CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211379Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 6, 2019
Application Type and Number:	NDA 211379
Product Name and Strength:	Hemady (dexamethasone) tablet, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Dexcel Pharma Technologies, Ltd. (Dexcel)
Panorama #:	2019-32933196
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Hemady, 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. Dexcel did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Dexcel previously submitted the proposed proprietary name, [redacted] (b) (4) on January 16, 2019 under NDA 211379. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name [redacted] (b) (4) unacceptable due to [redacted] (b) (4) [redacted] (b) (4)

Dexcel then submitted the name, Hemady, for review on July 3, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on July 3, 2019.

- Intended Pronunciation: Hem' uh dee
- Active Ingredient: dexamethasone
- Indication of Use: treatment of patients with multiple myeloma (MM), as part of combination regimens with anti-myeloma drugs
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 20 mg
- Dose and Frequency: 20 mg or 40 mg, orally, once daily, on specific days of each treatment cycle
- How Supplied: bottles of 100 tablets
- Storage: controlled room temperature 20°C to 25°C (68°F to 77°F)
- Reference Listed Drug/Reference Product: Decadron (NDA 011664)

2 RESULTS

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

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[a] DeGraw, S. Proprietary Name Review for [redacted] (b) (4) (NDA 211379). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 APR 8. Panorama No. 2019-28685206.

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Dexcel did not provide a derivation or intended meaning for the proposed name, Hemady 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 18, 2019 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to Hemady at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-eight (78) practitioners participated in DMEPA's prescription studies for Hemady. The responses did not overlap with any currently marketed products however, one participant in the voice study misinterpreted Hemady as "Hemade", which is similar to the currently marketed product, Humate-P (antihemophilic factor/von willebrand factor complex [human]).

Despite the close hit in the FDA name simulation study, we find that the name pair, Hemady and Humate-P, have minimal potential of confusion for the following reasons:

Orthographically, the suffixes (-dy vs -te-P) provide some differences between the names. Phonetically, the first and second syllables of this name pair have notable differences when spoken ('Hue-mate' vs. 'Hem-uh'). Hemady and Humate-P differ in terms of strength (20 mg *versus* 600 IU VWF/250 IU FVIII, 1200 IU VWF/500 IU FVIII, and 2400 IU VWF/1000 IU FVIII). Humate-P is administered as a one-time dose or loading dose that may be repeated or followed by smaller doses every 8-12 hours, unlike Hemady which is administered once daily on specific days of cyclical treatment regimens. Doses of Humate-P are individualized based on patient's body weight, type/severity of hemorrhage and baseline levels (e.g., FVIII level, VWF:RCo activity, etc.). Therefore, in the absence of overlapping product characteristics, we do not think that the name pair is vulnerable to name confusion (see Appendix E for evaluation of the name pair).

[b] USAN stem search conducted on July 25, 2019.

Appendix B contains the full results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 25 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. 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%	21
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 25 names contained in Table 1 determined none of the names will pose a risk for confusion with Hemady as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on September 5, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products (DHP) on September 6, 2019, they stated no additional concerns with the proposed proprietary name, Hemady.

3 CONCLUSION

The proposed proprietary name, Hemady, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

[c] POCA search conducted on July 25, 2019 in version 4.3.

3.1 COMMENTS TO DEXCEL PHARMA TECHNOLOGIES, LTD.

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

If any of the proposed product characteristics as stated in your submission, received on July 3, 2019, 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. [d]

[d] 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[e]. 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

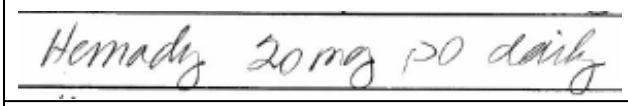
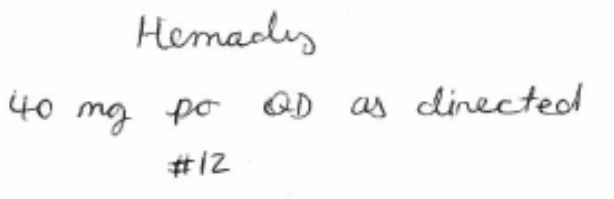
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

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

Figure 1. Hemady Study (Conducted on August 6, 2019)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Hemady
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

217 People Received Study
78 People Responded

Study Name: Hemady

Total 42 15 21

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
HEMACLY	4	0	0	4
HEMADAY	1	0	0	1
HEMADE	0	1	0	1
HEMADEE	0	3	0	3
HEMADI	0	2	0	2
HEMADRY	0	0	1	1
HEMADY	36	5	20	61
HEMADY 40 MG	1	0	0	1
HEMEDY	0	1	0	1
HEMIDY	0	2	0	2
HEMYDI	0	1	0	1

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

No.	**Proposed name:** Hemady **Established name:** dexamethasone **Dosage form:** tablet **Strength(s):** 20 mg **Usual Dose:** 20 mg or 40 mg, orally, once daily, on specific days of each treatment cycle	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.	Hemady	100	Subject of this review
2.	Hemax	73	Orthographically, the suffix of Hemady contains upstroke and downstroke letters which provide some orthographic differences (-dy vs x). Phonetically, the number of syllables in the name pair differ (2 vs. 3) and the 2nd half of name pair sound different ('ax' vs 'uh dee') when spoken. Hemax is a dietary supplement found in limited drug databases. Hemady is used in the treatment of multiple myeloma as part of combination regimens with other anti-myeloma drugs. Hemady is administered daily on specific days of cyclical treatment regimens, which would need to be specified on an order. Therefore, in this specific scenario, due to the above-mentioned factors, we find this name pair acceptable.
3.	Hemin	70	Orthographically, the suffix of Hemady contains upstroke and downstroke letters which provides some orthographic differences (-ady vs in). Phonetically, the number of syllables in the name pair differ (2 vs. 3) and the 2nd half of name pair sound different ('in' vs 'uh dee') when spoken. The following differences in product characteristics may also help to mitigate the risk of errors: • Strength: Hemin is available in two strengths (i.e. 313 mg and 350 mg) which differ from Hemady which is available in one strength (i.e. 20 mg). • Dose: Doses of Hemin are individualized based on an adult patient's body weight (i.e., 1 to 4 mg/kg/day), unlike the dose of Hemady which is 20 mg or 40 mg (1 or 2 tablets). Therefore, in this scenario, 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 (%)
4.	Hemofil	60

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:** Hemady **Established name:** dexamethasone **Dosage form:** tablet **Strength(s):** 20 mg **Usual Dose:** 20 mg or 40 mg, orally, once daily, on specific days of each treatment cycle	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
5.	Hemaway	68	Orthographically, Hemady contains an upstroke 'd' in the 5th position that is absent in Hemaway, which provides some orthographic difference. Phonetically, the third syllable of the name pair (-way vs. -dee) sound different when spoken. The following difference in product characteristics may also help to mitigate the risk of errors: • Dose/frequency: Hemaway is applied topically up to four times per day as needed, unlike the dose of Hemady which is 20 mg or 40 mg (1 or 2 tablets) administered daily on specific days of cyclical treatment regimens (specified on an order). There is no overlap in dose or frequency. Therefore, in this scenario, due to the above-mentioned factors, we find this name pair acceptable.
6.	Hemabate	65	This name pair has sufficient orthographic and phonetic differences.
7.	Hemoban	62	This name pair has sufficient orthographic and phonetic differences.
8.	Hemox A	61	This name pair has sufficient orthographic and phonetic differences.
9.	Hemo-Fin	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Hemady **Established name:** dexamethasone **Dosage form:** tablet **Strength(s):** 20 mg **Usual Dose:** 20 mg or 40 mg, orally, once daily, on specific days of each treatment cycle	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
10.	Humate-P	58	Orthographically, the suffixes (-dy vs -te-P) provide some differences between the names. Phonetically, the first and second syllables of this name pair have notable differences when spoken ('Hue-mate' vs. 'Hem-uh') The following differences in product characteristics may also help to mitigate the risk of errors: • Strength: Humate-P is available in three strengths (i.e. 600 IU VWF/250 IU FVIII, 1200 IU VWF/500 IU FVIII, and 2400 IU VWF/1000 IU FVIII) which differ from Hemady which is available in one strength (i.e. 20 mg). • Dose: Doses of Humate-P are individualized based on patient's body weight, type/severity of hemorrhage and baseline levels (e.g., FVIII level, VWF:RCo activity, etc.) unlike the dose of Hemady which is 20 mg or 40 mg (1 or 2 tablets). • Frequency: Humate-P is administered as a one-time dose or loading dose that may be repeated or followed by smaller doses every 8-12 hours, unlike Hemady which is administered once daily on specific days of cyclical treatment regimens. Therefore, in this scenario, due to the above-mentioned factors, we find this name pair acceptable.
11.	(b) (4)	58	This name pair has sufficient orthographic and phonetic differences.
12.	Hemorrodil	56	This name pair has sufficient orthographic and phonetic differences.
13.	Humatin	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 (%)
14.	Chemdal Hd	52

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
15.	(b) (4)	68	(b) (4) was found in the datasource 'Name entered by safety evaluator' but was not formally submitted to the Agency for review. It was an alternate name for IND (b) (4) and NDA (b) (4) NDA (b) (4) was withdrawn FR effective February 13, 2019.
16.	Hemorid	62	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.
17.	Hemp	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Hycomed	58	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.
19.	Hyphed	58	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.
20.	Chemdal	58	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.
21.	Chemdec	58	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.
22.	Hemaspan	56	Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available.

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

No.	Name	POCA Score (%)
23.	Embeda	56
24.	Phendry	56
25.	Vemlidy	56

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

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09/06/2019 02:56:28 PM

PROPRIETARY NAME REVIEW

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

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Date of This Review:	April 8, 2019
Application Type and Number:	NDA 211379
Product Name and Strength:	(b) (4) (dexamethasone) tablet, 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Dexcel Pharma Technologies, Ltd. (Dexcel)
Panorama #:	2019-28685206
DMEPA Safety Evaluator:	Stephanie DeGraw, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director:	Mishale Mistry, PharmD, MPH

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