CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761192Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	December 28, 2022
Application Type and Number:	BLA 761192
Product Name and Strength:	Nexobrid (anacaulase-bcdb) for topical gel, 8.8%
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MediWound, Ltd (MediWound)
PNR ID #:	2022-1044724661-1
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Nexobrid, based the revised nonproprietary name (anacaulase-bcdb), dosage form (for topical gel), and strength (8.8% after mixing). The proposed proprietary name, Nexobrid, was found acceptable under BLA 761192 on September 22, 2022.[a]

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names taking into account the change in the nonproprietary name (anacaulase-bcdb), dosage form (for topical gel), and strength (8.8% after mixing). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Nexobrid.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The December 28, 2022 search of USAN stems did not find any USAN stems in the proposed proprietary name, Nexobrid.

3 CONCLUSION

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

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

[a] Patel, M. Proprietary Name Review for Nexobrid (BLA 761192). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 SEP 22. PNR ID No. 2022-1044724661.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/

MADHURI R PATEL
12/28/2022 10:06:47 PM

MISHALE P MISTRY
12/29/2022 09:56:33 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Date of This Review:	10/13/2022
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761192
Product Name and Strength:	NexoBrid (anacaulase[a]-bcdb) topical lyophilized powder for gel[b], (b) (4)% kit or 2 g/20 g gel and 5 g/50 g gel[c]
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	MediWound, Ltd (MediWound)
Nexus NPNS ID #:	2022-117
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Division Director (acting):	Irene Z Chan, PharmD, BCPS

[a] Proposed core name submitted by the applicant is 'concentrate of proteolytic enzymes enriched in bromelain'. However, OPQ's recommendation for this core name is 'anacaulase'.

[b] The final dosage form has yet to be determined by the Agency at the time of this review.

[c] The final strength presentation has yet to be determined by the Agency at the time of this review.

1 PURPOSE OF REVIEW

This review is to re-assess the proposed suffix, -bcdb, for BLA 761192, which was found conditionally acceptable on June 25, 2021[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761192.

1.1 Regulatory History

FDA found the proposed suffix, -bcdb, acceptable for BLA 761192 on June 25, 2021[a]. However, BLA 761192 received a Complete Response (CR) letter on June 25, 2021[b]. Thus, MediWound submitted a Class 2 Resubmission on July 1, 2022.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

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

We determined that the proposed suffix -bcdb, 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 1 ANALYSIS

These findings were shared with OPDP. On October 13, 2022, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Dermatology and Dentistry (DDD) on October 13, 2022.

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[a] Mena-Grillasca C.M. Nonproprietary Name Suffix Review for anacaulase-bcdb (BLA 761192). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jun 25. Nexus NPNS ID.: 2020-35.

[b] Beitz J.G. Complete Response (BLA 761192). Silver Spring (MD): FDA, CDER, OND, OII (US); 2021 Jun 25.

[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 -bcdb acceptable and recommend the nonproprietary name anacaulase-bcdb be used throughout the labels and labeling. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendation for MediWound, Ltd

We find the nonproprietary name, anacaulase-bcdb, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, anacaulase-bcdb will be the proper name designated in the license. 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 will inform you of our findings.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
10/13/2022 09:31:58 PM

IRENE Z CHAN
10/17/2022 08:30:47 AM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 22, 2022
Application Type and Number:	BLA 761192
Product Name and Strength:	Nexobrid[a] (concentrate of proteolytic enzymes enriched in bromelain-xxxx)[b] topical lyophilized powder for gel[c], (b) (4)% Kit or 2 g/20 gel and 5 g/50 g gel[d]
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MediWound, Ltd (MediWound)
PNR ID #:	2022-1044724661
DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

[a] We considered in our assessment the product name NexoBrid and Nexobrid.

[b] The final nonproprietary name has yet to be determined by the Agency at the time of this review.

[c] The final dosage form has yet to be determined by the Agency at the time of this review.

[d] The final strength has yet to be determined by the Agency at the time of this review.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

MediWound previously submitted the proposed proprietary name, Nexobrid*** on October 19, 2012. We found the name, Nexobrid*** conditionally acceptable under IND 065448 on April 12, 2013.[e] Subsequently, MediWound submitted Nexobrid*** on June 29, 2020 under BLA 761192 and we found the name Nexobrid*** conditionally acceptable on September 22, 2020.[f] However, BLA 761192 received a Complete Response (CR) on June 25, 2021.

Thus, MediWound responded to the CR and re-submitted the name, Nexobrid[g], for review on July 1, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 1, 2022.

- Intended Pronunciation: nex' oh brid
- Nonproprietary Name: concentrate of proteolytic enzymes enriched in bromelain-xxxx[h]
- Indication of Use: eschar removal (debridement) in adults with deep partial thickness (DPT) and/or full thickness (FT) thermal burns
- Route of Administration: topical
- Dosage Form: topical lyophilized powder for gel[i]
- Strength: (b) (4) % Kit or 2 g/20 gel and 5 g/50 g gel[j]
- Dose and Frequency: 1 application/dose

[e] Mena-Grillasca, C. Proprietary Name Review for Nexobrid*** (IND 065448). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 APR 12. Panorama No. 2012-2474.

[f] Patel, M. Proprietary Name Review for Nexobrid*** (BLA 761192). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2020 SEP 22. PNR ID No. 2022-40949280.

[g] We considered in our assessment the product name NexoBrid and Nexobrid.

[h] The final nonproprietary name has yet to be determined by the Agency at the time of this review.

[i] The final dosage form has yet to be determined by the Agency at the time of this review.

[j] The final strength has yet to be determined by the Agency at the time of this review.

- 2 g lyophilized powder mixed with 20 g gel per 1% total body surface area (TBSA) of an adult
- 5 g lyophilized powder mixed with 50 g gel per 2.5% TBSA of an adult.
- may be applied to an area of up to 15% TBSA in one application. Leave the dressing and Nexobrid in place for 4 hours. A second application of NexoBrid may be applied twenty-four (24) hours later to the same or new burn wound area. The total treated area for both applications must not exceed 20% TBSA.

- How Supplied: NexoBrid is provided as two components that are mixed prior to application.
  - Each package of NexoBrid includes: one single use vial of powder, sealed with a rubber stopper and covered with a flip cap; and one jar of gel sealed with a rubber stopper and covered with a screw cap.
  - NexoBrid carton, NDC 69866-2002-3, contains 2g sterile lyophilized powder and 20g sterile gel
  - NexoBrid carton, NDC 69866-2005-3, contains 5g sterile lyophilized powder and 50g sterile gel
- Storage: Store and transport refrigerated (2 to 8°C). Store upright. Protect from light. Do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Nexobrid would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Nexobrid. The Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for Nexobrid.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[k] USAN stem search conducted on July 15, 2022.

2.2.2 Components of the Proposed Proprietary Name

MediWound did not provide a derivation or intended meaning for the proposed proprietary name, Nexobrid, 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 July 18, 2022, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Nexobrid at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred (n=100) practitioners participated in DMEPA's prescription studies for Nexobrid. 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[1] identified 169 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. No product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. However, we note the final nonproprietary name, dosage form, and strength is still under review by the Agency. Therefore, we identified seven names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) (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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	6

[1] POCA search conducted on July 15, 2022 in version 4.4.

Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 10 names contained in Table 1 determined none of the names will pose a risk for confusion with Nexobrid as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On September 22, 2022, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Nexobrid, is acceptable.

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO MEDIWOUND, LTD

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

If any of the proposed product characteristics as stated in your submission, received on July 1, 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. [m]

[m] 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[n]. 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

[n] 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.

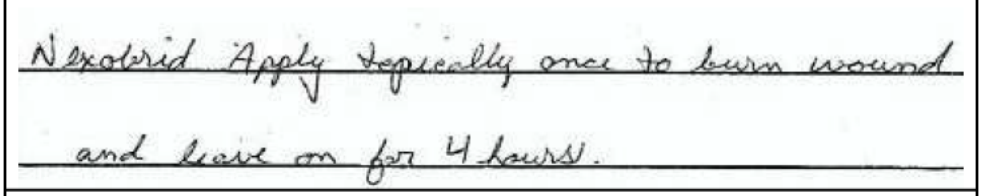
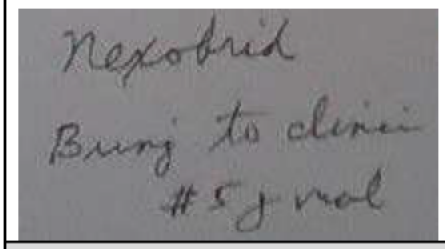
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Nexobrid Study (Conducted on July 15, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Nexobrid Bring to clinic. Dispense a 5 g vial.
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Nexobrid	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
100 People Responded

Study Name: Nexobrid

Total	24	21	28	27	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
EXOBRID	0	0	1	0	1
MEZOPRED	0	0	1	0	1
NEXOBID	0	0	0	1	1
NEXOBRID	24	21	24	25	94
NEXOBRIF	0	0	1	0	1
NEXOBRIL	0	0	0	1	1

NEXOGRID	0	0	1	0	1

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

No.	**Proposed name:** Nexobrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** topical lyophilized powder for gel **Strength(s):** (b)(4)% Kit or 2 g/20 gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. Leave on for 4 hours. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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.	Nexobrid***	100	Subject of this review
2.	Dexodryl	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Nexafed	70	Orthographically, the 'r' in the 6th position of Nexobrid, not present Nexafed, provides some orthographic difference. Phonetically, the last syllables ('brid' vs. 'fed') of this name pair sound different. In addition to the orthographic and phonetic differences, the following product characteristics would help to mitigate the error: • Nexafed is the root name for over-the-counter (OTC) products, Nexafed Nasal Decongestant (pseudoephedrine hydrochloride 30 mg) and Nexafed Sinus Pressure + Pain (acetaminophen/ pseudoephedrine hydrochloride 325 mg/30 mg). Hence, if one of these OTC products were written on a prescription or ordered, the modifier would have to be specified which would help minimize potential name confusion.

No.	**Proposed name:** Nexobrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** topical lyophilized powder for gel **Strength(s):** (b)(4)% Kit or 2 g/20 gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. Leave on for 4 hours. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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.**
			• The dosage form and route of administration of the products differ, if included on a prescription/medication order (tablet vs. lyophilized powder for gel; oral vs. topical). • Additionally, Nexobrid should be prepared at the patient's bedside within 15 minutes of wound debridement procedure by wound care specialist that are trained and familiar with the product and debridement procedure. Therefore, due to the above-mentioned factors we find this name pair acceptable.

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

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Nexobrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** topical lyophilized powder for gel **Strength(s):** (b) (4) % Kit or 2 g/20 gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. Leave on for 4 hours. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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)	62	This name pair has sufficient orthographic and phonetic differences.
2.		60	This name pair has sufficient orthographic and phonetic differences.
3.		58	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Verdinexor	50

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)		
2.	Dexased	55	Veterinary product.

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

° Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially

No.	Name	POCA Score (%)
1.	(b) (4)	56

Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

MADHURI R PATEL
09/22/2022 06:52:03 PM

MISHALE P MISTRY
09/23/2022 09:21:05 AM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	June 25, 2021
Responsible OND Division:	Division of Dermatology and Dentistry (DDD)
Application Type and Number:	BLA 761192
Product Name and Strength:	NexoBrid (anacaulase[a]-bcdb) Topical Lyophilized Powder for Gel, (b) (4)% Kit or 2 g/20 g gel and 5 g/50 g gel
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	MediWound, Ltd (MediWound)
FDA Received Date:	June 29, 2020
Nexus NPNS ID #:	2020-35
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

[a] Proposed core name submitted by the applicant is 'concentrate of proteolytic enzymes enriched in bromelain'. However, OPQ's recommendation for the core name is 'anacaulase'.

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by MediWound for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761192.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 29, 2020, MediWound submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. MediWound also provided findings from an external study conducted by the (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by MediWound:

Table 1. Suffixes submitted by MediWound***

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

(b) (4)

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

2.1 Proposed suffix -bcdb

MediWound's first proposed suffix, -bcdb, is comprised of 3 distinct letters (b, c, d). We note that the letters 'cd' in the suffix represent the medical abbreviations for 'controlled-delivery'. We considered whether the inclusion of the letters 'cd' within the suffix could be misleading or a source of confusion and errors, but we could not identify a plausible risk based on the expected use of this product or based upon known causes of medication errors.

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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated January 13, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Dermatology and Dentistry via e-mail on June 25, 2021.

4 CONCLUSION

We find MediWound's proposed suffix -bcdb conditionally acceptable. DMEPA will communicate our findings to the Applicant via letter during the next review cycle.

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

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
06/28/2021 08:19:31 AM

DANIELLE M HARRIS
06/28/2021 08:19:31 AM

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 22, 2020
Application Type and Number:	BLA 761192
Product Name and Strength:	NexoBrid (concentrate of proteolytic enzymes enriched in bromelain-xxxx)[a] Topical Lyophilized Powder for Gel; (b) (4) % Kit or 2 g/20 g gel and 5 g/50 g gel
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	MediWound, Ltd
Panorama #:	2020-40949280
DMEPA Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "concentrate of proteolytic enzymes enriched in bromelain-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

MediWound, Ltd previously submitted the proposed proprietary name, Nexobrid*** on October 19, 2012. We found the name, Nexobrid*** conditionally acceptable under IND 065448 on April 12, 2013.[b]

Thus, MediWound, Ltd re-submitted the name, NexoBrid [c], for review on June 29, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 29, 2020.

- Intended Pronunciation: nex' oh brid
- Nonproprietary Name: concentrate of proteolytic enzymes enriched in bromelain-xxxx
- Indication of Use: removal of eschar in adults with deep partial- and full-thickness thermal burns
- Route of Administration: topical
- Dosage Form: Topical Lyophilized Powder for Gel[d]
- Strength: [redacted] (b) (4) % Kit or 2 g/20 g gel and 5 g/50 g gel. [redacted] (b) (4)
- Dose and Frequency: 1 application/dose.
    - 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult
    - 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult
- How Supplied: NexoBrid is comprised of two components: a sterile lyophilized powder consisting of a concentrate of proteolytic enzymes enriched in bromelain in a single use

[b] Mena-Grillasca, C. Proprietary Name Review for Nexobrid*** (IND 065448). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 APR 12. Panorama No. 2012-2474.

[c] We considered in our assessment the product name NexoBrid and Nexobrid.

[d] Applicant submitted [redacted] (b) (4) The final dosage form has yet to be determined at the time of this review.

[redacted] (b) (4)

50 mL glass vial and a sterile Gel Vehicle in a single use 150 mL glass jar used for preparation of a gel for topical use in the following presentations:

- 2 g powder in a vial (b) (4) sealed with a rubber (b) (4) stopper and covered with a cap (aluminium), and 20 g gel in a bottle (b) (4) (b) (4), sealed with a rubber stopper and covered with a screw cap (b) (4) (b) (4)
- 5 g powder in a vial (b) (4) sealed with a rubber (b) (4), stopper and covered with a cap (aluminium), and 50 g gel in a bottle (b) (4) (b) (4), sealed with a rubber stopper and covered with a screw cap (b) (4) (b) (4)

- Storage: Store and transport refrigerated (2°C-8°C). Store upright to keep the gel at the bottom of the bottle and in the original package to protect from light. Do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that NexoBrid would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Dermatology and Dentistry (DDD) concurred with the findings of OPDP's assessment for NexoBrid .

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 16, 2020 e-mail, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to NexoBrid at the initial phase of the review.

[f] USAN stem search conducted on July 30, 2020.

2.2.4 FDA Name Simulation Studies

Eighty-five (n=85) practitioners participated in DMEPA's prescription studies for NexoBrid . We note that two (n=2) participants in the outpatient prescription study misinterpreted the proposed name as "Nexofrid", which is similar to the root name, "Nexafed", of the currently marketed over-the-counter (OTC) products, Nexafed Nasal Decongestant (pseudoephedrine hydrochloride 30 mg) and Nexafed Sinus Pressure + Pain (acetaminophen/ pseudoephedrine hydrochloride 325 mg/30 mg). Orthographically, the 'r' in the 6th position of Nexobrid, not present Nexafed, provides some orthographic difference. Phonetically, the last syllables ('brid' vs. 'fed') of this name pair sound different. In addition to the orthographic and phonetic differences, the following product characteristics would help to mitigate the risk of name confusion:

- Nexafed is the root name for over-the-counter (OTC) products, Nexafed Nasal Decongestant (pseudoephedrine hydrochloride 30 mg) and Nexafed Sinus Pressure + Pain (acetaminophen/ pseudoephedrine hydrochloride 325 mg/30 mg). Hence, if one of these OTC products were written on a prescription or ordered, the modifier would have to be specified which would help minimize potential name confusion.
- The dosage form and route of administration of the products differ, if included on a prescription/medication order (tablet vs. lyophilized powder for gel; oral vs. topical). If one of the OTC products were written on a prescription or ordered, the modifier would have to be specified which would help minimize potential name confusion.
- Nexobrid should be prepared at the patient's bedside within 15 minutes of wound debridement procedure by wound care specialist that are trained and familiar with the product and debridement procedure.

Therefore, due to the above-mentioned factors we find this name pair acceptable. We evaluate this name pair in Appendix C.

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[g] identified 162 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, 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**

[g] POCA search conducted on July 30, 2020 in version 4.4.

Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	149
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 164 names contained in Table 1 determined none of the names will pose a risk for confusion with NexoBrid as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Dermatology and Dentistry (DDD) via e-mail on September 15, 2020. At that time we also requested additional information or concerns that could inform our review. The Division of Dermatology and Dentistry (DDD) did not state additional concerns with the proposed proprietary name, NexoBrid .

3 CONCLUSION

The proposed proprietary name, NexoBrid , is acceptable.

If you have any questions or need clarifications, please contact Tri Minh Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO MEDIWOUND, LTD

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

If any of the proposed product characteristics as stated in your submission, received on June 29, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

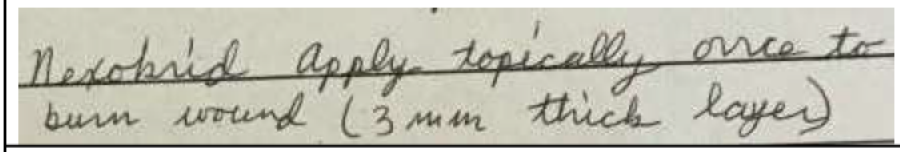
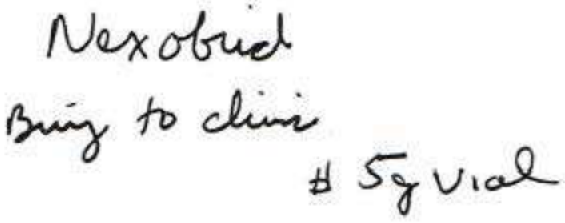
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. NexoBrid Study (Conducted on July 24, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	NexoBrid Bring to clinic. Dispense 5 g vial
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Nexobrid	

FDA Prescription Simulation Responses (Aggregate Report)

207 People Received Study
85 People Responded

Study Name: NexoBrid

Total	17	23	17	28	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
NECTOBRID	0	0	1	0	1
NECTO-BRID	0	0	1	0	1
NEXOBID	5	0	0	1	6
NEXOBIRD	1	0	0	0	1
NEXOBRED	0	0	1	0	1
NEXOBRID	6	23	11	24	64
NEXOBRID TOPICAL	0	0	0	1	1

NEXOBRIEL	1	0	0	0	1
NEXOBRIG	0	0	1	0	1
NEXOBUD	1	0	0	0	1
NEXOBUID	1	0	0	0	1
NEXOFRID	2	0	0	0	2
NEXOGRID	0	0	2	0	2
NEXOKRID	0	0	0	2	2

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

No.	**Proposed name:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b) (4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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.	Nexobrid***	100	Subject of this review.
2.	Dexodryl	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Nexafed	70	Orthographically, the 'r' in the 6th position of Nexobrid, not present Nexafed, provides some orthographic difference. Phonetically, the last syllables ('brid' vs. 'fed') of this name pair sound different. In addition to the orthographic and phonetic differences, the following product characteristics would help to mitigate the error: • Nexafed is the root name for over-the-counter (OTC) products, Nexafed Nasal Decongestant (pseudoephedrine hydrochloride 30 mg) and Nexafed Sinus Pressure + Pain (acetaminophen/ pseudoephedrine hydrochloride 325 mg/30 mg). Hence, if one of these OTC products were written on a prescription or ordered, the modifier would have to be specified which would help minimize potential name confusion. • The dosage form and route of administration of the products

No.	Proposed name: NexoBrid Established name: concentrate of proteolytic enzymes enriched in bromelain-xxxx Dosage form: Topical Lyophilized Powder for Gel Strength(s): (b)(4)% Kit or 2 g/20 g gel and 5 g/50 g gel Usual Dose: 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	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.
			differ, if included on a prescription/medication order (tablet vs. lyophilized powder for gel; oral vs. topical). • Additionally, Nexobrid should be prepared at the patient's bedside within 15 minutes of wound debridement procedure by wound care specialist that are trained and familiar with the product and debridement procedure. Therefore, due to the above-mentioned factors we find this name pair acceptable.

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	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:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b)(4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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.	Excedrin	69	This name pair has sufficient orthographic and phonetic differences.
5.	Dexedrine	68	This name pair has sufficient orthographic and phonetic differences.
6.	Nitro-Bid	68	This name pair has sufficient orthographic and phonetic differences.
7.	Exaprin	66	This name pair has sufficient orthographic and phonetic differences.
8.	Dexasporin	65	This name pair has sufficient orthographic and phonetic differences.
9.	Dextran	63	This name pair has sufficient orthographic and phonetic differences.
10.	Dextran 40	63	This name pair has sufficient orthographic and phonetic differences.
11.	Trexbrom	63	This name pair has sufficient orthographic and phonetic differences.
12.	Depopred	62	This name pair has sufficient orthographic and phonetic differences.
13.	Exoderm	62	This name pair has sufficient orthographic and phonetic differences.
14.	Neosporin	62	This name pair has sufficient orthographic and phonetic differences.
15.	Nexavir	62	This name pair has sufficient orthographic and phonetic differences.
16.	Nexterone	62	This name pair has sufficient orthographic and phonetic differences.
17.	Oxandrin	62	This name pair has sufficient orthographic and phonetic differences.
18.	Roxiprin	62	This name pair has sufficient orthographic and phonetic differences.
19.	Moexipril	61	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b) (4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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**
20.	Neofrin	61	This name pair has sufficient orthographic and phonetic differences.
21.	Dextrose 25%	60	This name pair has sufficient orthographic and phonetic differences.
22.	Dextrose 50%	60	This name pair has sufficient orthographic and phonetic differences.
23.	Dextrose 60%	60	This name pair has sufficient orthographic and phonetic differences.
24.	Doxteric	60	This name pair has sufficient orthographic and phonetic differences.
25.	Econopred	60	This name pair has sufficient orthographic and phonetic differences.
26.	Enoxaparin	60	This name pair has sufficient orthographic and phonetic differences.
27.	(b) (4)	60	This name pair has sufficient orthographic and phonetic differences.
28.	Macrobid	60	This name pair has sufficient orthographic and phonetic differences.
29.	Metformin	60	This name pair has sufficient orthographic and phonetic differences.
30.	Nexium IV	60	This name pair has sufficient orthographic and phonetic differences.
31.	Myxredlin	59	This name pair has sufficient orthographic and phonetic differences.
32.	Neocidin	59	This name pair has sufficient orthographic and phonetic differences.
33.	(b) (4)	59	This name pair has sufficient orthographic and phonetic differences.
34.	Bacter-Aid	58	This name pair has sufficient orthographic and phonetic differences.
35.	Benzedrine	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b)(4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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**
36.	Doxepin	58	This name pair has sufficient orthographic and phonetic differences.
37.	Doxidan	58	This name pair has sufficient orthographic and phonetic differences.
38.	Ecotrin	58	This name pair has sufficient orthographic and phonetic differences.
39.	Edoxaban	58	This name pair has sufficient orthographic and phonetic differences.
40.	Excedrin PM	58	This name pair has sufficient orthographic and phonetic differences.
41.	Icodextrin	58	This name pair has sufficient orthographic and phonetic differences.
42.	Magnebind	58	This name pair has sufficient orthographic and phonetic differences.
43.	Magnebind 250/300	58	This name pair has sufficient orthographic and phonetic differences.
44.	Magnebind 400/200	58	This name pair has sufficient orthographic and phonetic differences.
45.	Magnebind-300	58	This name pair has sufficient orthographic and phonetic differences.
46.	Midodrine	58	This name pair has sufficient orthographic and phonetic differences.
47.	Nexavar	58	This name pair has sufficient orthographic and phonetic differences.
48.	Nexium 24Hr	58	This name pair has sufficient orthographic and phonetic differences.
49.	Nexlizet	58	This name pair has sufficient orthographic and phonetic differences.
50.	Nicoderm	58	This name pair has sufficient orthographic and phonetic differences.
51.	Nitropress	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b)(4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	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**
52.	Praxbind	58	This name pair has sufficient orthographic and phonetic differences.
53.	Dexacidin	57	This name pair has sufficient orthographic and phonetic differences.
54.	Dexacorten	57	This name pair has sufficient orthographic and phonetic differences.
55.	Exondys	57	This name pair has sufficient orthographic and phonetic differences.
56.	Exondys 51	57	This name pair has sufficient orthographic and phonetic differences.
57.	Neo-Fradin	57	This name pair has sufficient orthographic and phonetic differences.
58.	Benzedrex	56	This name pair has sufficient orthographic and phonetic differences.
59.	Defibrotide	56	This name pair has sufficient orthographic and phonetic differences.
60.	Dexferrum	56	This name pair has sufficient orthographic and phonetic differences.
61.	Dexone	56	This name pair has sufficient orthographic and phonetic differences.
62.	Dexone 0.5	56	This name pair has sufficient orthographic and phonetic differences.
63.	Dexone 0.75	56	This name pair has sufficient orthographic and phonetic differences.
64.	Dexone 1.5	56	This name pair has sufficient orthographic and phonetic differences.
65.	Dexone 4	56	This name pair has sufficient orthographic and phonetic differences.
66.	Doxapram	56	This name pair has sufficient orthographic and phonetic differences.
67.	Doxorubicin	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** NexoBrid **Established name:** concentrate of proteolytic enzymes enriched in bromelain-xxxx **Dosage form:** Topical Lyophilized Powder for Gel **Strength(s):** (b)(4) % Kit or 2 g/20 g gel and 5 g/50 g gel **Usual Dose:** 1 application/dose. 2 g powder mixed with 20 g Gel Vehicle per 1% TBSA of an adult; 5 g powder mixed with 50 g Gel Vehicle per 2.5% TBSA of an adult	**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**
68.	Elixomin	56	This name pair has sufficient orthographic and phonetic differences.
69.	Exidine	56	This name pair has sufficient orthographic and phonetic differences.
70.	Fexmid	56	This name pair has sufficient orthographic and phonetic differences.
71.	Maxifed	56	This name pair has sufficient orthographic and phonetic differences.
72.	Medipred	56	This name pair has sufficient orthographic and phonetic differences.
73.	Menstridol	56	This name pair has sufficient orthographic and phonetic differences.
74.	Noxivent	56	This name pair has sufficient orthographic and phonetic differences.
75.	Onexton	56	This name pair has sufficient orthographic and phonetic differences.
76.	Oxyfrin	56	This name pair has sufficient orthographic and phonetic differences.
77.	Ronoxidil	56	This name pair has sufficient orthographic and phonetic differences.
78.	Brixadi	55	This name pair has sufficient orthographic and phonetic differences.
79.	Decadron	55	This name pair has sufficient orthographic and phonetic differences.
80.	Lexidronam	55	This name pair has sufficient orthographic and phonetic differences.
81.	Nicomide	55	This name pair has sufficient orthographic and phonetic differences.
82.	Texacort	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
83.	Nexium	53
84.	Aerobid	52
85.	Hexobendine	52
86.	Inderide	52
87.	Inderide-40/25	
88.	Inderide-80/25	
89.	Micturin	52
90.	Neoloid	52
91.	Norimode	52
92.	Doriden	51
93.	Obredon	49
94.	Bridion	46

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

No.	Name	POCA Score (%)	Failure preventions
95.	Dexatrim	68	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
96.	Nexgard	68	Veterinary product.
97.	Drixomed	64	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
98.	Dextran 1	63	Name identified in RxNorm database. Established name for product that is deactivated (Promit) and no generic equivalents are available.
99.	Dextran 110	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
100.	Dextran 70	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
101.	Dextran 75	63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
102.	Nexiclon	63	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
103.	Dexophed	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
104.	Drexophed	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
105.	Dendrid	61	Brand discontinued with no generic equivalents available. NDA 014169 withdrawn pending FR notice.
106.	Hexabrix	61	Brand discontinued with no generic equivalents available. NDA 018905 withdrawn FR effective 05/24/2017.
107.	Dexacort	60	Brand discontinued with no generic equivalents available. NDA 013413 and NDA 014242 withdrawn FR effective 06/16/2006 and 12/07/2007, respectively.
108.	Disobrom	60	Product discontinued with no generic equivalents available. ANDA 070770 withdrawn FR effective 04/26/1996.
109.	Dixarit	60	International product marketed in Denmark, Belgium, Ireland, New Zealand, Netherlands, South Africa, Singapore, United Kingdom, and formerly marketed in Australia, Canada, Germany, Hong Kong, and Malaysia.
110.	Hex-O-Prep	60	Veterinary product.
111.	Nitro-Bid IV	60	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
112.	Cefobid	59	Brand discontinued with no generic equivalents available. NDA 050613 and ANDA 063333 withdrawn FR effective 06/18/2009 and 07/27/2020, respectively. NDA 050551 withdrawn pending FR notice.
113.	(b) (4)	59	NDA 012806 approved in 1965, and is currently marketed under the proprietary name Cordran. (b) (4) was the proposed proprietary name for (b) (4) found unacceptable by DMEPA (OSE# 2016-10855836 dated 01/12/2017).
114.	Nexcede	59	Brand discontinued with no generic equivalents available. NDA 022470 withdrawn FR effective 01/05/2015.
115.	Nitrogard	59	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
116.	Nycopren	59	International product formerly marketed in United Kingdom, Belgium, Austria, Denmark, Finland, Greece, Switzerland, and Netherlands.

No.	Name	POCA Score (%)	Failure preventions
117.	Tensopril	59	International product marketed in Argentina and Israel and formerly marketed in Portugal, Ireland, and United Kingdom.
118.	Brexidol	58	International product marketed by Italy, Norway, and Sweden and formerly marketed by Germany, Canada, Switzerland, United Kingdom, Finland, Denmark, and Austria.
119.	(b) (4)	58	Proposed proprietary name for NDA 202342 found unacceptable by DMEPA (OSE# 2011-3165 on 11/07/2011). NDA 202342 approved under the established name.
120.	Gonabreed	58	Veterinary product.
121.	Magnebind-200	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
122.	Maxibolin	58	Brand discontinued with no generic equivalents available. NDA 014005 and NDA 014006 withdrawn FR effective 11/03/2016 and 07/21/2017, respectively.
123.	Maxidone	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
124.	Nadroparin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
125.	Neo-Predef	58	Veterinary product.
126.	Nexphen Pd	58	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
127.	Noctamid	58	International product marketed in Belgium, Germany, Ireland, New Zealand, Switzerland, Spain, France, and formerly marketed in South Africa, Austria, Greece, Netherlands, Italy, and Portugal.
128.	Norisodrine	58	Brand discontinued with no generic equivalents available. NDA 006905 and NDA 016814 withdrawn FR effective 07/11/1990 and 05/06/1985, respectively.
129.	Octodrine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	Remoxipride	58	Established name for international product formerly marketed in Austria, Netherlands, Sweden, and United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
131.	Spectrobid	58	Brand discontinued with no generic equivalents available. NDA 050520 and NDA 050556 withdrawn FR effective 11/12/2015.
132.	Amoxi Drop	57	Veterinary product.
133.	Amoxidin	57	International product formerly marketed in the United Kingdom.
134.	Decabid	57	Brand discontinued with no generic equivalents available. NDA 019693 withdrawn FR effective 09/04/1996.
135.	Dexomon Sr	57	International product marketed in the United Kingdom.
136.	(b) (4)	57	Proposed proprietary name for NDA 211970 found unacceptable by DMEPA (OSE# 2018-28117624). NDA 211970 approved under the proprietary name Vyondys 53.
137.	Exubera	57	Brand discontinued with no generic equivalents available. NDA 021868 withdrawn FR effective 06/18/2009.
138.	Menhibrix	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
139.	Rinade-B.I.D.	57	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
140.	Benperidol	56	Established name for international products marketed in United Kingdom and formerly marketed in Ireland, France, Netherlands, Belgium, Germany, Greece, and Italy.
141.	Drixoral	56	Brand discontinued with no generic equivalents available. NDA 013483 and NDA 019453 withdrawn FR effective 11/03/2016 and 01/05/2015, respectively.
142.	Medcodin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
143.	Metrodin	56	Brand discontinued with no generic equivalents available. NDA 019415 withdrawn FR effective 07/21/2017.
144.	Mosapride	56	Established name for international products marketed and formerly marketed in various countries, not in the United States.
145.	Moxonidine	56	Active ingredient in international products marketed and formerly marketed in various countries outside of the US.

No.	Name	POCA Score (%)	Failure preventions
146.	Nasabid	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
147.	Nicomide-T	56	Name identified in RxNorm database. Root name for product that is deactivated and no generic equivalents are available.
148.	Nobrium	56	International product formerly marketed in Ireland, Italy, Netherlands, Spain, Switzerland, United Kingdom, and Hungary.
149.	Peptone,Dried	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
150.	Tetroxoprim	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
151.	Vicoprin	56	Product discontinued with no generic equivalents available. ANDA 086333 withdrawn FR effective 02/22/1991.
152.	Amines Brand	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
153.	Biclora-D	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
154.	Dextraven-110	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
155.	Dynex Vr	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
156.	Laxoberal	55	International product marketed in Denmark, Sweden, Germany, and Norway, and formerly marketed in United Kingdom, Chile, Ireland, and Philippines.
157.	Paxidorm	55	International product marketed in Singapore and United Kingdom.
158.	Ricobid	55	Product formerly marketed in Puerto Rico
159.	Toxi-Sorb	55	Veterinary product.

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

[j] 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 (%)
160.	Benzepril	57
161.	Oxyblend	57
162.	(b) (4)	56
163.		56
164.		55

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/s/

MADHURI R PATEL
09/22/2020 11:04:10 AM

SEVAN H KOLEJIAN
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