

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208114Orig1s000

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 8, 2015
Application Type and Number:	IND 62118, NDA 208114
Product Name and Strength:	Defitelio (defibrotide) Injection, 200 mg per 2.5 mL (80 mg per mL)
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gentium S.P.A. (a Jazz Pharmaceuticals company)
Panorama #:	2015-80410
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Defitelio, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the March 27, 2015 and July 31, 2015 proprietary name submission.

- Intended Pronunciation: def-ih-TELL-ee-yo
- Active Ingredient: defibrotide
- Indication of Use: (b) (4) hepatic veno-occlusive disease (VOD), also known as sinusoidal (b) (4) syndrome (SOS), in hematopoietic stem cell transplantation (HSCT) therapy
- Route of Administration: Intravenous infusion
- Dosage Form: Solution for intravenous infusion
- Strength: 200 mg per 2.5 mL (concentration of 80 mg/mL) vial
- Dose and Frequency: Administer 6.25 mg/kg body weight given as a 2 hours intravenous infusion every 6 hours.

Initiate treatment as soon as diagnosis of hepatic VOD (b) (4). Treat for a minimum of 21 days. If after 21 days signs and symptoms of VOD have not resolved, continue treatment until resolution.

- How Supplied: Single-use 2.5 mL clear glass vials, packaged in 10-vial cartons
- Storage: Store unused vials at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP controlled room temperature). (b) (4). Once diluted, should be used within 24 hours. Do not re-use partially used vials.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Defitelio 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 FDA Name Simulation Studies

Eighty-one practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 16, 2015 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search² organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	98
Low similarity name pair: combined match percentage score $\leq 49\%$	2

¹USAN stem search conducted on July 7, 2015.

² POCA search conducted on April 22, 2015.

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

Our analysis of the 101 names contained in Table 1 determined all 101 names will not pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on July 17, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on July 24, 2015, they stated no additional concerns with the proposed proprietary name, Defitelio.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 31, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. **Phonetic and Orthographic Computer Analysis (POCA)**

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

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.³

³ 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 medical and/or coined abbreviations in the proprietary name?
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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.

- 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 $\geq 70\%$).

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 do not share a common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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
<p>Step 2</p>	<p>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 <u>with</u> overlapping or similar strengths or doses.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Defitelio Study (Conducted on 4/27/15)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> <p><i>Defitelio 6.25mg/kg IV q 6 hours</i></p>	<p>Defitelio</p> <p>Bring to clinic</p> <p>#10</p>
<p>Outpatient Prescription:</p> <p><i>Defitelio</i></p> <p><i>Bring to clinic #10</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

246 People Received Study
81 People Responded

Study Name: Defitelio

Total	26	27	28	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DAFATALIO	0	1	0	1
DEFATALIO	0	1	0	1
DEFATELIO	0	2	0	2
DEFATELLIO	0	3	0	3
DEFETALIO	0	1	0	1
DEFETELIO	0	3	0	3
DEFITELIO	21	6	0	27
DEFITELLIO	0	2	0	2
DEFITELLO	0	1	0	1

DEFITLIO	1	0	0	1
DEPATELLIO	0	1	0	1
DESATELLIO	0	1	0	1
DESETELLIO	0	1	0	1
DEFERTELIO	0	1	0	1
DESITELIO	0	3	0	3
DETITELIO	2	0	0	2
DIBITELIO	0	0	2	2
DIFETLIO	1	0	0	1
DIFITELIO	0	0	26	26
DIFITELO	1	0	0	1

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

No.	Proposed name: Defitelio Established name: Defibrotide Dosage form: Solution for intravenous infusion Strength(s): 200 mg per 2.5 mL (80 mg/mL) Usual Dose: 6.25 mg/kg over two hours four times a day for a minimum of 21 days and continued until the symptoms of severe veno-occlusive disease (VOD) resolve; thus the dosing interval is individualized. The maximum daily dose is 25 mg/kg/day.	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.	DEFITELIO***	100	Subject of this review

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	DELTALIN	58
2.	DIVIGEL	58
3.	DECITABINE	57
4.	DESITIN	56
5.	DESITIN CLEAR	55
6.	DENTAGEL	54
7.	DERIFIL	54
8.	DELZICOL	53
9.	DAPTACEL	52
10.	DEBACTEROL	52
11.	DENTA 5000 PLUS	52
12.	DESYREL	52

No.	Name	POCA Score (%)
13.	DICYCLOCOT	52
14.	DEXILANT	51
15.	DEXACIDIN	50
16.	DEXALONE	50
17.	DEXASOL	50
18.	(b) (4) ***	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	<p>Proposed name: Defitelio</p> <p>Established name: Defibrotide</p> <p>Dosage form: Solution for intravenous infusion</p> <p>Strength(s): 200 mg per 2.5 mL (80 mg/mL)</p> <p>Usual Dose: 6.25 mg/kg over two hours four times a day for a minimum of 21 days and continued until the symptoms of severe veno-occlusive disease (VOD) resolve; thus the dosing interval is individualized. The maximum daily dose is 25 mg/kg/day.</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	<p>DOFETILIDE</p> <p>(Phonetic Score: 71)</p> <p>(The Brand name for this product is Tikosyn.)</p>	66	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains an extra syllable.</p> <p>Tykosyn is under REMS and is only available for in-hospital settings to providers who have had training and must be certified to prepare the product. Thus, products have different settings of use. Additionally, Tikosyn is available and dosed at 125 mcg, 250 mcg and 500 mcg vs. Defitelio dose is individualized at 6.25 mg/kg.</p>
2.	DEFINITY	58	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains an extra syllable.</p>
3.	DIPHENYLIN	58	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains an extra syllable.</p>
4.	(b) (4) ***	59	(b) (4)

No.	<p>Proposed name: Defitelio</p> <p>Established name: Defibrotide</p> <p>Dosage form: Solution for intravenous infusion</p> <p>Strength(s): 200 mg per 2.5 mL (80 mg/mL)</p> <p>Usual Dose: 6.25 mg/kg over two hours four times a day for a minimum of 21 days and continued until the symptoms of severe veno-occlusive disease (VOD) resolve; thus the dosing interval is individualized. The maximum daily dose is 25 mg/kg/day.</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
5.	DIFICID	57	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains extra syllables.</p>
6.	DIPHENYL	52	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains extra syllables.</p>
7.	<p>(b) (4) ***</p> <p>(This is a proposed established name.)</p>	51	(b) (4)
8.	DEP MEDALONE 80	50	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The Dep Medalone 80 name contains an extra syllable.</p>
9.	DELTA-LUTIN	50	<p>The prefixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains an extra syllable.</p>
10.	DEPLETITE	50	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains extra syllables.</p>
11.	DIBENIL	50	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The Defitelio name contains extra syllables.</p>

No.	Proposed name: Defitelio Established name: Defibrotide Dosage form: Solution for intravenous infusion Strength(s): 200 mg per 2.5 mL (80 mg/mL) Usual Dose: 6.25 mg/kg over two hours four times a day for a minimum of 21 days and continued until the symptoms of severe veno-occlusive disease (VOD) resolve; thus the dosing interval is individualized. The maximum daily dose is 25 mg/kg/day.	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
12.	DIMOTAL	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The Defitelio name contains extra syllables.
13.	DIPHEDRYL	50	The infixes of this name pair have sufficient orthographic differences. The Defitelio name contains extra syllables.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 49\%$)

No.	Name	POCA Score (%)
1.	FELBATOL	40
2.	FORTEO	36

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
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No.	Name	POCA Score (%)	Failure preventions
1.	DESTOLIT	64	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
2.	DEFEN-LA	62	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
3.	DEFEND II	60	<p>This name was identified by the RxNorm database.</p> <p>However, this is a veterinary product</p>
4.	DE-SONE LA	59	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
5.	DEMIBID II	56	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
6.	DEPIXOL	56	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>

No.	Name	POCA Score (%)	Failure preventions
7.	DEXONE LA	56	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
8.	DISIPAL	56	<p>This name was identified by the Drugs at FDA database and RxNorm.</p> <p>The Brand is discontinued with no generic equivalent available. (b) (4)</p> <p>[REDACTED]</p>
9.	DESAL II	55	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
10.	DIGITER	54	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
11.	DESONIL	53	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>

No.	Name	POCA Score (%)	Failure preventions
12.	DOFSOL-A	53	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
13.	DECONSAL II	52	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
14.	DERMATOL 10	52	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
15.	DIFEMERINE	52	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
16.	DIFETARSONE	52	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>

No.	Name	POCA Score (%)	Failure preventions
17.	(b) (4)***	52	<p>This name was identified in the Names Entered By Safety Evaluator Database.</p> <p>(b) (4)</p>
18.	DUVADILAN	52	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
19.	DETTOL	51	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
20.	DEXATRIM	51	<p>This name was identified by the RxNorm database.</p> <p>However, this product is listed as deactivated in Redbook without generic equivalent.</p>
21.	DIBENYLIN	51	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>

No.	Name	POCA Score (%)	Failure preventions
22.	DIPHENIDOL	51	<p>This name was identified by the Drugs at FDA database and RxNorm.</p> <p>(b) (4)</p>
23.	D&C YELLOW NO. 11	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases. This product is not a drug.</p>
24.	DACTIL	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
25.	(b) (4) ***	50	<p>This name was identified in the Name entered by Safety Evaluator database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases or internal databases. This name is an established name from a USAN Ballot review.</p>
26.	(b) (4) ***	50	<p>This name was identified in the Name Entered By Safety Evaluator database.</p> <p>However, we are unable to find product characteristics in internal databases.</p>

No.	Name	POCA Score (%)	Failure preventions
27.	(b) (4)***	50	<p>This name was identified in the Names Entered By Safety Evaluator Database.</p> <p>(b) (4)</p>
28.	DECAN-4-OLIDE	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
29.	DEPMEDALONE	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>
30.	DESEMPACHO	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find complete product characteristics in commonly used drug databases.</p>
31.	DINITOLMIDE	50	<p>This name was identified in the RxNorm database.</p> <p>However, we were unable to find product characteristics in commonly used drug databases.</p>

No.	Name	POCA Score (%)	Failure preventions
32.	DURASAL II	50	This name was identified by the RxNorm database. However, this product is listed as deactivated in Redbook without generic equivalent.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	MEXITIL	56
2.	PRESTALIA	56
3.	TESTOLIN	56
4.	VITACILINA	55
5.	BREVITAL	54
6.	SANAFITIL	54
7.	VITADIL 2A	54
8.	VITADIL 5A	54
9.	1,10-DECANEDIOL	53
10.	GEFITINIB	53
11.	BASIC YELLOW 57	52
12.	BEPRIDIL	52
13.	BREVIDIL	52
14.	INDERIDE LA	52
15.	INDERIDE LA 120/50	52
16.	INDERIDE LA 160/50	52
17.	INDERIDE LA 80/50	52
18.	JINTELI	52
19.	NIFURATEL	52

No.	Name	POCA Score (%)
20.	REVITOL	52
21.	BIFEMELANE	51
22.	CEVIMELINE	51
23.	EPITOL	51
24.	MODAFINIL	51
25.	(b) (4)	51
26.	ADRAFINIL	50
27.	CEFAZOLIN	50
28.	PREPIDIL	50
29.	TASIMELTEON	50
30.	(b) (4) ***	50
31.	TEDIZOLID	50
32.	TERTATOLOL	50
33.	TESTOPEL	50
34.	VENTOLIN	50
35.	VISINE L.R.	50

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MICHELLE K RUTLEDGE
09/09/2015

YELENA L MASLOV
09/14/2015