceptable.

3.1 COMMENTS TO BIOCON BIOLOGICS INC.

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

A request for proprietary name review for Jobevne should be submitted once your marketing application is submitted.

[m] POCA search conducted on January 2, 2025 in version 5.9.

If any of the proposed product characteristics as stated in your submission, received on November 13, 2024, and amendment received on November 21, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

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

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[n]

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - 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[o]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

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

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

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

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 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 as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

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

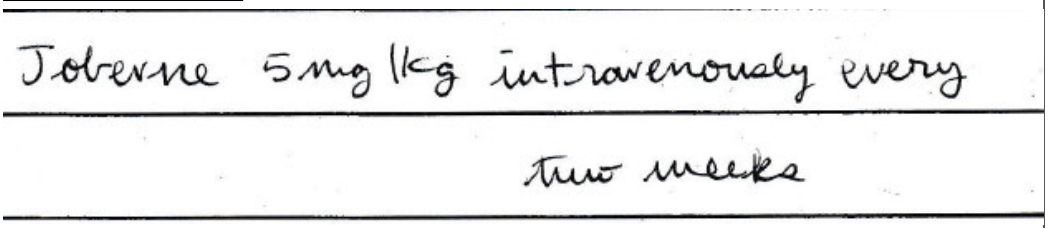
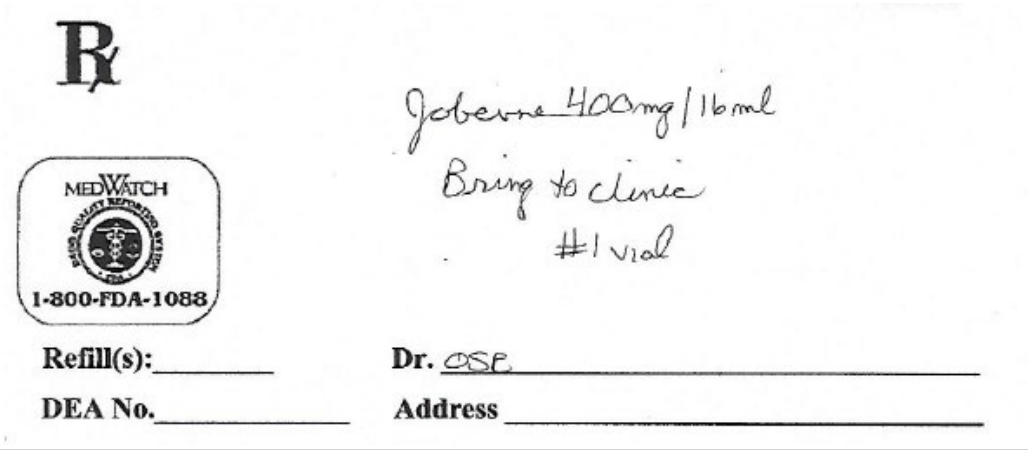
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤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. Jobevne Study (Conducted on 11/29/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Jobevne 400 mg/16 mL Bring to clinic. Dispense 1 vial.
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Jobevne	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Jobevne People Received Study: 180 People Responded: 94					
Total	27	27	16	24	94
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BESNI	0	0	1	0	1
GIOVESNI	0	0	1	0	1
JOBEFNEE	0	0	1	0	1
JOBENSVY	0	0	1	0	1
JOBERNA	0	1	0	0	1
JOBERNE	11	1	0	0	12
JOBESKNEE	0	0	1	0	1
JOBESNI	0	0	1	0	1
JOBEVERNE	0	1	0	0	1
JOBEVNA	0	7	0	0	7
JOBEVNE	14	14	0	24	52
JOBEVNEE	0	0	1	0	1
JOBEVNI	0	0	2	0	2
JOBEVNY	0	0	4	0	4
JOBEVRE	0	1	0	0	1
JOBEZNI	0	0	1	0	1
JOBEZNY	0	0	2	0	2
JOBREVNE	1	0	0	0	1
JOFERNE	1	0	0	0	1
JOLENE	0	1	0	0	1
ZOBEVNE	0	1	0	0	1

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

No.	Proposed name: Jobevne Pronunciation: joh-BEV-nee Established name: bevacizumab-nwgd Dosage form: Injection Strength(s): 100 mg/4 mL (25 m/mL) and 400 mg/16 mL (25 mg/mL) Dosage: 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	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.
	N/A		

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

No.	Name	POCA Score (%)
	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: Jobevne Pronunciation: joh-BEV-nee Established name: bevacizumab-nwgd Dosage form: Injection Strength(s): 100 mg/4 mL (25 m/mL) and 400 mg/16 mL (25 mg/mL) Dosage: 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	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.	Jubereq***	56	Orthographically, Jubereq*** has a downstroke letter "q" in the last position, while Jobevne does not contain any downstroke letters, which provides some orthographic differences when scripted. Phonetically, the ending sound of the second syllables ("BEV" vs. "BURR") and the last syllables ("nee" vs. "eck") sound different when spoken. There is no overlap in strength (100 mg/4 mL and 400 mg/16 mL vs. 120 mg/1.7 mL), route of administration (intravenously vs. subcutaneously), and frequency of administration (every 2 weeks and every 3 weeks vs. every 4 weeks).

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.	(b) (4)	62	Proposed proprietary name for BLA 761392 found to be unacceptable by DMEPA due to a conflict with a marketed product (PNR ID # 2024-1044725624). Subsequently, the proposed proprietary name Ospomyv*** was found conditionally acceptable for BLA 761392.

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

No.	Name	POCA Score (%)
	N/A	

[p] 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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SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	1/23/2025
Responsible OND Division:	Division of Oncology 3 (DO3)
Application Type and Number:	BLA 761175
Product Name and Strength:	Jobevne (bevacizumab-nwgd) injection 100 mg/4 mL and 400 mg/16 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
Nexus NPNS ID #:	2024-292
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -nwgd, for BLA 761175, which was found conditionally acceptable on September 1, 2020[a] and December 5, 2023[b], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761175.

1.1 Regulatory History

- FDA generated a four-letter suffix, -nwgd, for BLA 761175 on September 1, 2020.
- BLA 761175 received a Complete Response (CR) letter on February 6, 2023.[c]
- Biocon submitted a Class 2 Resubmission on August 11, 2023.
- FDA re-reviewed the four-letter suffix, -nwgd, for BLA 761175 on December 5, 2023.
- BLA 761175 received a CR letter on February 7, 2024.[d]
- Biocon submitted a Class 2 Resubmission on November 13, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously generated four-letter suffix, -nwgd, using the principles described in the applicable guidance[e].

We determined that the FDA-generated suffix -nwgd, 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

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for bevacizumab-nwgd (BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Sep 01. RCM No.: 2020-1493.

[b] Mena-Grillasca, C. Nonproprietary Name Suffix Review for bevacizumab-nwgd (BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2023 Dec 05. Nexus No.: 2023-205.

[c] Fashoyin-Aje, L. Complete Response (BLA 761175). Silver Spring (MD): FDA, CDER, OND, DO3 (US); 2023 Feb 06.

[d] Fashoyin-Aje, L. Complete Response (BLA 761175). Silver Spring (MD): FDA, CDER, OND, DO3, (US); 2024 Feb 07.

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

be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On January 8, 2025, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 3 (DO3) on January 23, 2025.

4 CONCLUSION

We find the suffix -nwgd acceptable and recommend the nonproprietary name bevacizumab-nwgd be used throughout the draft labels and labeling.

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/s/

CARLOS M MENA-GRILLASCA
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SUFFIX REVIEW FOR NONPROPRIETARY NAME

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

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	12/5/2023
Responsible OND Division:	Division of Oncology 3 (DO3)
Application Type and Number:	BLA 761175
Product Name and Strength:	Jobevne (bevacizumab-nwgd) injection 100 mg/4 mL and 400 mg/16 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
Nexus NPNS ID #:	2023-205
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -nwgd, for BLA 761175, which was found conditionally acceptable on September 1, 2020[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761175.

1.1 Regulatory History

FDA generated a four-letter suffix, -nwgd, for BLA 761175 on September 1, 2020[a]. However, BLA 761175 received a Complete Response (CR) letter on February 6, 2023[b]. Thus, Biocon submitted a Class 2 Resubmission on August 11, 2023.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

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

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

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On November 22, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMAMES also communicated our findings to the Division of Oncology 3 (DO3) on December 5, 2023.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for bevacizumab-nwgd (BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Sep 01. RCM No.: 2020-1493.

[b] Fashoyin-Aje, L. Complete Response (BLA 761175). Silver Spring (MD): FDA, CDER, OND, DO3 (US); 2023 Feb 06.

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

4 CONCLUSION

We find the suffix -nwgd acceptable and recommend the nonproprietary name bevacizumab-nwgd be used throughout the draft labels and labeling.

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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 1, 2023
Application Type and Number:	BLA 761175
Product Name and Strength:	Jobevne (bevacizumab-nwgd) injection, 100 mg/4 mL (25 m/mL) or 400 mg/mL (25 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biocon Biologics Inc. (Biocon)
PNR ID #:	2023-1044725285
DMEPA 2 Safety Evaluator:	Ngoc-Linh Do, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Jobevne, 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. Biocon submitted an external name study, conducted by [redacted (b) (4)]., for this proposed proprietary name.

1.1 REGULATORY HISTORY

Mylan previous submitted the proposed proprietary name, [redacted (b) (4)] under IND 122927 on October 16, 2019, and under BLA 761175 on December 27, 2019. The name was found conditionally acceptable on March 25, 2020.[a] However, we later found the name, [redacted (b) (4)] unacceptable due to [redacted (b) (4)] on August 9, 2021.[b]

Subsequently, Mylan submitted the name, Jobevne, for review on January 18, 2022. The name was found conditionally acceptable on April 13, 2022.[c] However, BLA 761175 received a complete response on February 6, 2023.[d]

On March 9, 2023, Mylan Pharmaceutical transferred ownership of BLA 761175 to Biocon.

Thus, Biocon submitted a Class 2 Resubmission of the BLA on August 11, 2023 in response to the Complete Response letter and concurrently submitted a request for proprietary name review of Jobevne, which is the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 11, 2023.

- Intended Pronunciation: joh-BEV-nee
- Nonproprietary Name: Bevacizumab-nwgd
- Indication of Use: For the treatment of:
    - Metastatic colorectal cancer
        - In combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment

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[a] Stewart, J. Proprietary Name Review for [redacted (b) (4)] (IND 122927 and BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAR 25. Panorama ID No. 2019-35135944 and 2019-36801673

[b] Thomas, S. Proprietary Name Review for [redacted (b) (4)] (IND 122927 and BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 AUG 9. Panorama ID No. 2019-35135944-1 and 2019-36801673-1

[c] Thomas, S. Proprietary Name Review for Jobevne (BLA 761175), Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 APR 13. PNR ID No. 2022-1044724395

[d] https://darrts.fda.gov/darrts/ViewDocument?documentId=090140af806b03a9

- In combination with fluoropyrimidine-irinotecan, or fluoropyrimidine-oxaliplatin-based chemotherapy for second line treatment in patients who have progressed on a first-line bevacizumab product containing regimen

Limitation of Use: not indicated for adjuvant treatment

- In combination with carboplatin and paclitaxel, for the first line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer

- Recurrent glioblastoma in adults

- In combination with interferon alfa for the treatment of metastatic renal cell carcinoma

- In combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of patients with persistent, recurrent, or metastatic cervical cancer

- Epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - in combination with carboplatin and paclitaxel, followed by Jobevne as a single agent, for stage III or IV disease following initial surgical resection
  - in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens
  - in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by Jobevne as a single agent, for platinum-sensitive recurrent disease

- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 100 mg/4 mL (25 m/mL) or 400 mg/mL (25 mg/mL)
- Dose and Frequency:

Metastatic colorectal cancer
- 5 mg/kg every 2 weeks with bolus-IFL
- 10 mg/kg every 2 weeks with FOLFOX4
- 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin-based chemotherapy after progression on a first-line bevacizumab product-containing regimen

First-line non−squamous non−small cell lung cancer
- 15 mg/kg every 3 weeks with carboplatin and paclitaxel

Recurrent glioblastoma
- 10 mg/kg every 2 weeks

Metastatic renal cell carcinoma

- 10 mg/kg every 2 weeks with interferon alfa

Persistent, recurrent, or metastatic cervical cancer

- 15 mg/kg every 3 weeks with paclitaxel and cisplatin, or paclitaxel and topotecan

Epithelial ovarian, fallopian tube, or primary peritoneal cancer

Stage III or IV Disease Following Initial Surgical Resection

- 15 mg/kg intravenously every 3 weeks in combination with carboplatin and paclitaxel for up to 6 cycles, followed by 15 mg/kg every 3 weeks as a single agent for a total of up to 22 cycles or until disease progression, whichever occurs earlier.

Recurrent Disease

Platinum Resistant

- 10 mg/kg intravenously every 2 weeks in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan (every week).

- 15 mg/kg intravenously every 3 weeks in combination with topotecan (every 3 weeks).

Platinum Sensitive

- 15 mg/kg intravenously every 3 weeks, in combination with carboplatin and paclitaxel for 6 to 8 cycles, followed by Jobevne 15 mg/kg every 3 weeks as a single agent until disease progression.

- 15 mg/kg intravenously every 3 weeks, in combination with carboplatin and gemcitabine for 6 to 10 cycles, followed by Jobevne 15 mg/kg every 3 weeks as a single agent until disease progression.

- How Supplied: a clear to slightly opalescent, colorless to pale brown, sterile solution for intravenous infusion supplied in a single-dose vial within a carton in the following strengths:
  - 100 mg/4 mL (25 mg/mL)
  - 400 mg/16 mL (25 mg/mL)
- Storage: Store refrigerated at 2° to 8°C (36° to 46°F) in the original carton to protect from light
- Jobevne (bevacizumab-nwgd) is a proposed biosimilar to US-licensed Reference Product, Avastin (bevacizumab) BLA 125085

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Jobevne would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Jobevne. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Jobevne.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On September 13, 2023, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Jobevne at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-seven (87) practitioners participated in DMEPA's prescription studies for Jobevne. The responses did overlap with one marketed product, Joenja.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name, Joenja, from the dynamic contains pick list. However, the participant entered an incorrect sequence of letters, 'Joen' instead of 'Job' when searching for the study name. As a result, the CPOE generated picklist did not contain Jobevne as a choice. The participant proceeded to incorrectly select Joenja as their response after 41 seconds in order to proceed with the FDA prescription stimulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Despite this, we further evaluated Jobevne vs. Joenja.

[e] USAN stem search conducted on September 25, 2023.

The name pair has sufficient orthographic and phonetic differences. Additionally, there are multiple product characteristic differences between Jobevne and Joenja. The products do not overlap in strength (100 mg/4 mL and 400 mg/mL vs. 70 mg), dose (5 mg/kg, 10 mg/kg, 7.5 mg/kg, or 15 mg/kg vs. 70 mg), dosage form (injection vs. tablet), frequency (every 2 weeks or every 3 weeks vs. every 12 hours), or route of administration (intravenous infusion vs. oral). Hence, we find the name pair has sufficient product characteristic, orthographic, and phonetic differences, and Joenja is included in Appendix D.

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified forty-four (44) 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 four (4) names not previously analyzed. These names and our re-evaluation of Joenja (direct hit from CPOE described in Section 2.2.4) are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	5
Low similarity name pair: combined match percentage score ≤54%	0

[f] POCA search conducted on September 28, 2023 in version 5.2.

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

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

2.2.8 Communication of DMEPA's Determination

On November 1, 2023, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Jobevne, is conditionally acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO BIOCON BIOLOGICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 11, 2023, 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. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, 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.

   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.

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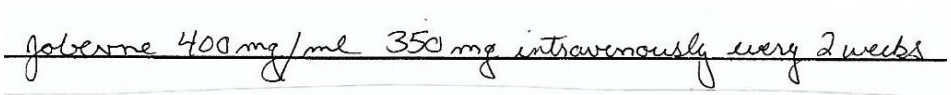
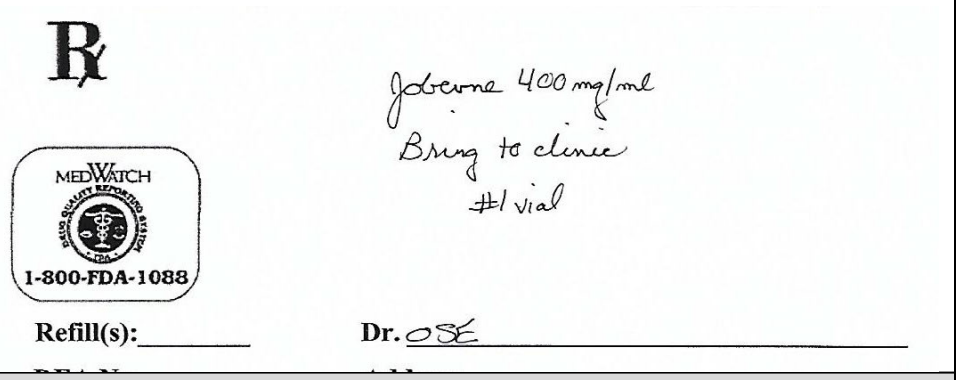
Appendix B: Prescription Simulation Samples and Results

Figure 1. Jobevne Study (Conducted on September 5, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Jobevne Bring to clinic. Dispense 1 vial
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Jobevne	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Jobevne

People Received Study: 253

People Responded: 87

Total	28	20	18	21	87
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
ABMYVO	1	0	0	0	1
GOBEVEN	1	0	0	0	1
JOBENE	1	0	0	0	1
JOBEUNE	0	1	0	0	1
JOBEVENE	0	0	1	0	1
JOBEVMI	0	0	1	0	1
JOBEVNE	23	19	0	20	62
JOBEVNI	0	0	8	0	8
JOBEVNY	0	0	6	0	6
JOBEVVY	0	0	1	0	1
JOENJA	0	0	0	1	1
JOGOVNEE	0	0	1	0	1
ZOBEVNE	2	0	0	0	2

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

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 m/mL) or 400 mg/mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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.**
	N/A		

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

No.	Name	POCA Score (%)
1.	Joenja	60
2.	Cobenfy***	58

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:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 m/mL) or 400 mg/mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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.	Voquezna	60	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4)	56	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)	56	The name pair has sufficient orthographic differences.

No.	Proposed name: Jobevne Established name: bevacizumab-nwgd Dosage form: injection Strength(s): 100 mg/4 mL (25 m/mL) or 400 mg/mL (25 mg/mL) Usual Dose: 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			(b) (4)

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/

NGOC - LINH DO
11/01/2023 04:17:40 PM

ASHLEIGH V LOWERY
11/02/2023 12:23:58 PM

CHI-MING TU
11/02/2023 02:22:59 PM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	April 12, 2022
Application Type and Number:	BLA 761175
Product Name and Strength:	Jobevne (bevacizumab-nwgd[a]) injection, 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mylan GmbH (Mylan)
PNR ID #:	2022-1044724395
DMEPA 2 Safety Evaluator:	Sarah Thomas, PharmD
DMEPA 2 Team Leader:	Janine Stewart, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] The proposed nonproprietary name (bevacizumab-nwgd) is only conditionally accepted for this product until the application is approved; see Mena-Grillasca, C M. Suffix Review for Nonproprietary Name for (b) (4) (BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Sept 1. OSE RCM No.: 2020-1493.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Jobevne, 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. Mylan submitted an external name study, conducted by [redacted] (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

Mylan previously submitted the proposed proprietary name, [redacted] (b) (4) on October 16, 2019 under IND 122927 and on December 27, 2019 under BLA 761175. However, we found the name, [redacted] (b) (4) unacceptable due to [redacted] (b) (4) on July 30, 2021.[b]

Thus, Mylan submitted the name, Jobevne, for review on January 18, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 18, 2022.

- Intended Pronunciation: joh-BEV-nee
- Nonproprietary Name: bevacizumab-nwgd
- Indication of Use: Jobevne is a vascular endothelial growth factor inhibitor indicated for the treatment of:
    - Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first-or second-line treatment.
    - Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan-or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.
    - Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.
    - Recurrent glioblastoma in adults.
    - Metastatic renal cell carcinoma in combination with interferon alfa.
    - Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.

[b] Thomas, S. Proprietary Name Review for [redacted] (b) (4) (IND 122927 and BLA 761175). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 JULY 30. Panorama ID No. 2019-35135944-1 and 2019-36801673-1.

- Route of Administration: intravenous
- Dosage Form: injection
- Strength: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL)
- Dose and Frequency:

  Metastatic colorectal cancer
  - 5 mg/kg every 2 weeks with bolus-IFL
  - 10 mg/kg every 2 weeks with FOLFOX4
  - 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy after progression on a first-line bevacizumab product-containing regimen

  First-line non−squamous non−small cell lung cancer
  - 15 mg/kg every 3 weeks with carboplatin and paclitaxel

  Recurrent glioblastoma
  - 10 mg/kg every 2 weeks

  Metastatic renal cell carcinoma
  - 10 mg/kg every 2 weeks with interferon alfa

  Persistent, recurrent, or metastatic cervical cancer
  - 15 mg/kg every 3 weeks with paclitaxel and cisplatin, or paclitaxel and topotecan
- How Supplied: a clear to slightly opalescent, colorless to pale brown, sterile solution for intravenous infusion supplied in a single-dose vial within a carton
- Storage: Store refrigerated at 2° to 8°C (36° to 46°F) in the original carton until time of use to protect from light.
- Reference Listed Drug/Reference Product: Avastin, BLA 125085

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Jobevne would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Jobevne. The Division of Oncology 3 (DO3) did not comment on the findings of OPDP's assessment for Jobevne.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

As of March 7, 2022, the Division of Oncology 3 (DO3) did not forward any comments or concerns relating to Jobevne at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 39 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 (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

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

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	38
Low similarity name pair: combined match percentage score ≤54%	4

[c] USAN stem search conducted on January 21, 2022.

[d] POCA search conducted on January 21, 2022 in version 4.4.

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

Our analysis of the 42 names contained in Table 1 determined none of the names will pose a risk for confusion with Jobevne as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On April 4, 2022, DMEPA 2 communicated our determination to the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Jobevne, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO MYLAN GMBH

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

If any of the proposed product characteristics as stated in your submission, received on January 18, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

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

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

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

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

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

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

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

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

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

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

   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.

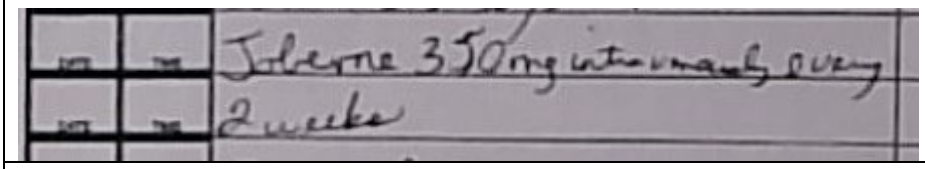
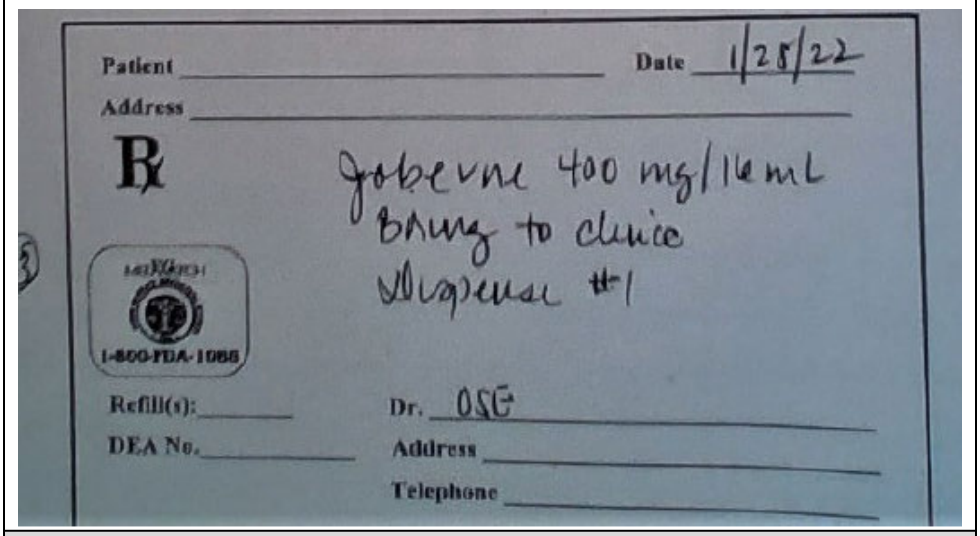
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Jobevne Study (Conducted on January 31, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Jobevne 400 mg per 16 mL Bring to clinic Dispense one
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Jobevne	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Jobevne

As of Date 2/15/2022

262 People Received Study
114 People Responded

Study Name: Jobevne

Total	27	28	23	36	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
JABEVNE	2	0	0	0	2
JABEYNE	0	0	0	1	1
JOBEME	0	0	0	5	5
JOBENE	0	0	0	2	2
JOBERN	0	0	0	1	1
JOBERNA	0	0	0	3	3
JOBERNE	1	0	0	13	14
JOBERNE 350MG	0	0	0	1	1
JOBEVNE	24	28	1	2	55
JOBEVNEE	0	0	1	0	1
JOBEVNI	0	0	5	0	5
JOBEVNY	0	0	14	0	14
JOBEYNE	0	0	0	2	2
JOBYRNE	0	0	0	1	1
JOLERNA	0	0	0	1	1
JOLERNE	0	0	0	2	2
JOLEVNE	0	0	0	1	1
JOVENFI	0	0	1	0	1
TOBERNE	0	0	0	1	1
YOBEVNY	0	0	1	0	1

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

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	N/A		

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

No.	Name	POCA Score (%)
1.	Bevespi	57

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:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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)	65	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4)	62	This name pair has sufficient orthographic and phonetic differences.
3.	Joenja***	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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**
4.	Obezine	60	This name pair has sufficient orthographic and phonetic differences.
5.	Jubbonti***	59	This name pair has sufficient orthographic and phonetic differences.
6.	Jantoven	58	This name pair has sufficient orthographic and phonetic differences. Although the products share numerical similarity in dose (5 mg/kg vs. 5 mg), Jobevne's nonoverlapping multiple strengths (100 mg/4 mL and 400 mg/16 mL vs. 1 mg, 2 mg, 2½ mg, 3 mg, 4 mg, 5 mg, 6 mg, 7½ mg, or 10 mg), as well as different dosage forms (injection vs. tablets), routes of administration (intravenous vs. oral), and frequency of administration (every 2 or 3 weeks vs. once daily) provide further differentiation between the name pair when prescribed.
7.	Jevtana	58	The extra letter "v" before the upstroke letters and infixes (bev vs. ta) provide sufficient orthographic differentiation. This name pair has sufficient phonetic differences. Both Jobevne and Jevtana are injectable oncology drugs that typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the difference

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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**
			in dosing units of measurement (e.g., mg/kg vs. mg/m^2) is minimized.
8.	Obephen	58	This name pair has sufficient orthographic and phonetic differences.
9.	Jatenzo	56	The suffixes of this name pair (-ne versus -zo) provide some orthographic differentiation. The second syllables (BEV versus TEN) and third syllables (nee versus zoh) sound different. Although Jobevne and Jatenzo can share similarity in dose (e.g., 396 mg), the name pair differs in strength [100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) versus 158 mg, 198 mg, 237 mg]. Also, this name pair differs in dosage form (injection versus capsule), route of administration (intravenous versus oral), and frequency of administration (every 2 weeks or every 3 weeks versus twice daily), which all may help to provide differentiation if included on a prescription. Additionally, injectable oncology drugs typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the difference in strength, dosage form,

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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**
			route of administration, and frequency of administration is minimized.
10.	Obestin-30	56	This name pair has sufficient orthographic and phonetic differences.
11.	Jadenu	55	The extra letter "v" in the infix of Jobevne provides some orthographic differentiation. The second syllables (BEV versus de) and third syllables (nee versus nue) sound different. Although Jobevne and Jadenu share similarity in dose (e.g., 10 mg/kg vs. 10 mg/kg/day), the name pair differs in strength [100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) versus 90 mg, 180 mg, 360 mg]. Also, this name pair differs in dosage form (injection versus tablet), route of administration (intravenous versus oral), and frequency of administration (every 2 weeks or every 3 weeks versus once daily), which all may help to provide differentiation if included on a prescription. Additionally, injectable oncology drugs typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the difference in strength, dosage form,

No.	**Proposed name:** Jobevne **Established name:** bevacizumab-nwgd **Dosage form:** injection **Strength(s):** 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) **Usual Dose:** 5 mg/kg intravenously every 2 weeks, 10 mg/kg intravenously every 2 weeks, 7.5 mg/kg intravenously every 3 weeks, 15 mg/kg intravenously every 3 weeks	**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**
			route of administration, and frequency of administration is minimized.

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

No.	Name	POCA Score (%)
1.	Januvia	42
2.	Ubrelvy	42
3.	Yohimbe	37

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.	Avobenzone	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Per Google search, avobenzone is an ingredient found in sunscreen products.
2.	Donnazyme	58	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
3.	Junifen	57	International product marketed in Spain and formerly marketed in Belgium, United Kingdom, Portugal, Thailand, and Austria per Micromedex database.
4.	Lobeline	57	Product is not a drug. It is an alkaloid extracted from the lobelia flower per Clinical Pharmacology database.

No.	Name	POCA Score (%)	Failure preventions
5.	(b) (4)	56	Proposed proprietary name for IND 122927 and BLA 761175 found unacceptable by DMEPA on July 30, 2021 (Panorama ID#s: 2019-35135944-1 and 2019-36801673-1). BLA 761175 is pending per DARRTS application status, and subsequent proposed proprietary name Jobevne was submitted for review on January 18, 2022 under BLA 761175, which is the subject of this review.
6.	Jolivette	56	Branded generic discontinued with no generic equivalents available per Micromedex Redbook database.
7.	(b) (4)	49	Proposed proprietary name for NDA 214869 found unacceptable by DMEPA (Panorama #: 2020-43497029 dated November 6, 2020). NDA 214869 approved under the proprietary name, Dhivy.

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.	Robafen	60
2.	Robafen Pe	60
3.	Vonvendi	59
4.	Besivance	58
5.	(b) (4)	58
6.	Dodecene	58
7.	Bovadine	57
8.	Novoseven	57
9.	Benerva	56
10.	Betavent	56
11.	Dovonex	56
12.	Fovane	56
13.	Novafed A	56
14.	Xopenex	56
15.	Combivent	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

No.	Name	POCA Score (%)
16.	Cymevene	55
17.	Remeven	55
18.	Robafen Ac	55
19.	Vibisone	55
20.	Zimovane	55

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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:	August 13, 2021
Application Type and Number:	IND 122927 and BLA 761175
Product Name and Strength:	(b) (4) (bevacizumab-nwgd) Injection, 25 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mylan GmbH (Mylan)
Panorama ID#:	2019-35135944-1 and 2019-36801673-1
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA Associate Director of Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

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CHI-MING TU
08/13/2021 01:02:01 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	September 1, 2020
Responsible OND Division:	Division of Oncology 3 (DO3)
Application Type and Number:	BLA 761175
Product Name and Strength:	(b) (4) (bevacizumab-nwgd) injection 100 mg/4 mL and 400 mg/16 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Mylan GmbH (Mylan)
OSE RCM #:	2020-1493
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 suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761175.

1.1 Regulatory History

Mylan was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

bevacizumab-nwgd

FDA generated a four-letter suffix, -nwgd. This suffix was evaluated using the principles described in the applicable guidance[b].

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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated September 1, 2020, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology 3 (DO3) via e-mail on September 1, 2020.

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[a] Harris, D. General Advice Letter for BLA 761175. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2020 Mar 05.
[b] 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

4 CONCLUSION

We find the suffix -nwgd acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to bevacizumab-nwgd. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendation for Mylan GmbH

We find the nonproprietary name, bevacizumab-nwgd, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, bevacizumab-nwgd 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 this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/s/

CARLOS M MENA-GRILLASCA
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DANIELLE M HARRIS
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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:	March 25, 2020
Application Type and Number:	IND 122927 and BLA 761175
Product Name and Strength:	(b) (4) (bevacizumab-xxxx)[a] Injection, 25 mg/mL
Total Product Strength:	100 mg/4 mL and 400 mg/16 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mylan GmbH (Mylan)
Panorama #:	2019-35135944 and 2019-36801673
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] (b) (4) has been developed as a proposed biosimilar to US-licensed Avastin (bevacizumab). Since the proper name for (b) (4) has not yet been determined, "bevacizumab-xxxx" is used throughout this review as the proper name for this product.

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