CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206709Orig1s000
207223Orig1s000

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:	November 27, 2017
Application Type and Number:	NDA 207223
Product Name and Strength:	Diacomit (stiripentol) powder, for suspension 250 mg and 500 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Biocodex
Panorama #:	2017-17493235
DMEPA Safety Evaluator:	Briana Rider, PharmD
DMEPA Team Leader:	Lolita White, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Diacomit on December 11, 2015 for stiripentol oral capsules, 250 mg and 500 mg (NDA 206709). The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Diacomit, under NDA 206709 conditionally acceptable in OSE Review #2015-2259072, dated March 2, 2016.[a] NDA 206709 is under review by the agency.

On September 5, 2017, the Applicant submitted the name, Diacomit, for review under NDA 207223, for stiripentol powder for oral suspension, 250 mg and 500 mg. Product information for NDA 207223 and NDA 206709 is included in Section 1.2 below.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 5, 2017 proprietary name submission for NDA 207223 and the December 11, 2015 proprietary name submission for NDA 206709.

Table 1. Relevant Product Information for Diacomit (stiripentol) powder for oral suspension (NDA 207223) and Diacomit (stiripentol) oral capsules (NDA 206709)

Application #	NDA 207223	NDA 206709
Intended Pronunciation	dī-ə-kä-mət	dī-ə-kä-mət
Active Ingredient	stiripentol	stiripentol
Indication of Use	(b) (4) treatment of (b) (4) (b) (4) seizures associated with Dravet syndrome in patients (b) (4).	(b) (4) treatment of (b) (4) (b) (4) seizures associated with Dravet syndrome in patients (b) (4).
Route of Administration	oral	oral
Dosage Form	powder for oral suspension	capsules
Strength	250 mg, 500 mg	250 mg, 500 mg

[a] Myers, D. Proprietary name review for Diacomit (stiripentol) oral capsules (NDA 206709). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 MAR 02. RCM No.: 2015-2259072.

Dose and Frequency	50 mg/kg/day administered in 2 or 3 divided doses	50 mg/kg/day administered in 2 or 3 divided doses
How Supplied	250 mg packets, 500 mg packets: cartons of 60	Bottles of 60 capsules in a carton containing one bottle
Storage	Store (b) (4) in a dry place. Store in original package to protect from light.	Store (b) (4) in a dry place. Store in original package to protect from light.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Diacomit, is derived from "comitialité" which is a French word for epilepsy. 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, October 6, 2017 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-one practitioners participated in DMEPA's prescription studies. The responses did not directly overlap with any currently marketed products or any products in the pipeline.

[b] USAN stem search conducted on September 12, 2017.

Diacomit versus Deponit

One respondent in the outpatient study interpreted the proposed proprietary name as "Deaconit", which is a close variation to the currently marketed product "Deponit". We evaluated the name pair, Diacomit and Deponit, further and find that there are sufficient orthographic and phonetic differences between the name pair. The infixes of this name pair have sufficient orthographic differences; Deponit has the downstroke letter 'p' in the infix that is not present in Diacomit.

The first syllable "dī", second syllable "ə", and third syllable "kä" of Diacomit sound different than the first syllable "dee", second syllable "po" and third syllable "nit" of Deponit and Diacomit contains an extra syllable.

Additionally, there are no overlaps in strength (250 mg and 500 mg versus 0.2 mg/hr [5 mg/24 hours] and 0.4 mg/hr [10 mg/24 hours]) between Diacomit and the discontinued brand Deponit (nitroglycerin) transdermal patch. Thus, we find there is minimal risk of name confusion for this name pair (see Appendix E).

Diacomit versus Commit

In the voice study, sixteen respondents in the voice study interpreted the proposed proprietary name as "Diacommit" and one respondent interpreted the proposed proprietary name as "Dia-commit" which are close variations to the currently marketed product "Commit" in that the name "Commit" is contained within the names "Diacommit" and "Dia-commit". We evaluated the name pair, Diacomit and Commit, further and find that there are sufficient orthographic and phonetic differences between the name pair. The prefixes of this name pair have sufficient orthographic differences, specifically, Diacommit contains the prefix letter string "Dia" that is not present in Commit.

The first syllable "dī" and second syllable "ə" of Diacomit sound different than the first syllable "ko" and second syllable "mit" in Commit and Diacomit contains two extra syllables.

Additionally, there are no overlaps in strength (250 mg and 500 mg versus EQ 2 mg base and EQ 4 mg base) between Diacomit and the over-the-counter product, Commit. Thus, we find there is minimal risk of name confusion for this name pair (see Appendix E).

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 198 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some the names in our previous proprietary name review for Diacomit under the NDA 206709 for stiripentol oral capsules. We note that the Sponsor is proposing the powder for oral suspension formulation in 250 mg and 500 mg strengths, which are the same strengths previously evaluated for the capsule formulation. 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 and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 72 names not previously analyzed. These names are included in Table 1 below.

[c] POCA search conducted on September 12, 2017 in version 4.2.

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 FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	65
Low similarity name pair: combined match percentage score ≤54%	6

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

Our analysis of the 74 names contained in Table 1 determined 74 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Multiple Dosage Forms under a Single Proprietary Name

The proposed proprietary name, Diacomit, was found conditionally acceptable for stiripentol oral capsules, 250 mg and 500 mg (NDA 206709)[d] and NDA 206709 is currently under review by the agency. We considered the appropriateness of using the proprietary name, Diacomit, for the proposed 250 mg and 500 mg powder for oral suspension under NDA 207223. We note that the Diacomit powder for oral suspension share the same active ingredient, indication for use, strengths, and recommended doses as the proposed Diacomit capsules. However, the products differ in dosage form (capsules versus powder for oral suspension) and administration technique, (swallow whole with a glass of water during a meal versus mix in a glass of water and take immediately after mixing during a meal).

If marketed under the same proprietary name, we anticipate that patients may be switched between the two dosage forms, which may result in medication errors if the products are not substitutable on a milligram-to-milligram basis. Given this potential, we discussed with the review team whether switching between the two dosage forms would produce clinically relevant differences in therapeutic effects and/or adverse events. Per email communication on November 17, 2017, the review team confirmed that the two dosage forms are bioequivalent. Because the capsules and powder for oral suspension are interchangeable, our concern for marketing the proposed powder for oral suspension under the same proprietary name is alleviated.

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[d] Myers, D. Proprietary name review for Diacomit (stiripentol) oral capsules (NDA 206709). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 MAR 02. RCM No.: 2015-2259072.

We also note that it is common and accepted practice to have a product line with multiple dosage forms managed under a shared proprietary name, and while the dosage forms and administration technique are different, these differences can be managed with labels and labeling.

Given the aforementioned reasons, our evaluation finds the use of the proprietary name, Diacomit, for the proposed powder for oral suspension is acceptable.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 17, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on November 24, 2017, they stated no additional concerns with the proposed proprietary name, Diacomit.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 5, 2017 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

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

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.

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

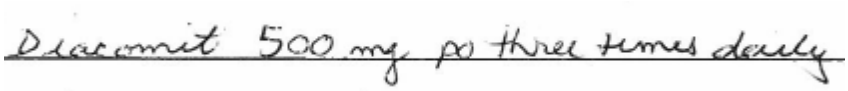
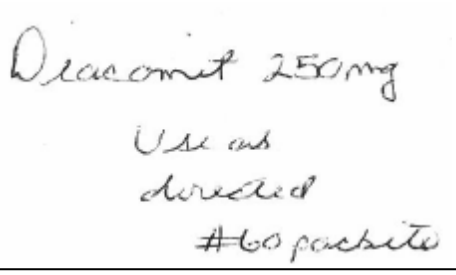
<table>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>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?</td><td>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?</td></tr>
</table>

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. Diacomit Study (Conducted on September 22, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	"Diacomit 250 mg use as directed. Dispense 60 packets"
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

308 People Received Study
91 People Responded

Study Name: Diacomit

Total	34	27	30	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DEACOMET	2	0	0	2
DEACOMIT	1	0	1	2
DEACONIT	1	0	0	1
DECOMIT	0	0	1	1
DIACLIMIT	0	1	0	1
DIACOMENT	0	1	0	1
DIACOMET	2	0	0	2
DIACOMIT	25	4	28	57
DIA-COMIT	0	1	0	1

DIACOMMIT	0	16	0	16
DIA-COMMIT	0	1	0	1
DIACOMT	1	0	0	1
DIACONIT	1	0	0	1
DIAKAMET	0	1	0	1
DIAKAMIT	0	1	0	1
DIETHOMATE	0	1	0	1
DIOACOMET	1	0	0	1

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

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** powder, for oral suspension **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses. Mix in a glass of water.	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.	Diacomit	100	Subject of this review.
2.	Dicomal-Ph	70	Name identified in RxNorm database. Brand deactivated with no generics available.
3.	Nicomide-T	70	Name identified in RxNorm database. Brand deactivated with no generics available.

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

No.	Name	POCA Score (%)
1.	Triamcot	62
2.	Crotamiton	56
3.	Indiomin	56

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:** Diacomit **Established name:** stiripentol **Dosage form:** powder, for oral suspension **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses. Mix in a glass of water.	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**

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** powder, for oral suspension **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses. Mix in a glass of water.	**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.	Commit	66	This name pair has sufficient orthographic and phonetic differences. The prefixes of this name pair have sufficient orthographic differences, specifically, Diacommit contains the prefix letter string “Dia” that is not present in Commit. The first syllable “dī” and second syllable “ə” of Diacomit sound different than the first syllable “ko” and second syllable “mit” in Commit and Diacomit contains two extra syllables. Additionally, there are no overlaps in strength (250 mg and 500 mg versus EQ 2 mg base and EQ 4 mg base) between Diacomit and the over-the-counter product, Commit (nicotine polacrilex) oral troche/lozenge.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** powder, for oral suspension **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses. Mix in a glass of water.	**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**
2.	Deponit	66	This name pair has sufficient orthographic and phonetic differences. The infixes of this name pair have sufficient orthographic differences; Deponit has the downstroke letter 'p' in the infix that is not present in Diacomit. The first syllable 'dī", second syllable "ə", and third syllable "kä" of Diacomit sound different than the first syllable "dee", second syllable "po" and third syllable "nit" of Deponit and Diacomit contains an extra syllable. Additionally, there are no overlaps in strength (250 mg and 500 mg versus 0.2 mg/hr [5 mg/24 hours] and 0.4 mg/hr [10 mg/24 hours]) between Diacomit and Deponit. The brand, Deponit, is discontinued. However, generic nitroglycerin transdermal patches are available.
3.	Daptomycin	58	This name pair has sufficient orthographic and phonetic differences.
4.	Dtic-Dome	58	This name pair has sufficient orthographic and phonetic differences.
5.	Bisacodyl	56	This name pair has sufficient orthographic and phonetic differences.
6.	diabetic Dm	56	This name pair has sufficient orthographic and phonetic differences.
7.	Diocto	56	This name pair has sufficient orthographic and phonetic differences.
8.	Driminate	56	This name pair has sufficient orthographic and phonetic differences.
9.	Mi-Acid	56	This name pair has sufficient orthographic and phonetic differences.
10.	mitomycin	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** powder, for oral suspension **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses. Mix in a glass of water.	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**
11.	Triacin C	56	This name pair has sufficient orthographic and phonetic differences.
12.	Triacin-C	56	This name pair has sufficient orthographic and phonetic differences.
13.	Clomid	55	This name pair has sufficient orthographic and phonetic differences.
14.	Dioctyl	55	This name pair has sufficient orthographic and phonetic differences.
15.	Diovan Hct	55	This name pair has sufficient orthographic and phonetic differences.
16.	Disalcid	55	This name pair has sufficient orthographic and phonetic differences.
17.	DACTINOMYCIN	54	This name pair has sufficient orthographic and phonetic differences.
18.	DIMOTAL	53	This name pair has sufficient orthographic and phonetic differences.
19.	AMFICOT	52	This name pair has sufficient orthographic and phonetic differences.
20.	AmitID	50	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.	N/A	

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

No.	Name	POCA Score (%)	Failure preventions

No.	Name	POCA Score (%)	Failure preventions
1.	Atromid	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Diclotard	60	International product formerly marketed in the UK.
3.	Dogmatil	58	International product marketed in Turkey, Switzerland, Spain, Singapore, Portugal, the Netherlands, Malaysia, France, Denmark, the Czech Republic, Brazil, Australia, Belgium, and Indonesia and formerly marketed in the Philippines, Hong Kong, Germany, and Mexico.
4.	Micomp-Pb	58	Name identified in RxNorm database. Brand deactivated with no generics available.
5.	Triac Cold	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Miacalcic	57	International product marketed in Ukraine, the UK, Turkey, Thailand, Switzerland, Sweden, Spain, Singapore, South Africa, Russia, Poland, the Phillippines, Norway, New Zealand, Mexico, Malaysia, Israel, Indonesia, India, Hungary, Hong Kong, Greece, France, Finland, Denmark, the Czech Republic, China, Brazil, Belgium, Australia and formerly marketed in Venezuela, Portugal, Ireland, Chile, Austria, and Italy.
7.	Atromid-S	56	Brand discontinued with no generic equivalent available. NDA 016099 withdrawn FR effective 06/16/2006.
8.	Coldmist	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Daricon	56	Brand discontinued with no generic equivalent available. NDA 011612 withdrawn FR effective 09/22/1999.
10.	Demi-Cof	56	Name identified in RxNorm database. Brand deactivated with no generics available.
11.	Dioctocal	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Triactin	56	Name identified in RxNorm database. Brand deactivated with no generics available.
13.	Butacote	55	International product formerly marketed in the UK and Ireland.

No.	Name	POCA Score (%)	Failure preventions
14.	Dactil	55	International product marketed in the UK and formerly marketed in Belgium, Japan, and France.
15.	Metomidate	55	Veterinary product.
16.	DomiCAL	54	International product formerly marketed in Ireland, the UK, and Hong Kong.
17.	MACADAMIA OIL	46	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Cocamide	60
2.	Glutamic-500	58
3.	Medcodin	58
4.	Mucobid Dm	58
5.	Pattotic	58
6.	Macrotec	57
7.	Metramid	57
8.	Nicoderm	57
9.	Actamin	56
10.	Adipic Acid	56
11.	Cosamin	56
12.	Edetic Acid	56
13.	Foamcoat	56
14.	Iodoxamid	56
15.	Malic Acid	56
16.	Micardis	56
17.	Micatin	56
18.	Micotil	56
19.	Miocamycin	56
20.	Nitro-Bid	56
21.	Pidotimod	56
22.	Podactin	56
23.	Ricobid H	56

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

No.	Name	POCA Score (%)
24.	Tia Doce	56
25.	Tinactin	56
26.	Triaminic	56
27.	Triaminic-12	56
28.	Bioclate	55
29.	Boric Acid	55
30.	Cinnamate	55
31.	Zilactin	55

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	N/A

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

/s/

BRIANA B RIDER
11/27/2017

LOLITA G WHITE
11/27/2017

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:	March 2, 2016
Application Type and Number:	NDA 206709
Product Name and Strength:	Diacomit (stiripentol) Capsules, 250 mg and 500 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Biocodex
Panorama #:	2015-2259072
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

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1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the December 11, 2015 proprietary name submission.

- Intended Pronunciation: dī-ə-kä-mət
- Active Ingredient: stiripentol
- Indication of Use: for (b) (4) treatment of (b) (4) seizures associated with Dravet syndrome
- Route of Administration: oral
- Dosage Form: capsules
- Strength: 250 mg and 500 mg

  The Sponsor intends to file a subsequent NDA for the following dosage forms in the near future:

  250 mg powder for oral suspension (b) (4) *and 500 mg powder for oral suspension* (b) (4)
- Dose and Frequency: The daily dosage is 50 mg/kg/day administered in 2 or 3 divided doses.

  (b) (4)
  (b) (4)
- How Supplied: 250 mg capsules: 60-count in a 50 mL bottle

  500 mg capsules: 60-count in a 100 mL bottle
- Storage: Store (b) (4) in a dry place. Store in original package to protect from light.
- Container and Closure Systems: The capsules are packaged in opaque (b) (4) bottle closed with a (b) (4) (b) (4) cap.

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 Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Diacomit, was derived from "comitialité," which is a French word for epilepsy. The Applicant noted in their Request for Proprietary Review submission that stiripentol is currently marketed under the trade name of Diacomit in the European Union, Canada, and Japan. 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

Sixty-eight 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.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 14, 2016 e-mail, the Division of Neurology Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1

[1]USAN stem search conducted on December 16, 2015.

[2] POCA search conducted on December 16, 2015.

Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	230
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 231 names contained in Table 1 determined that none of the 231 names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on February 29, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on February 29, 2016, they stated no additional concerns with the proposed proprietary name, Diacomit.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact CDR Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 11, 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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 ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤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 ≥ 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 ≥50% 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.

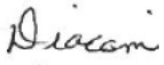
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤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. Diacomit Study (Conducted on December 31, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Diacomit 500 mg Take one capsule by mouth three times a day. Dispense #90
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

239 People Received Study
68 People Responded

Study Name: Diacomit

Total	24	18	26	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
DIACAMENT	0	0	1	1
DIACAMET	0	0	2	2
DIACAMIT	0	0	11	11
DIACEMIT	1	0	0	1
DIACOMET	5	0	0	5
DIACOMIT	18	4	4	26
DIACOMITT	0	1	0	1
DIACOMMIT	0	12	0	12

DIATIMIT	0	1	0	1
DIOCAMET	0	0	1	1
DIOCAMIT	0	0	3	3
DIOCOMIT	0	0	4	4

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

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg/day administered orally in 2 or 3 divided doses	**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.	Deponit	70 (individual phonetic score of 75)	The infixes of this name pair have sufficient orthographic differences; Deponit has the downstroke letter p in the infix that is not present in Diacomit. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable. There is no strength overlap between these products (Diacomit will be available in 250 mg and 500 mg vs. Deponit which is available in 0.2 mg/hr (5 mg/24 hours) and 0.4 mg/hr (10 mg/24 hours)). There is no dose overlap (Diacomit is to be dosed as 250 mg to (b) (4) mg three times daily vs. Deponit which is dosed as "1 patch" or "0.2 mg/hr" or "0.4 mg/hr" applied as a daily patch-on period of 12 to 14 hours and a daily patch –off period of 10-12 hours).

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

No.	Name	POCA Score (%)
1.	Diastat	62
2.	Betaconnect***	58
3.	Aconite	58
4.	(b) (4) ***	57
5.	Discovisc	56
6.	Dolomite	55
7.	Definity	54
8.	Dibent	54

No.	Name	POCA Score (%)
9.	Dicyclocot	54
10.	Dicyclomine	54
11.	Denatonium	53
12.	Dienogest	53
13.	Disofenin	53
14.	Decavac	52
15.	Duetact	52
16.	Dexacen-4	50
17.	Aconitine	50
18.	Dialyvite 800	50
19.	Dilacor	50

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

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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.	Diapedic	62 (individual phonetic score of 74)	The infixes and suffixes of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
2.	Commit	60	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Diacomit contains two extra syllables. There is no strength overlap between these products (Diacomit will be available in 250 mg and 500 mg vs. Commit which is available in EQ 2 mg base and EQ 4 mg base). There is no dose overlap (Diacomit is dosed as 250 mg to (b) (4) mg three times daily vs. Commit which is dosed as "1 lozenge" or "2mg" or "4mg" administered according to a 12 week schedule: Weeks 1 to 6 - 1 lozenge every 1 to 2 hours; Weeks 7 to 9 - 1 lozenge every 2 to 4 hours; Weeks 10 to 12 - 1 lozenge every 4 to 8 hours).
3.	Dacogen	60	The suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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.	Mucomyst-10	60	The prefixes and suffixes of this name pair (Diacomit vs. the root name Mucomyst) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Mucomyst. In addition, Mucomyst-10 contains a modifier '10' making the pair sound different when spoken, if included.
5.	Mucomyst-20	60	The prefixes and suffixes of this name pair (Diacomit vs. the root name Mucomyst) have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Mucomyst. In addition, Mucomyst-20 contains a modifier '20' making the pair sound different when spoken, if included.
6.	Nicomide	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
7.	Mucomyst	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
8.	Tagamet	60 (individual phonetic score of 71)	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
9.	Triacort	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
10.	Drixomed	58	The infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
11.	Disotate	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
12.	Desonate	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
13.	Depacon	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different, and Diacomit contains an extra syllable.
14.	Depakote	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
15.	Decongest	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
16.	Dermacort	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
17.	Di-Gel Mint	56	The infixes and suffixes of this name pair (Diacomit vs. Di-gel Mint) have sufficient orthographic differences. The second syllables of this name pair sound different, and Diacomit contains two extra syllables compared to the root name Di-gel. In addition, Di-Gel Mint contains a modifier 'Mint' making the pair sound different when spoken, if included.
18.	Diocto-C	56	The infixes and suffixes of this name pair (Diacomit vs. the root name Diocto) have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Diocto. In addition, Diocto-C contains a modifier 'C' making the pair sound different when spoken, if included.
19.	Nitromist	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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.	Diabeta	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
21.	Calomist	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
22.	Depocyt	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
23.	Desonide	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
24.	Diabinese	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
25.	Damason-P	54	The infixes and suffixes of this name pair (Diacomit vs. the root name Damason) have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Damason. In addition, Damason-P contains a modifier 'P' making the pair sound different when spoken, if included.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
26.	Delcort	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Diacomit contains two extra syllables.
27.	Diasorb	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.
28.	Dioctyn	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Diaomit contains an extra syllable.
29.	Docu Soft	54	The infixes and suffixes of this name pair (Diacomit vs. Docu Soft) have sufficient orthographic differences. The first, second, and third syllables of this name pair (Diacomit vs. Docu Soft) sound different, and Diacomit contains an extra syllable.
30.	Diazepam	53	The infixes and suffixes of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
31.	Vistacot	53	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
32.	Diamox	52	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
33.	Digoxin	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
34.	Dilaudid	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
35.	Decaject	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
36.	Decofed	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
37.	Depotest	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
38.	Diamode	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.
39.	Dia-Tuss	52	The infixes and suffixes of this name pair (Diacomit vs. Dia-Tuss) have sufficient orthographic differences. The third syllables of this name pair (Diacomit vs Dia-Tuss) sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
40.	Digitek	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
41.	Dilaudid-5	52	The infixes and suffixes of this name pair (Diacomit vs. the root name Dilaudid) have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Dialudid. In addition, Dilaudid-5 contains a modifier '5' making the pair sound different when spoken, if included.
42.	Dionex	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.
43.	Duoplant	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
44.	Nasacort	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
45.	Triacet	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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**
46.	Cetacort	51	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
47.	Dermabet	51	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
48.	Dioctyl S.S.	51	The infixes and suffixes of this name pair (Diacomit vs. the root name Dioctyl) have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Dioctyl. In addition, Dioctyl S.S. contains the modifier 'S.S.' making the pair sound different when spoken, if included.
49.	Niacor B3	51	The suffixes of this name pair (Diacomit vs. the root name Niacor) have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable compared to the root name Niacor. In addition, Niacor B3 contains a modifier 'B3' making the pair sound different when spoken, if incluuded.
50.	Novacort	51	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
51.	Declomycin	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, third, and fourth syllables of this name pair sound different.

No.	**Proposed name:** Diacomit **Established name:** stiripentol **Dosage form:** capsule **Strength(s):** 250 mg and 500 mg **Usual Dose:** 50 mg/kg administered orally in 2 or 3 divided doses	**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.	Dasatinib	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, third, and fourth syllables of this name pair sound different.
53.	Dialose	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.
54.	Dimetapp	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Diacomit contains an extra syllable.
55.	Paracort	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
56.	Docusate	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
57.	Duocet	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.
58.	Thalomid	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Diacomit contains an extra syllable.

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

No.	Name	POCA Score (%)
1.	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
1.	Dicomal-PH	64 (individual phonetic score of 72)	Brand discontinued with no generic equivalent available (per RedBook).
2.	Diosmin	64	Product is not a drug. It is only availbe per RedBook as a powder; 1 gram package size for compounding.
3.	Deconex	62 (individual phonetic score of 72)	Brand discontinued with no generic equivalent available (per RedBook).
4.	Dyspamet	62	International product marketed in Ireland and the United Kingdom.
5.	Nicomide-T	62	Brand discontinued with no generic equivalent available (per RedBook).
6.	Dicopac Kit	62	Brand discontinued with no generic equivalent available (per RedBook).
7.	Glucamet	61 (individual phonetic score of 72)	International product marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
8.	Diclozip	60	International product marketed in the United Kingdom.
9.	Dixarit	60	International product marketed in Canada, Australia, Germany, Australia, Hong Kong, Malaysia, Belgium, Ireland, Netherlands, New Zealand, South Africa, Singapore, the United Kingdom, and Denmark.
10.	Dytan-At	60	Brand discontinued with no generic equivalent available (per RedBook).
11.	Tagamet 100	60 (individual phonetic score of 71)	Brand discontinued with no generic equivalent available (per RedBook).
12.	Decabid	59 (individual phonetic score of 71)	Brand discontinued with no generic equivalent available (per RedBook).
13.	Diamond	59	International product marketed in Turkey.
14.	Beclomist	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Dalacin T	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Dicomal-DH	58	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
17.	Diosmetin	58	Product is not a drug. It is a flavonoid.
18.	Dexacort	58	Brand discontinued with no generic equivalent available (per RedBook).
19.	Dricort	58	Brand discontinued with no generic equivalent available (per RedBook).
20.	Disomer	57	Brand discontinued with no generic equivalent available (per RedBook).
21.	Dawnmist	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Della Soft	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Destolit	56	International product marketed in France, the United Kingdom, and Portugal.
24.	Diatensec	56	International product marketed in the United Kingdom.
25.	Dietrim ES	56	Brand discontinued with no generic equivalent available (per RedBook).
26.	Diocto-K	56	Brand discontinued with no generic equivalent available (per RedBook).
27.	Droncit	56	Veterinary product.
28.	D-Tann AT	56	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
29.	Diapid	56	Brand discontinued with no generic equivalent available (per RedBook).
30.	Dectomax	55	Veterinary product.
31.	Dome-Cort	55	International product marketed in Columbia.
32.	Deracoxib	54	Veterinary product.
33.	Diabetuss	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Diet Aid	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Diocaps	54	International product (docusate sodium) marketed in Mexico. International product (loperamide hydrochloride) marketed in the United Kingdom.
36.	Dolacet	54	Brand discontinued with no generic equivalent available (per RedBook).
37.	Doxatet	54	International product marketed in the United Kingdom.
38.	Duro Cort	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Lincomed	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
40.	Lincomix	54	Veterinary product.
41.	Pediamist	54	Brand discontinued with no generic equivalent available (per RedBook).
42.	Diucardin	54	Brand discontinued with no generic equivalent available (per RedBook).
43.	Decazate	53	International product marketed in the United Kingdom.
44.	Dibunate	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Cyclomin	52	International product marketed in the United Kingdom.
46.	Deconsal CT	52	Brand discontinued with no generic equivalent available (per RedBook).
47.	Desonil	52	International product marketed in Greece.
48.	Dexdomitor	52	Veterinary product.
49.	Diabetamide	52	International product marketed in the United Kingdom.
50.	Diazemuls	52	International product marketed in Australia, New Zealand, Germany, Hong Kong, Ireland, Netherlands, the United Kingdom, Canada, and Italy.
51.	Doconexent	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
52.	Drocon-CS	52	Brand discontinued with no generic equivalent available (per RedBook).
53.	Pediacof	52	Brand discontinued with no generic equivalent available (per RedBook).
54.	Promit	52	Brand discontinued with no generic equivalent available (per RedBook).
55.	Ditate-DS	51	Brand discontinued with no generic equivalent available (per RedBook).
56.	Dimetane DC	51	Product withdrawn from the market due to safety concerns.
57.	Dinitolmide	51	Veterinary product.
58.	Duranest	51	Brand discontinued with no generic equivalent available (per RedBook).
59.	Kenacort	51	Brand discontinued with no generic equivalent available (per RedBook).
60.	Darvocet	50	Product withdrawn from the market due to safety concerns (cardiotoxicity).
61.	Depakote CP	50	Brand discontinued with no generic equivalent available (per RedBook).
62.	Diazoxide	50	Brand discontinued with no generic equivalent available (per RedBook) other than powder for compounding.
63.	Dimetane	50	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
64.	(b) (4)***	50	Proposed proprietary name withdrawn by the Applicant April 10, 2013. No new proprietary name has been submitted.
65.	Disobrom	50	Brand discontinued with no generic equivalent available (per RedBook).
66.	Aconitate	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
67.	Citraconate	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
68.	Decoquinate	50	Veterinary product.
69.	Depakota	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
70.	Diar-Aid	50	Brand discontinued with no generic equivalent available (per RedBook).
71.	Dibekacin	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
72.	Diclomax SR	50	International product marketed as Diclomax in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
73.	Diloxanide	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
74.	Dimetapp ND	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
75.	Diocalm Ultra	50	International product marketed in the United Kingdom.
76.	Domitor	50	Veterinary product.
77.	Dura-Vent	50	Product withdrawn from the market due to safety concerns. Brand discontinued with no generic equivalent available (per RedBook).

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

No.	Name	POCA Score (%)
1.	Nazo-Mist	59
2.	Viscoat	57
3.	Cesamet	56
4.	Janumet	56
5.	Nitro Mist	56
6.	Vasovist***	56
7.	Vicodin	56
8.	(b) (4) ***	56
9.	(b) (4) ***	56

No.	Name	POCA Score (%)
10.	Aldomet	55
11.	Atamet	54
12.	Cefetamet	54
13.	Cetazone T	54
14.	Cyanokit	54
15.	Invokamet	54
16.	Liquimat	54
17.	Niconil	54
18.	Quadramet	54
19.	Riomet	54
20.	Ruconest	54
21.	Stie-Cort	54
22.	Macrobid	53
23.	Medicort	53
24.	Ricobid	53
25.	Silicones	53
26.	Viracept	53
27.	Beractant	52
28.	Galenamet	52
29.	Isomalt	52
30.	Magonate	52
31.	Meclomen	52
32.	Nitoman	52
33.	Prandimet	52
34.	Ricobid D	52
35.	Sinemet	52
36.	Tiamate	52
37.	Treximet	52
38.	Vanobid	52
39.	Vazobid	52

No.	Name	POCA Score (%)
40.	Vicoprin	52
41.	Visonex	52
42.	Vitamin D	52
43.	Vitamin D3	52
44.	Vitamin K	52
45.	Vitamin K 1	52
46.	Vitamin K 2	52
47.	Vitamin K 3	52
48.	Vitamin K1	52
49.	Bionect	51
50.	Citanest	51
51.	Cotameth	51
52.	Hydromet	51
53.	Tatum-T	51
54.	Vitamin B 12	51
55.	Vitamin B6	51
56.	Vitamin B9	51
57.	(b) (4)***	51
58.	Biocorneum	50
59.	Gadovist***	50
60.	Macuvite	50
61.	Mekinist	50
62.	Melatonin	50
63.	Mykacet	50
64.	Nasonex	50
65.	Nicabate	50
66.	Noctamid	50
67.	Sinumist	50
68.	Tycolet	50
69.	Valicot	50

No.	Name	POCA Score (%)
70.	Vasotate	50
71.	Vicodin ES	50
72.	Vicotuss	50
73.	Vincamine	50
74.	Viractin	50
75.	Vitamin A	50
76.	Zetacet	50

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/s/

DEBORAH E MYERS
03/02/2016

DANIELLE M HARRIS
03/02/2016