CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207987Orig1s000

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:	March 20, 2018
Application Type and Number:	NDA 207987
Product Name and Strength:	Ablysinol (dehydrated alcohol injection, USP), ≥ (b) (4)%, 99%, (b) (4)
Total Product Strength:	≥ (b) (4)%, 99%, (b) (4)
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Belcher Pharmaceuticals, LLC
Panorama #:	2017-19922890
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ablysinol, 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, Ablysinol*** on March 30, 2015. We found the name, Ablysinol***, acceptable under NDA 207987 on June 16, 2015.[a] NDA 207987 received a complete response on December 9, 2015.

NDA 207987 was resubmitted on December 22, 2017 as a Class 2 Resubmission. The Applicant submitted the proposed proprietary name, Ablysinol***, for review on December 22, 2017. We note the following changes in product characteristics from our previous review:

Product Characteristics	March 30, 2015 Submission	December 22, 2017 Submission
Strengths	(b) (4)	(b) (4), 99%, (b) (4)
Dose	(b) (4)	(b) (4) to 5 mL

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 22, 2017.

- Intended Pronunciation: ə-blĭs′-ĭn-ôl
- Active Ingredient: Dehydrated alcohol
- Indication of Use: Induce controlled cardiac septal infarction to improve exercise capacity in patients with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy.
- Route of Administration: Percutaneous injection
- Dosage Form: Injection
- Strength: ≥ (b) (4), 99%, (b) (4) [b]

[a] Stewart, J. Proprietary Name Review for Ablysinol (NDA 207987). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 JUNE 16. Panorama No. 2015-80409.

[b] We communicated an internal email to the Division of Cardiovascular and Renal Products (DCRP) on January 19, 2018 requesting clarification regarding the intended strength for Ablysinol. DCRP responded on January 19, 2018 that the proposed strength is (b) (4) However, we note that the proposed proprietary name submission mentions that the (b) (4) , and that the proposed container label and carton labeling state "each mL contains: ≥ 99% by volume ethyl alcohol." Also, we note on the Form 356h that the strength is listed as (b) (4). Therefore, we are considering

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- Dose and Frequency: [redacted]
- How Supplied: Dehydrated Alcohol Injection is a [redacted] USP [redacted] are supplied in a carton containing ten, 1 mL single-dose ampules.
- Storage: Store at room temperature, between 20°C and 25°C (68°F and 77°F) [redacted] Do not refrigerate. [redacted] Highly flammable, store away from any heat source.
- Reference Product (505(b)(2)): Alcohol and Dextrose Injection (NDA 04589)/Published literature

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 Cardiovascular and Renal Products (DCRP) 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[c].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Ablysinol, was created from the notion that ideally, there is happiness inside each one of us; "a bliss in all" people. Additionally, the Applicant stated "although not the original intention, the suffix -ol in the name Ablysinol can indicate that the drug is an alcohol, which is correct, since the drug is pure ethanol."

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the following doses and strengths in our evaluation of dose/strength overlap with comparator names: [redacted], 99%, [redacted] up to 5 mL dose.

[c] USAN stem search conducted on January 31, 2018.

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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. We note the presence of the letters "-ol" in the suffix of Ablysinol. We are not aware of "-ol" as a medical abbreviation and find many drug product names end in "-ol" (atenolol, droperidol, Tylenol, etc.), with no standard meaning for "-ol". Thus, since "-ol" is a common letter string used in drug nomenclature, it does not appear that the ending letters "-ol" are only associated with alcohol or any standard meaning. Therefore, we do not object to the use of "-ol" in Ablysinol.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 11, 2018 e-mail, the Division of Cardiovascular and Renal Products (DCRP) 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 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 124 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

We considered the following strengths for Ablysinol: (b) (4), 99%, (b) (4) Since (b) (4) are not typical strengths that are commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. The search for the (b) (4) produced no names. None of the names with strength overlap retrieved from the (b) (4) search had potential orthographic, spelling, and phonetic similarities with Ablysinol. These names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

[d] POCA search conducted on January 31, 2018 in version 4.2. POCA tool updated to incorporate a revised orthographic algorithm.

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Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	114
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 124 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on March 16, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on March 20, 2018, they stated no additional concerns with the proposed proprietary name, Ablysinol.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on December 22, 2017, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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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.

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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.

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***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%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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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.

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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?		

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

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

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

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

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

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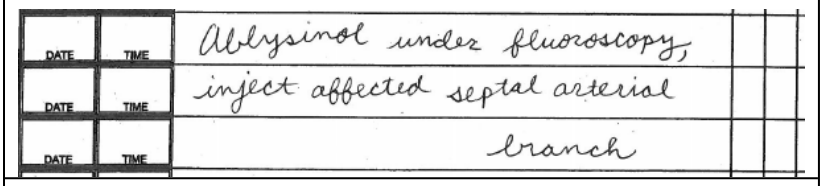
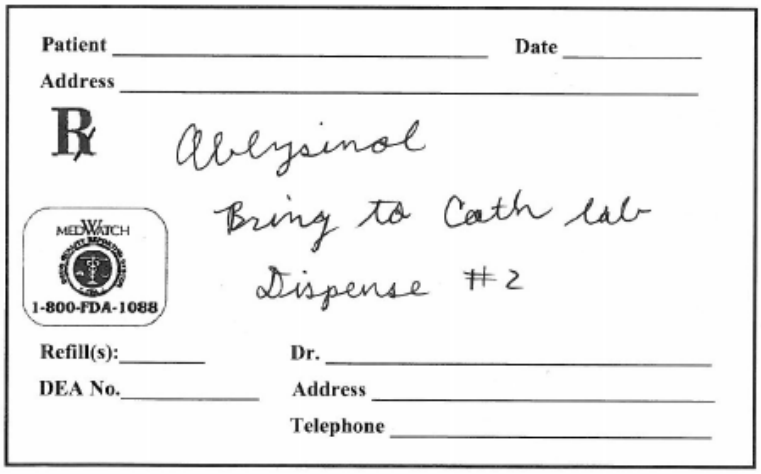
Appendix B: Prescription Simulation Samples and Results

Figure 1. Ablysinol Study (Conducted on January 16, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Ablysinol Bring to Cath lab Dispense #2

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FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Ablysinol

As of Date 2/2/2018

293 People Received Study

90 People Responded

Study Name: Ablysinol

Total	34	24	32	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ABBYSINOL	1	0	2	3
ABLESINOL	0	1	0	1
ABLICINOL	0	1	0	1
ABLISINOL	0	16	0	16
ABLISONAL	0	1	0	1
ABLISONOL	0	1	0	1
ABLISSINOL	0	1	0	1
ABLUSINOL	1	0	0	1
ABLYSINO	1	0	0	1
ABLYSINOL	30	2	28	60
ABLYSINOL UNDER FLUOROSCOPY	0	0	1	1
AFLEXTENOL	0	1	0	1
ALBLYSINOL	1	0	0	1
ALLYSINOL	0	0	1	1

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

No.	**Proposed name:** Ablysinol **Established name:** Dehydrated Alcohol Injection, USP **Dosage form:** Injection **Strength(s):** (b) (4), 99%, (b) (4) **Usual Dose:** (b) (4) into affected septal arterial branch, up to a maximum dose of 5 mL	**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.	Ablysinol***	100	Proposed proprietary name is the subject of this review.
2.	Platinol	70	Platinol (Cisplatin) is a discontinued brand product. Orthographically, the names in this name pair have different shapes, begin with orthographically different letters (P vs. A), and contain orthographically different infixes (upstroke t in 4th position vs. downstroke y in 4th position). Phonetically, the first and second syllables (pla ti vs. ə-blĭs′) sound different.

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

No.	Name	POCA Score (%)
	N/A	

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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:** Ablysinol **Established name:** Dehydrated Alcohol Injection, USP **Dosage form:** Injection **Strength(s):** (b) (4), 99%, (b) (4) **Usual Dose:** (b) (4) into affected septal arterial branch, up to a maximum dose of 5 mL	**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**
3.	1-Butanol	58	This name pair has sufficient orthographic and phonetic differences.
4.	A+D Original	56	This name pair has sufficient orthographic and phonetic differences.
5.	Adlyxin	64	This name pair has sufficient orthographic and phonetic differences.
6.	Afrinol	58	This name pair has sufficient orthographic and phonetic differences.
7.	Akrinol	58	This name pair has sufficient orthographic and phonetic differences.
8.	Albatussin La	56	This name pair has sufficient orthographic and phonetic differences.
9.	Alevazol	55	This name pair has sufficient orthographic and phonetic differences.
10.	Allopurinol	58	This name pair has sufficient orthographic and phonetic differences.
11.	Altenol	64	This name pair has sufficient orthographic and phonetic differences.
12.	Anbesol	58	This name pair has sufficient orthographic and phonetic differences.
13.	Angidol	55	This name pair has sufficient orthographic and phonetic differences.
14.	Anise Oil	56	This name pair has sufficient orthographic and phonetic differences.
15.	Antizol	55	This name pair has sufficient orthographic and phonetic differences.
16.	Aplisol	66	This name pair has sufficient orthographic and phonetic differences.
17.	Atropisol	56	This name pair has sufficient orthographic and phonetic differences.
18.	Bal In Oil	65	This name pair has sufficient orthographic and phonetic differences.

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19.	Bisabolol	60	This name pair has sufficient orthographic and phonetic differences.
20.	Clioquinol	56	This name pair has sufficient orthographic and phonetic differences.
21.	Dronabinol	59	This name pair has sufficient orthographic and phonetic differences.
22.	Gablofen	56	This name pair has sufficient orthographic and phonetic differences.
23.	Inositol	58	This name pair has sufficient orthographic and phonetic differences.
24.	Iodixanol	56	This name pair has sufficient orthographic and phonetic differences.
25.	Lactinol	60	This name pair has sufficient orthographic and phonetic differences.
26.	Lanolin Oil	60	This name pair has sufficient orthographic and phonetic differences.
27.	Lansinoh	54	Ablysinol and Lansinoh HPA Lanolin (available per Micromedex Redbook database) have sufficient orthographic and phonetic differences.
28.	Lansinoh Baby	46	Ablysinol and Lansinoh Baby product (available per DailyMed database) have sufficient orthographic and phonetic differences.
29.	Lisinopril	59	This name pair has sufficient orthographic and phonetic differences.
30.	Lysine	50	This name pair has sufficient orthographic and phonetic differences.
31.	Lysine Plus	57	Available per DailyMed database as Lip Clear Lysine Plus ointment, Lip Clear Lysine Plus Coldstick lipstick, Super Lysine Plus ointment, Super Lysine Plus Coldstick lipstick, Super Lysine Plus Strawberry Lip Treatment lipstick, and Super Lysine Plus Tangerine Lip Treatment lipstick. These name pairs have sufficient orthographic and phonetic differences.
32.	Marinol	56	This name pair has sufficient orthographic and phonetic differences.
33.	Micanol	56	This name pair has sufficient orthographic and phonetic differences.
34.	Milkinol	62	This name pair has sufficient orthographic and phonetic differences.
35.	Olysio	56	This name pair has sufficient orthographic and phonetic differences.
36.	Platinol-Aq	60	This name pair has sufficient orthographic and phonetic differences.
37.	Resinol	62	This name pair has sufficient orthographic and phonetic differences.

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38.	Resorcinol	55	This name pair has sufficient orthographic and phonetic differences.
39.	Salsolinol	67	This name pair has sufficient orthographic and phonetic differences.
40.	Silanol	58	This name pair has sufficient orthographic and phonetic differences.
41.	Ubiquinol	60	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 (%)
	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
42.	2-Aminophenol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as an organic compound that is used as a reagent for the synthesis of dyes and heterocyclic compounds.
43.	3-Aminophenol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as substance used in the synthesis of 3-(diethylamino)phenol, key intermediate for the preparation of several fluorescent dyes (e.g., Rhodamine B). Other uses for the compound include hair dye colorants and stabilizers for chlorine-containing thermoplastics.
44.	3-Nonylphenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Per Google search, nonylphenols are used in manufacturing antioxidants, lubricating oil additives, laundry and dish detergents, emulsifiers, and solubilizers.

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No.	Name	POCA Score (%)	Failure preventions
45.	4-Aminophenol	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as compound commonly used as a developer for black-and-white film.
46.	4-Nonylphenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a compound used as a surfactant in cleaning and cosmetic products, and as a spermicide in contraceptives.
47.	(b) (4) ***	58	Proposed proprietary name found unacceptable by DMEPA (Panorama #: 2015-5661660). NDA 207202 was approved under new proprietary name, Abilify MyCite.
48.	(b) (4) ***	56	Proposed proprietary name found acceptable on July 16, 2015 (Panorama #: 2015-887015). However, the proposed proprietary name was subsequently withdrawn under NDA 207202 on September 21, 2015. NDA 207202 was approved under new proprietary name, Abilify MyCite.
49.	Aclacin	55	International product marketed in the United Kingdom per Micromedex database.
50.	Adrafinil	64	International product marketed in France per Micromedex database.
51.	Alexitol	62	International product marketed in many countries including the United Kingdom and Ireland, per Micromedex database.
52.	(b) (4) ***	58	Proposed proprietary name found unacceptable by DMEPA under NDA 206977/ (b) (4) (Panorama #: (b) (4)). NDA 206977/ (b) (4) received a complete response (b) (4)
53.	Alibendol	67	International product marketed in France per Micromedex database.
54.	Allylestrenol	60	International product marketed in many countries including the United Kingdom and Mexico, per Micromedex database.

No.	Name	POCA Score (%)	Failure preventions
55.	(b) (4) ***	63	Proposed proprietary name found unacceptable by DMEPA on June 6, 2017 (Panorama #: (b) (4) (b) (4) NDA (b) (4) is under pre-submission status in DARRTS, and a new proposed proprietary name, (b) (4) ***, was found conditionally acceptable on September 25, 2017 (Panorama #: (b) (4)).
56.	Aminosol 5%	57	Brand discontinued with no TE codes provided per Drugs@FDA database.
57.	Amyl Cinnamal	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a synthetically produced scent ingredient.
58.	Anabolin La	57	Anabolin LA-100 brand discontinued with no generic equivalents available per Micromedex Redbook database.
59.	Ansolysen	62	Brand discontinued with no TE codes provided per Drugs@FDA database.
60.	Apple Seed Oil	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a fixed oil found in apple seeds that is used in the cosmetic and medical industries.
61.	Baltussin	56	Brand discontinued with no generic equivalents available per Clinical Pharmacology and Micromedex Redbook databases.
62.	Basil Oil	58	Basil Oil Comoros (Basil Oil) brand discontinued with no generic equivalents available per Micromedex Redbook database.
63.	Bisphenol A	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a synthetic compound used to make certain plastics and epoxy resins.
64.	(b) (4) ***	64	Proposed proprietary name found unacceptable by DMEPA on August 10, 2017 under NDA 209570 (Panorama #: 2017-16447196). NDA 209570 was approved under established name, Benznidazole.

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No.	Name	POCA Score (%)	Failure preventions
65.	(b) (4) ***	58	Proposed proprietary names (b) (4) *** and (b) (4) *** found unacceptable by DMEPA on October 26, 2015 under BLA 761042 (Panorama #: 2015-1210669 and 2015-1210671). BLA 761042 was approved under new proprietary names, Erelzi and Erelzi Sensoready Pen.
66.	Cannabinol	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a non-psychoactive cannabinoid found only in trace amounts in Cannabis.
67.	Cardinol	55	International product marketed in the United Kingdom, New Zealand, and Australia, per Micromedex database.
68.	Clobutinol	57	International product marketed in many countries including the Chile, Argentina, Germany, Spain, Brazil, per Micromedex database.
69.	Delmopinol	56	International product marketed in France, Israel, and the United Kingdom, per Micromedex database.
70.	Eprozinol	61	International product marketed in Spain, France, and Italy, per Micromedex database.
71.	Linalool, ()-	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as used as a scent in perfumed hygiene products and cleaning agents, as well as used as a chemical intermediate and insecticide.
72.	Linalool, (-)-	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as used as a scent in perfumed hygiene products and cleaning agents, as well as used as a chemical intermediate and insecticide.
73.	Linalool, (+)-	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as used as a scent in perfumed hygiene products and cleaning agents, as well as used as a chemical intermediate and insecticide.

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No.	Name	POCA Score (%)	Failure preventions
74.	Linalool, (+-)-	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as used as a scent in perfumed hygiene products and cleaning agents, as well as used as a chemical intermediate and insecticide.
75.	Meptazinol	56	International product marketed in many countries including Germany, Austria, and Greece, per Micromedex database.
76.	Nasin Nasal	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
77.	N-Nonylphenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
78.	Nonylphenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Per Google search, Nonylphenol is used in manufacturing antioxidants, lubricating oil additives, laundry and dish detergents, emulsifiers, and solubilizers.
79.	Policosanol	60	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
80.	Pridinol	59	International product marketed in Brazil, Argentina, Poland, Mexico, and other countries per Micromedex database.
81.	Salbulin	50	International product marketed in the United Kingdom, Mexico, and other countries per Micromedex database.
82.	Talinolol	56	International product marketed in many countries including Germany, per Micromedex database.
83.	Travenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Per Micromedex database, Travenol represents a drug manufacturer.
84.	Xanthinol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
85.	Zonulysin	59	International product marketed in South Africa and the United Kingdom per Micromedex database.

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No.	Name	POCA Score (%)	Failure preventions
86.	1-Propanol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Identified per Google search as a primary alcohol that is used as a solvent in the pharmaceutical industry mainly for resins and cellulose esters.

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 (%)
87.	Babassu Oil	56
88.	Betimol	56
89.	Bicillin L-A	56
90.	Biclotymol	60
91.	Bleomycin	56
92.	Blincyto	62
93.	Blis-To-Sol	66
94.	Brexidol	59
95.	Brexin L.A.	56
96.	Bricanyl	60
97.	Butylvinal	58
98.	Bystolic	56
99.	Calcidol	60
100.	Clinisol 15	60
101.	Clinsol	56
102.	Clopidol	55
103.	Clostebol	56
104.	Dill Seed Oil	56
105.	Labetalol	55
106.	Lexinal	57
107.	Libanil	58
108.	Lice-Nil	58
109.	Linseed Oil	58
110.	Lusonal	58
111.	Mallisol	58
112.	Maltitol	58

[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

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No.	Name	POCA Score (%)
113.	Mazindol	57
114.	Modafinil	56
115.	Parsidol	60
116.	Placidyl	58
117.	Polycidin	55
118.	Polycin	55
119.	Polycin-B	58
120.	Polytine D	56
121.	Poly-Vi-Sol	63
122.	Salmon Oil	55
123.	Sleepinal	60
124.	Tacalcitol	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.	Barium Sulfate For Suspension
2.	Benzoyl Peroxide
3.	Benzoyl Peroxide Emollient
4.	Buffered Eye-Lert
5.	Calcium Gluconate
6.	Ovace
7.	SL Eye Wash
8.	SODIUM SULFACETAMIDE
9.	Vanilla SilQ HD
10.	Water

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/s/

SARAH E THOMAS
03/20/2018

CHI-MING TU
03/20/2018

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:	June 16, 2015
Application Type and Number:	NDA 207987
Product Name and Strength:	Ablysinol (dehydrated alcohol injection, USP), (b) (4)%
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Belcher Pharmaceuticals, LLC
Panorama #:	2015-80409
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ablysinol, 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 March 30, 2015 proprietary name submission.

- Intended Pronunciation: ə-blĭs′-ĭn-ŏl
- Active Ingredient: dehydrated alcohol injection, USP
- Indication of Use: To improve [redacted] exercise capacity in patients with symptomatic, [redacted], hypertrophic obstructive cardiomyopathy [redacted]
- Route of Administration: percutaneous injection
- Dosage Form: solution for injection
- Strength: [redacted]% by volume
- Dose and Frequency: [redacted]
- How Supplied: Supplied in a box of 10-[redacted] glass ampules containing 1 mL of [redacted]% by volume ethyl alcohol in each [redacted] clear glass ampule.
- Storage: Store at room temperature, between 20°C and 25°C (68°F and 77°F). [redacted]. Do not refrigerate. [redacted]. Highly flammable, store away from any heat source.
- Container and Closure Systems:
- Reference Listed Drug: Published Literature

***We note in our internal May 29, 2015 email communication with the Office of New Drug Products (ONDP), the proposed strengths [redacted] (on form 356h). [redacted] (per container label and carton labeling), [redacted]% by volume (per name submission) may not be acceptable to ONDP. Thus, we evaluated the proposed proprietary name by reviewing for dose and strength overlaps for:

- [redacted]
- [redacted]

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- [redacted] (b) (4)
- 1 mL. (b) (4)

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 Cardiovascular & Renal Products (DCRP) 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, Ablysinol, was created from the notion that ideally, there is happiness inside each one of us; "a bliss in all" people. 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

Seventy-six 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. Common verbal misinterpretations identified in the prescription studies included 'A' being mistaken for 'E', and 'G'; the 'b' being mistaken for a 'c' , 'g' , 'k' , and 'p'; the 'y' being mistaken for an 'i'; and the 's' being mistaken for a 'c'. Common misinterpretations of the written prescription studies included 'b' being mistaken for a 'p', the 's' being mistaken for a 'b', and the 'o' being mistaken for an 'a'. Appendix B contains the results from the verbal and written prescription studies.

[1]USAN stem search conducted on April 13, 2015.

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2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 15, 2015 e-mail, the Division of Cardiovascular & Renal Products (DCRP) 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
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	155
Low similarity name pair: combined match percentage score ≤49%	0

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed strength for Ablysinol is (b) (4)%. ONDP is still evaluating the strength, but suggest the correct strength for this proposed product may be (b) (4)%. Since this is not commonly marketed strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Ablysinol that were not identified in POCA, and found to have an overlap in strength (b) (4) with Ablysinol.

Our search did not identify any names with potential orthographic, spelling, or phonetic similarities that overlap in strength with the proposed product, Ablysinol.

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

Our analysis of the 156 names contained in Table 1 determined 156 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular & Renal Products (DCRP) via e-mail on June 10, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from

[2] POCA search conducted on April 30, 2015.

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the DCRP on June 16, 2015, they stated no additional concerns with the proposed proprietary name, Ablysinol.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Darrel Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 30, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

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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 DNCE. OPDP or DNCE 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 DNCE 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.

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***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.

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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 checklist (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.

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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.

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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 do 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?		

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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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o 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.

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	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?

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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.

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Appendix B: Prescription Simulation Samples and Results

Figure 1. Ablysinol Study (Conducted on 4/17/15)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Ablysinol - under fluoroscopy, inject 1mL into affected septal branch Outpatient Prescription: Patient _____ Date 4-17-15 Address _____ ℞ Ablysinol Bring to cath lab #2 Refill(s): _____ Dr. OSE DEA No. _____ Address _____ Telephone _____	Ablysinol Bring to Cath Lab Dispense #2

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FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Ablysinol

As of Date 5/21/2015

247 People Received Study

76 People Responded

Study Name: Ablysinol

Total	27	20	29	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ABLEZINOL	0	1	0	1
ABLISINOL	0	2	0	2
ABLYBINAL	1	0	0	1
ABLYSIMAL	2	0	2	4
ABLYSIMOL	1	0	0	1
ABLYSINAL	7	0	17	24
ABLYSINOL	15	1	6	22
ABYLISINOL	0	0	1	1
ABYLSINAL	1	0	0	1
ACLISINOL	0	1	0	1
ACLISONAL	0	1	0	1
AGLISONDOL	0	1	0	1
AGLYCENOL	0	1	0	1
AGLYCINOL	0	4	0	4
AKLINSONOL	0	1	0	1
AMPLICINOL	0	1	0	1
APLICIDOL	0	1	0	1

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APLICINOL	0	1	0	1
APLISINOL	0	1	0	1
APLISSINOL	0	1	0	1
APLYSINAL	0	0	3	3
EPLISINOL	0	1	0	1
GLYCINOL	0	1	0	1

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

No.	**Proposed name: Ablysinol** **Established name: dehydrated alcohol, USP** **Dosage form: injection** **Strength(s): (b) (4) %** **Usual Dose: (b) (4) mL per septal branch injected by slow percutaneous injection**	**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.	Ablysinol	100	The subject of this review.

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.	1-PROPANOL	50
2.	A+D ORIGINAL	54
3.	AFRINOL	59
4.	AIM CLINICAL	50
5.	AKRINOL	58
6.	ALLANFOL	50
7.	ALL-NITE COLD	50
8.	ALLZITAL ***	56
9.	ALPHADROL	56
10.	ALPRENOLOL	50
11.	ALTENOL	64
12.	AMBENYL	50
13.	AMBROXOL	50
14.	AMINOSOL 5%	53
15.	AMLACTIN	50
16.	AMPHICOL	56
17.	ANAFRANIL	50
18.	ANBESOL	50
19.	ANTI-FUNGAL	51
20.	APLENZIN	50
21.	APSIFEN F	50
22.	APSOLOL	50
23.	ARIDOL	50
24.	ARMODAFINIL	52
25.	CANNABINOL	55
26.	CARDINOL	53

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No.	Name	POCA Score (%)
27.	CLIOQUINOL	52
28.	CLOBUTINOL	52
29.	DIQUINOL	54
30.	DOCOSANOL	52
31.	DRONABINOL	54
32.	FOSRENOL	50
33.	HALENOL	54
34.	INOSITOL	52
35.	LACTINOL	57
36.	LANOLIN OIL	50
37.	LEVORPHANOL	50
38.	LISINOPRIL	56
39.	MARINOL	54
40.	MEPTAZINOL	54
41.	MILKINOL	60
42.	OLYSIO	50
43.	PANTHENOL	52
44.	PHYSIOSOL	50
45.	PLATINOL-AQ	54
46.	POLICOSANOL	52
47.	PROMINOL	50
48.	RESINOL	59
49.	RESORCINOL	51
50.	TYLENOL	52
51.	UBIQUINOL	58
52.	VISINE L.R.	52

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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: Ablysinol** **Established name: dehydrated alcohol injection, USP** **Dosage form: injection** **Strength(s): (b) (4) %** **Usual Dose: (b) (4) mL per septal branch injected by slow percutaneous injection**	**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.	ACLACIN	54	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
2.	ADRAFINIL	66 Phonetic 76	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
3.	ALEVAZOL	54	The infixes of this name pair have sufficient orthographic differences. The second, third, and forth syllables of this name pair sound different.
4.	ALFACALCIDOL	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second, third, and forth syllables of this name pair sound different. The name Alfacalcidol contains an extra syllable.
5.	ALFENTANIL	50	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

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No.	**Proposed name: Ablysinol** **Established name: dehydrated alcohol injection, USP** **Dosage form: injection** **Strength(s): (b) (4)** **Usual Dose: (b) (4) mL per septal branch injected by slow percutaneous injection**	**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**
6.	ALLERSOL	50	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
7.	ALLOPURINOL	58	The infixes of this name pair have sufficient orthographic differences. The second, third, and forth syllables of this name pair sound different. The name Allopurinol contains an extra syllable.
8.	AMLEXANOX	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, third, and forth syllables of this name pair sound different.
9.	ANISE OIL	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
10.	ANSOLYSEN	57	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, third, and forth syllables of this name pair sound different.
11.	ANTIZOL	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.

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No.	**Proposed name: Ablysinol** **Established name: dehydrated alcohol injection, USP** **Dosage form: injection** **Strength(s): (b) (4)** **Usual Dose: (b) (4) mL per septal branch injected by slow percutaneous injection**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
12.	APLISOL	64	The prefixes and infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
13.	(b) (4) ***	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
14.	ATROPISOL	54	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
15.	GABLOFEN	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
16.	PATANOL	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.
17.	PLATINOL	66 Phonetic 75	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. The name Ablysinol contains an extra syllable.

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No.	Proposed name: Ablysinol Established name: dehydrated alcohol injection, USP Dosage form: injection Strength(s): (b) (4) Usual Dose: (b) (4) mL per septal branch injected by slow percutaneous injection	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
18.	TRAVENOL	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. The name Ablysinol contains an extra syllable.

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

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

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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.	1-BUTANOL	53	Name identified in RxNorm database. Product is not a drug. It is used as an industrial and pharmaceutical solvent and as an extraction solvent in food processing
2.	2-PHENYLPHENOL	55	Name identified in RxNorm database. Product is not a drug. It is an antiseptic, disinfectant and preservative.
3.	3-AMINOPHENOL	56	Name identified in RxNorm database. Product is not a drug. It is a raw material used in pesticides and dyes.
4.	3-NONYLPHENOL	55	Name identified in RxNorm database. Product is not a drug. This compound is used in the manufacture of plastics.
5.	4-AMINOPHENOL	56	Name identified in RxNorm database. Product is not a drug. It is a raw material used in hair dyes.
6.	(b) (4) ***	50	Name identified in Names Entered by SE database. This name was denied in OSE RCM# 2011-3928. The product was approved under the name Abilify Maintena in OSE RCM# 2012-492.
7.	ALIBENDOL	57	Name identified in RxNorm database. International coloretic product marketed in Ireland and France.
8.	ALLYLESTRENOL	59	Name identified in RxNorm database. International progestogen product marketed in Asia.
9.	ALOGLUTAMOL	52	Name identified in RxNorm database. International antacid product marketed in Italy, Spain, and Mexico.
10.	AMPHETAMINIL	52	Name identified in RxNorm database. International central stimulant product marketed in Germany.
11.	AMYL CINNAMAL	58	Name identified in RxNorm database. Product is not a drug. It is a synthetic fragrance ingredient used in cosmetic and personal care products
12.	APPLE FRUIT OIL	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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No.	Name	POCA Score (%)	Failure preventions
13.	BISPHENOL A	55	Name identified in RxNorm database. Product is not a drug. It is a chemical used in certain food contact materials.
14.	DELMOPINOL	58	Name identified in RxNorm database. International dental product marketed in France, Israel, and UK.
15.	EPROZINOL	62 Phonetic 72	Name identified in RxNorm database. International mucolytic product marketed in Europe.
16.	ETHYLESTRENOL	52	Name identified in RxNorm database. International anabolic steroid product marketed in South Africa, Australia, and Belgium.
17.	HEPTAMINOL	50	Name identified in RxNorm database. International cardiac stimulant product marketed in Africa, Asia, and Europe.
18.	LYNESTRENOL	50	Name identified in RxNorm database. International progesterone product marketed in South Africa, Europe, Sweden, Switzerland, and Germany.
19.	METHANOL	50	Name identified in RxNorm database. Product is not a drug. It is used as a solvent, antifreeze, fuel and a denaturant for ethanol.
20.	N-NONYLPHENOL	54	Name identified in RxNorm database. Product is not a drug. It is a compound used to manufacture plastics.
21.	PRIDINOL	56	Name identified in RxNorm database. International muscle relaxant product marketed in France and Italy.
22.	SALSOLINOL	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	SILANOL	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	XANTHINOL	56	Name identified in RxNorm database. International vasodilator product marketed in multiple countries.
25.	ZONULYSIN	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	BAL IN OIL	53
2.	BETIMOL	58
3.	BICLOTYMOL	52
4.	BLEPHAMIDE	50
5.	BLIS-TO-SOL	61
6.	BRETYLOL	53
7.	BREVIDIL	53
8.	BREVITAL	52
9.	BREXIDOL	60
10.	BRICANYL	52
11.	BROMPHENYL	52
12.	BRONCHITOL	50
13.	BUPHENYL	50
14.	BUTYLVINAL	56
15.	CALCIDOL	60
16.	CAPLENAL	56
17.	CLINISOL 15	50
18.	CLOPIDOL	55
19.	CLOSTEBOL	52
20.	CYCLOFENIL	50
21.	DELZICOL	55
22.	DERMA CIDOL	52
23.	DESONIL	54
24.	DIBENIL	52
25.	DICLOFENAL	54
26.	DILL SEED OIL	56
27.	DIPHENIDOL	52
28.	DIPHENYL	50
29.	DISIPAL	52
30.	DRISDOL	55
31.	DRYSOL	52
32.	ELYZOL	54
33.	ERYTHRITOL	51
34.	EUCALYPTOL	52
35.	GLYCO GEL	50
36.	HABITROL	52
37.	HYBRISIL	54
38.	LICE-NIL	54
39.	LIPIODOL	50
40.	LUMINAL	50

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No.	Name	POCA Score (%)
41.	LUSONAL	55
42.	MALLISOL	52
43.	MALTITOL	56
44.	MAZINDOL	52
45.	MODAFINIL	54
46.	MUSCINIL	52
47.	O-CYMEN-5-OL	52
48.	PARSELY SEED OIL	50
49.	PARSIDOL	59
50.	PLACIDYL	55
51.	PLAQUENIL	51
52.	PLUM SEED OIL	50
53.	POLYCIN-B	50
54.	POLYTINE D	51
55.	POLY-VI-SOL	58
56.	SLEEPINAL	58
57.	TACALCITOL	56
58.	TACTINAL	50
59.	VISICOL	52
60.	VISICOL 398/1102	52

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/s/

CHI-MING TU on behalf of JANINE A STEWART
06/16/2015

CHI-MING TU
06/16/2015