CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204427Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services Public Health Service Food and Drug Administration Center for Drug Evaluation and Research Office of Surveillance and Epidemiology Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	January 17, 2014
Reviewer:	Carlos M Mena-Grillasca, RPh Division of Medication Error Prevention and Analysis
Team Leader:	Lubna Merchant, MS, PharmD Division of Medication Error Prevention and Analysis
Division Director (Acting):	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Kerydin (Tavaborole) Topical Solution, 5%
Application Type/Number:	NDA 204427
Applicant/Sponsor:	Anacor Pharmaceuticals
OSE RCM #:	2013-16423

*** This document contains proprietary and confidential information that should not be released to the public.***

CONTENTS

1 INT	RODUCTION	1
1.1	Regulatory History	1
1.2	Product Information	1
2 RES	ULTS	1
2.1	Promotional Assessment	1
2.2	Safety Assessment	1
3 CON	ICLUSIONS	9
3.1	Comments to the Applicant	9
4 REF	ERENCES	
APPEND	DICES	11

1 INTRODUCTION

This review evaluates the proposed proprietary name, Kerydin, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 **REGULATORY HISTORY**

The applicant initially submitted the proposed proprietary name, ^{(b) (4)} during the IND phase. DMEPA found the proposed name unacceptable in OSE review 2012-1949, dated January 25, 2013. Subsequently, the applicant submitted a request for reconsideration for the proposed name

^{(b) (4)}. DMEPA found the name unacceptable upon reconsideration in OSE review 2013-797, dated September 13, 2013.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 30, 2013 proprietary name submission.

- Active Ingredient: Tavaborole
- Indication of Use: Treatment of onychomycosis
- Route of Administration: Topical
- Dosage Form: Solution
- Strength: 5%
- Dose and Frequency: Apply to affected nails once daily for 48 weeks.
- How Supplied: 10 mL in an amber glass bottle. A glass-tip dropper is provided.
- Storage: 20-25°C (69-77°F); excursions permitted to 15-30°C (59-86°F)
- Container and Closure Systems: 12 mL amber USP (b) (4) glass bottle and black (b) (4) liner.
- Intended Pronunciation: ker' i din

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Dermatology and Dental Products concurred with the findings of OPDP's promotional 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

The December 30, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Kerydin, was derived from a blank canvas and has no intended meaning. 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 practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Sixteen participants interpreted the name correctly (outpatient n=14; inpatient n=2). Fifteen participants in the inpatient study misinterpreted the up stroke letter 'd' for the letter 't' (n=10) and the letter 's' (n=5). Five participants in the outpatient study misinterpreted the down stroke letter 'y' for the letter 'g'. None of the participants in the voice study interpreted the name correctly. Fifteen participants in the voice study misinterpreted the letter 'Ca' and the letter 'y' for the letter 'y' for the letter 'a' (n=9), 'i' (n=4), 'e' (n=1), and 'o' (n=1). Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 2, 2013 e-mail, the Division of Dermatology and Dental Products (DDDP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the names retrieved from our POCA search, with the combined orthographic and phonetic score of greater than 50%. Table 1 also includes the names identified from the FDA Prescription Simulation studies or by the ^{(b) (4)}) not identified by DMEPA and that require further evaluation.

Table 1: Collective List of Potentially Similar Names (POCA, Rx Studies, and External Name Study)

Highly similar pair: combined match percentage score ≥70%

Names	Combined POCA Score
kerydin	100
jeridin	74
erymin	70

Moderately similar pair: combined	match percentage score	\geq 50% to \leq 69%
	Combined POCA Score	
	69	
varidin	69	
Karidium	68	
	68	
ceradon	66	
ceresin	66	
doriden	66	
eraldin	66	
ferrimin	66	
claradin	65	
terocin	65	
Ketadim	64	
(5)(4)	64	
sarenin	64	
chrysin	63	
ketodan	63	
	63	
iduridin	62	
kloromin	62	
trypsin	62	
kemadrin	61	
beldin	60	
cerubidin	60	
claritin	60	
coricidin	60	
eridium	60	
keracyanin	60	
kerosene	60	
prandin	60	
keflin	59	
kerlone	59	
kirwan	59	
sarapin	59	
tremin	59	
agrylin	58	
biperiden	58	
(b) (4)	58	
cardene	58	
cordran	58	
corwin	58	
dermatin	58	
eryderm	58	
karbinal	58	
kerodex	58	
metrodin	58	
orfadin	58	
orgadin	58	
percodan	58	

prodrin	58
secretin	58
serutan	58
silybin	58
teldrin	58
trexydin	58
candin	57
cereflin	57
duradin	57
kadian	57
preludin	57
ser-a-gen	57
suramin	57
uritin	57
aricin	56
carimune	56
curdlan	56
dermacin	56
desirudin	56
desitin	56
ferotrin	56
geridium	56
hesperidin	56
(b) (4)	56
kao-tin	56
kedbumin	56
(b) (4)	56
keralyt	56
klor-con	56
lepirudin	56
operidine	56
otrivin	56
paraffin	56
perdiem	56
piriton	56
priftin	56
quercetin	56
tridane	56
uridon	56
veregen	56
eradacin	55
furacin	55
heroin	55
muricin	55
narasin	55
naropin	55
terbium	55
terramycin	55
uridine	55
urimin	55

arestin	54
asendin	54
b-12 resin	54
baridium	54
bepadin	54
(b) (4)	54
c30-45 olefin	54
cardinol	54
ceprotin	54
cortan	54
dryphen	54
eribulin	54
eryped	54
(b) (4)	54
fergon	54
herbon	54
iridium	54
kafocin	54
kariva	54
kelferon	54
(b) (4)	54
key-pred	54
miradon	54
neo-fradin	54
oxeladin	54
panretin	54
paroven	54
perestan	54
periactin	54
perisine	54
pertussin	54
pyridium	54
(b) (4)	54
rifadin	54
seromycin	54
(b) (4)	54
termene	54
torecan	54
triacin	54
triban	54
tritan	54
triveen	54
tusscidin	54
zeroxin	54
benvlin	53
berman	53
curcumin	53
del-mycin	53
keftid	53
kerledex	53

paremyd	53
penbritin	53
perazine	53
peri-d.o.s.	53
predone	53
pridinol	53
puregon	53
teramine	53
ak-tracin	52
alkeran	52
atridine	52
cephadyn	52
cheratussin	52
cordon d	52
cosamin	52
crinone	52
daricon	52
(b) (4)	52
(b) (4)	52
fucidin	52
ael-tin	52
kanamycin	52
keratol	52
keri	52
klaron	52
klarist d	52
kolophrin	52
kurotok	52
Kurelek	52
neociain	52
permapen	52
pitressin	52
pre-pen	52
	52
	52
serevent	52
teargen	52
teorigen	52
tenormin	52
terazosin	52
teveten	52
triadine	52
tridione	52
verazinc	52
verelan	52
aerodine	51
	51
cresatin	51
dermoneen	51
eprident	51
errin	51

aaramikain	E 1
garamycin	51
giyumi	51
goserein	51
nencin	51
nyserpin	51
korlym	51
orbenin	51
peri-ds	51
(b) (4)	51
phloretin	51
prefrin	51
quelicin	51
serenus	51
spherulin	51
terazoosin	51
tylosin	51
verrugon	51
aerolin	50
alcortin	50
anergan	50
arbutin	50
bervllium	50
cardizem	50
catechin	50
cerefolin	50
cervidil	50
chorigon	50
coracten	50
convza_dm	50
crotan	50
dormabon	50
diugardin	50
duragan	50
duraten	50
duratan	50
duraxin	50
eczemin	50
e-mycin	50
eucardic	50
eumydrin	50
formadon	50
fragmin	50
(D) (4)	50
gelatin	50
herpid	50
hyrexin	50
kaolin	50
keepan	50
kerafoam	50
keralac	50
kerasal	50

keratex	50	
ketamine	50	
ketaved	50	
khellin	50	
klaricid iv	50	
korostatin	50	
leukeran	50	
melamin	50	
meperidine	50	
meridia	50	
meronem	50	
naringin	50	
oradent	50	
paredrine	50	
paromycin	50	
phenytoin	50	
polydine	50	
prodium	50	
pyocidin	50	
ry-tann	50	
serzone	50	
skelaxin	50	
sorbitan	50	
targretin	50	
terodiline	50	
tetracyn	50	
theramycin	50	
tilarin	50	
(b) (4)	50	
tridil	50	
tridrane	50	
udderdine	50	
vascardin	50	
viridium	50	
Low similarity: combined match percentage score <49%		
Names	Combined POCA Score	
kerol	<50	
ketoprofen	<50	

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

Our analysis of the 287 names contained in Table 1 determined 286 names will not pose a risk for confusion as described in Appendices C through F. However, the proposed name could be confused with Varidin.

Varidin is a multivitamin that can be found in the following databases: Red Book online and Facts and Comparison. Per the United States Patent and Trademark Office, the Varidin trademark was cancelled as of June 20, 2008. All this seems to indicate that the product is no longer manufactured and/or marketed. On January 9, 2014, DMEPA held a teleconference with

the Applicant to discuss the safety concerns regarding Varidin and their proposed name Kerydin. On January 16, 2014, the applicant submitted a general correspondence describing all efforts made to confirm that Varidin is no longer a marketed product; AC Nielsen sales data on multivitamin and nutritional supplements for the past 5 years, IMS Health data over the past 5 years, NDC Directory, several major retail and hospital pharmacies, and F&C unsuccessful efforts to confirm that the manufacturer is still in existence. Additionally, this general correspondence included copies of the letters submitted to Red Book and Facts and Comparisons requesting removal of the name Varidin from their databases.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Dermatology and Dental Products via email on January 8, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on January 14, 2014, they stated:

"We concur with your determination of acceptable with one provision from our Clinical team:

As long as OPDP has no issues with the obvious similarity to keratin, a protein that is a component of skin, hair and nails, I have no objections. There are a lot of OTC "keratin hair treatments" out there, most of which are not regulated."

We note that OPDP found the name acceptable from a promotional perspective and DMEPA evaluated the name Keratin in the safety assessment of the proposed name Kerydin.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 30, 2013 submission are altered, the name must be resubmitted for review.

4 **REFERENCES**

1. 1. 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).

Center for Biologic Evaluation and Research (CBER) Products

The CBER products Web-site contains most of the biologic products currently regulated by CBER. Many of the labels, approval letters, reviews, and other information are available for products approved from 1996 to the present (http://www.fda.gov/cber/products.htm).

Electronic online version of FDA's Orange Book

This Orange Book Web site provides a compilation of approved drug products with therapeutic equivalence evaluations (<u>http://www.fda.gov/cder/ob/default.htm</u>).

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#).

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

- 1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. 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.¹

	Affirmative answers to these questions indicate a potential area of
	concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other
	Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active
	Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

*Table 2- Prescreening Checklist for Proposed Proprietary Name

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:

¹ National Coordinating Council for Medication Error Reporting and Prevention. <u>http://www.nccmerp.org/aboutMedErrors.html</u>. Last accessed 10/11/2007.

- Highly similar pair: combined match percentage score \geq 70%.
- Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 49\%$.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).
- 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 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 (see Step 1 of the Moderately Similar Checklist).

	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?		

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 have a higher potential for confusion and should be evaluated further (see Step 2).
	For single strength products, also consider circumstances where the strength may not be expressed.
	For any combination drug products, 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 these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names <u>with</u> overlapping or similar strengths or doses.

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

1	
 Orthographic Checklist (Y/N to each question) Do the names begin with different first letters? 	 Phonetic Checklist (Y/N to each question) Do the names have different number of syllables?
 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? 	 Do the names have different syllabic stresses? Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
*FDA considers the length of names different if the names differ by two or more letters.	• Across a range of dialects, are the names consistently pronounced differently?
• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?	
• Is there different number or placement of cross-stroke or dotted letters present in the names?	
• Do the infixes of the name appear dissimilar when scripted?	
• Do the suffixes of the names appear dissimilar when scripted?	

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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Kerydin Study (Conducted on December 11, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:	Kerydin
N	Use as Directed
Kengton apply ance daily	Dispense #1
Outpatient Prescription:	
Kerydin Use an directel #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

As of Date 12/31/2013

192 People Received Study 61 People Responded

Study N	lame: Kerydin				
	Total	19	21	21	
	INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
	CARADEN	0	3	0	3
	CARADIN	0	6	0	6
	CAREDIN	0	1	0	1
	CARIDEN	0	3	0	3
	CARIDIN	0	1	0	1
	CARODIN	0	1	0	1
	KE	0	0	1	1
	KERADIN	0	1	0	1
	KERATIN	0	2	0	2
	KERGDIN	4	0	0	4
	KERGIN	1	0	0	1
	KERIDEN	0	2	0	2
	KERRADIN	0	1	0	1
	KERYDIN	14	0	2	16
	KERYLTIN	0	0	1	1
	KERYSIN	0	0	3	3
	KERYSIR	0	0	1	1
	KERYSIS	0	0	1	1
	KERYSKIN	0	0	1	1
	KERYTIN	0	0	10	10
	NUCALA	0	0	1	1

No.	Name	POCA Score
1.	Jeridin	74
2.	Erymin	70
3.	(b) (4) *** Name not found in Proposed Names List	69
4.	Karidium	68
5.	(b) (4) *** Name not found in Proposed Names List	68
6.	Ceradon	66
7.	Ceresin	66
8.	Doriden	66
9.	Eraldin	66
10.	Claradin	65
11.	Kefadim	64
12.	Sarenin	64
13.	Chrysin	63
14.	Iduridin	62
15.	Kloromin	62
16.	Trypsin	62
17.	Kemadrin	61
18.	Beldin	60
19.	Eridium	60
20.	Keracyanin	60
21.	Kerosene	60
22.	Kirwan	59
23.	Sarapin	59
24.	Tremin	59
25.	Biperiden	58
26.	(b) (4) *** Name found unacceptable for NDA (b) (4)	58
27.	Corwin	58
28.	Metrodin	58
29.	Orgadin	58
30.	Serutan	58
31.	Silybin	58

Appendix C: Names with unidentified product characteristics.

No.	Name	POCA Score
32.	Trexydin*** Name not found in Proposed Names List	58
33.	Cereflin	57
34.	Duradin	57
35.	Preludin	57
36.	Ser-A-Gen	57
37.	Suramin	57
38.	Uritin	57
39.	Aricin	56
40.	Curdlan	56
41.	Dermacin	56
42.	Geridium	56
43.	Hesperidin	56
44.	(b) (4) *** Name not found in Proposed Names List	56
45.	Operidine	56
46.	Otrivin	56
47.	Paraffin	56
48.	Piriton	56
49.	Tridane	56
50.	Uridon	56
51.	Eradacin	55
52.	Furacin	55
53.	Heroin	55
54.	Muricin	55
55.	Narasin	55
56.	Terbium	55
57.	Terramycin	55
58.	Uridine	55
59.	Urimin	55
<u>60</u> .	B-12 Resin	54
<u>61</u> .	Bepadin	54
62.	NDA $^{(b) (4)}$ approved under the name $^{(b) (4)}$	54
63.	C30-45 Olefin	54
64.	Cardinol	54

No.	Name	POCA Score
65	(b) (4) ***	54
	Name not found in Proposed Names List	
66.	Herbon	54
67.	Iridium	54
68.	Kafocin	54
69.	Kelferon	54
70.	(b) (4) *** Name found unacceptable. NDA the name (b) (4) was approved under	54
71.	Key-Pred	54
72.	Miradon	54
73.	Oxeladin	54
74.	Paroven	54
75.	Perestan	54
76.	Perisine	54
77.	Pertussin	54
78.	(b) (4) *** Name not found in Proposed Names List	54
79.	^{(b) (4)} *** Name not found in Proposed Names List	54
80.	Termene	54
81.	Triacin*** Name not found in Proposed Names List	54
82.	Triban	54
83.	Tritan	54
84.	Triveen	54
85.	Tusscidin	54
86.	Zeroxin	54
87.	Berman	53
88.	Benylin	53
89.	Curcumin	53
90.	Keftid	53
91.	Kerledex NDA 019807 was withdrawn FR effective 8/19/2013. No generic equivalents available.	53
92.	Perazine	53
93.	Peri-D.O.S.	53

No.	Name	POCA Score
94.	Pridinol	53
95.	Puregon	53
96.	Teramine	53
97.	Atridine	52
98.	Cephadyn Combination product that contains more than 325 mg (i.e. 650 mg) Acetaminophen per unit	52
99.	Cordon D	52
100.	Daricon NDA 011612 was withdrawn FR effective 09/22/1999. No generic equivalents available.	52
101.	NDA $(b) (4)$ status is Refuse to File as of $(b) (4)$.	52
102.	^{(b) (4)} *** Name not found in Proposed Names List	52
103.	Fucidin	52
104.	Gel-tin	52
105.	Kolephrin	52
106.	Kuretek	52
107.	Pitressin NDA 003402 was withdrawn FR effective 09/25/1998. No generic equivalents available.	52
108.	Quarzan NDA 010355 was withdrawn FR effective 09/25/1998. No generic equivalents available.	52
109.	(b) (4) *** Name not found in Proposed Names List	52
110.	Tedrigen	52
111.	Triadine	52
112.	Verazinc	52
113.	^{(b) (4)} *** Name not found in Proposed Names List	51
114.	Cresatin	51
115.	Dermoneen	51
116.	Eprident	51
117.	Glytrin	51
118.	Hyserpin NDA 010581 was withdrawn FR effective 08/07/1997. No generic equivalents available.	51
119.	Orbenin	51

No.	Name	POCA Score
120.	Peri-DS	51
121.	^{(b) (4)} *** Name not found in Proposed Names List	51
122.	Phloretin	51
123.	Prefrin	51
124.	Serenus	51
125.	Spherulin	51
126.	Terazoosin	51
127.	Tylosin	51
128.	Verrugon	51
129.	Aerolin	50
130.	Alcortin	50
131.	Arbutin	50
132.	Beryllium	50
133.	Catechin	50
134.	Chorigon	50
135.	Coracten	50
136.	Crotan	50
137.	Dermabon	50
138.	Diucardin ANDA 083383 was withdrawn FR effective 11/18/2004. No generic equivalents available.	50
139.	Duragen	50
140.	Duraxin	50
141.	Eczemin	50
142.	Eucardic	50
143.	Eumydrin	50
144.	^{(b) (4)} *** Name not found in Proposed Names List	50
145.	Gelatin	50
146.	Herpid	50
147.	Hyrexin	50
148.	Kaolin	50
149.	Keepan	50
150.	Keratex	50
151.	Ketaved	50

No.	Name	POCA Score
152.	Khellin	50
153.	Klaricid	50
154.	Korostatin	50
155.	Melamin	50
156.	Meridia NDA 020632 was withdrawn FR effective 12/21/2010. No generic equivalents available.	50
157.	Meronem	50
158.	Naringin	50
159.	Oradent	50
160.	Paredrine	50
161.	Paromycin	50
162.	Pyocidin ANDA 061606 was withdrawn FR effective 11/04/1996. No generic equivalents available.	50
163.	Sorbitan	50
164.	Terodiline	50
165.	Tetracyn ANDA 060082 was withdrawn FR effective 5/25/99. ANDAs 060095, 060096, and 060285 were withdrawn FR effective 3/7/97. No generic equivalents available.	50
166.	Tilarin	50
167.	(b) (4) *** Name not found in Proposed Names List	50
168.	Tridrane	50
169.	Udderdine	50
170.	Vascardin	50
171.	Viridium	50

Appendix D: Low Similarity Names (i.e., combined POCA score is <49%).

No.	Name	POCA Score
172.	Kerol	<50
173.	Ketoprofen	<50

<u>Appendix E:</u> Moderately Similar Names (i.e., combined POCA score is \geq 50% to \leq 69%) with no overlap in Strength and Dose.

No.	No. Proposed name: Kerydin Strength(s): 5%	
	Usual Dose: Apply once daily to affected nails for 48 weeks	
	(b) (4) ***	
174.	(Secondary name for NDA Primary name (b) (4) found conditionally acceptable)	64
	(b) (4) _{***}	
175.	(Name found conditionally acceptable for IND ^{(b) (4)})	63
176.	Cerubidin	60
177.	Coricidin	60
178.	Prandin	60
179.	Keflin	59
180.	Kerlone	59
181.	Agrylin	58
182.	Cardene	58
183.	Cordran	58
184.	Eryderm	58
185.	Kerodex	58
186.	Secretin	58
187.	Candin	57
188.	Carimune	56
189.	(Name found conditionally acceptable for NDA ^{(b) (4)} ; currently under review during the second review cycle for this NDA)	56
190.	Kao-tin	56
191.	Lepirudin	56
192.	Priftin	56

No.	Proposed name: Kerydin Strength(s): 5%	POCA Score
	Usual Dose: Apply once daily to affected nails for 48 weeks	
193.	Quercetin	56
194.	Naropin	55
195.	Ceprotin	54
196.	Eryped	54
197.	Periactin	54
198.	Pyridium	54
199.	Rifadin	54
200.	Torecan	54
201.	Penbritin	53
202.	Predone	53
203.	Cheratussin AC Cheratussin DAC	52
204.	Cosamin DS Cosamin ASU	52
205.	Crinone	52
206.	Kanamycin	52
207.	Klerist-D	52
208.	Teveten	52
209.	Verelan	52
210.	Goserelin	51
211.	Helicin	51
212.	Quelicin	51
213.	Cardizem	50
214.	Coryza-D Coryza-DM	50
215.	Duratan DM Duratan Forte Duratan PE	50
216.	E-mycin	50

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply once daily to affected nails for 48 weeks	POCA Score
217.	Fragmin	50
218.	Skelaxin	50

<u>Appendix F:</u> Moderately Similar Names (i.e., combined POCA score is \geq 50% to \leq 69%) with overlap in Strength and Dose.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
219.	Varidin (multivitamin) Dosage: One capsule orally daily.	69	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'V'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter 'y' that is not present in Varidin, which gives the names a different shape when scripted.Dose: Apply to affected nails or UAD vs. 1 capsule Other:Per USPTO the trademark for the name Varidin was cancelled as of June 20, 2008. The Applicant has requested that the name Varidin be removed from the Red Book online and Facts and Comparisons databases.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
220.	Ferrimin 150 (Iron) Tablets, 150 mg Dosage: 1 – 2 tablets orally daily (OTC)	66	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'F'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke ('y') and an up stroke ('d') that are not present in Ferrimin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.The first syllable begins with different consonant sounds ('F' is labio-dental fricative vs. 'K' is plosive velar).Same 2 nd syllable 'i'.Third syllable begins with different consonant sound ('m' is bilabial nasal vs. 'd' is alveolar plosive).Dose: Apply to affected nails or UAD vs. 1 tablet

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
221.	Terocin (Lidocaine and Menthol) Patch, 4%/4% Dosage: Apply patch to affected area 1 to 2 times daily. (Methyl Salicylate, Capsaicin, Menthol, and Lidocaine) Lotion, 25%/0.025%/10%2.50% Dosage: Gently rub over area of pain. Use is not recommended more than four times a day. (OTC)	65	Both products are single strength and may be used once daily	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke ('y') and an up stroke ('d') that are not present in Terocin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with a consonant plosive sound 'T' vs. 'K', followed by the same letter sting 'er'.Second syllable in both names is a single vowel sound 'ee' vs. 'o', which may sound similar when spoken. One participant in the voice study misinterpreted these sounds.Third syllable end in the same letter string 'in' and begin with the similar alveolar sounding letters 'd' (plosive alveolar) and 's' (fricative alveolar). Five participants in the voice study misinterpreted the 'd' sound for an 's' sound.Dosage Forms: Kerydin is available as a topical solution only vs. Terocin is available as a lotion or a patch and the prescription would need to include additional information to dispense the product.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
222.	Ketodan (Ketoconazole) Foam, 2% Dosage: Apply to affected area twice daily for 4 weeks	63	Both products are single strength and may be written as "apply to the affected area" or UAD.	Orthographic:Kerydin contains a down stroke letter ('y') that is not present in Ketodan, whereas Ketoday contains an additional up stroke letter 't' that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with the same sound 'Ke'. The ending sounds in the syllable (approximant 'r' vs. plosive 't') may sound different when spoken.Second syllable in both names is a single vowel sound 'ee' vs. 'o', which may sound similar when spoken. One participant in the voice study misinterpreted these sounds.Third syllable begin and end in the same letters 'd' and 'n'. The middle vowel sounds in the syllables 'a' vs. 'o' may sound different when spoken.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
223.	Claritin (Loratadine) Oral Solution, 5 mg/5 mL Dosage: 1-2 tsp orally daily Tablets, 10 mg Dosage: 1 tablet orally daily Chewable Tablets, 5 mg Dosage: Chew 1-2 tablets daily (OTC)	60	There is strength similarity between Kerydin 5% and Claritin 5 mg.	Orthographic:Kerydin contains a down stroke letter ('y') that is not present in Claritin, whereas Claritin contains an additional up stroke letter 'l' that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins and ends with the same sounds 'K' vs. 'C' and 'r'. There are reports of confusion with names that begin with these letters in ISMP's list of confused drug names. However, Claritin has the additional sound 'la' in the middle of the syllable.Same 2 nd syllable 'i'.The first consonant sounds in the syllables 'd' vs. 't' may sound similar when spoken as they are both plosive alveolar. Two participants in the voice study misinterpreted these sounds. Both syllables end in the same letters 'in'.Dose: Apply to affected nails or UAD vs. XX tablet or XX tsp or XX mL

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
224.	Dermatin (Clotrimazole) Cream, 1% Dosage: Apply to the affected area twice daily (OTC)	58	Both products are single strength and may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'D'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Dermatin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with a plosive sound 'K' vs. 'D', which may sound similar when spoken. Both syllables end in the same sound 'er'.Second syllable 'ee' vs. 'ma' sound different when spoken.The first consonant sounds in the syllables 'd' vs. 't' may sound similar when spoken as they are both plosive alveolar. Two participants in the voice study misinterpreted these sounds. Both syllables end in the same letters 'in'.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
225.	Karbinal ER (Carbinoxamine Maleate) Oral Suspension, 4 mg/5 mL Dosage: 3.75 to 20 mL every 12 hours	58	Both products are single strength.	Orthographic:Kerydin contains a down stroke letter ('y') that is not present in the root name Karbinal, whereas Karbinal contains an additional up stroke letter that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic:Both root names have 3 syllables.First syllable begins and ends with the same sound 'K' and 'r'. The middle vowel sound 'e' vs. 'a' may sound similar when spoken (voice study showed that 15/21 participants confused these sounds).Second syllable share the 'e' sound ('y' vs 'i'); however, Kar-bi-nal has an additional consonant sound 'b' at the beginning of the syllable.Third syllable share the 'n' sound in opposite positions ('-dyn' vs. 'nal') and the other sounds in the syllables are different ('d' and 'y' vs. 'a' and 'l').Dose: Apply to affected nails or UAD vs. XX mg or XX mL
No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
------	---	---------------	--	---
226.	Orfadin (Nitisinone) Capsules 2 mg, 5 mg, 10 mg Dosage: 1 to 2 mg/kg/day divided in two daily doses.	58	There is strength similarity between Kerydin 5% and Orfadin 5 mg.	Orthographic:Both names begin with different letters ('K' vs.'O'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Orfadin, whereas Orfadin contains an additional up stroke letter that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic: Both root names have 3 syllables.First syllable share the 'r' sound in different positions ('Ker-' vs. 'Orf-') and the other sounds in the syllables are different ('K' and 'e' vs. 'O' and 'f').Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds.Same third syllable 'din'.Dose: Apply to affected nails or UAD vs. XX mg or XX tabs

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
227.	Percodan (Oxycodone Hydrochloride and Aspirin) Tablets 4.8355 mg/325 mg Dosage: 1 tablet orally every 6 hours pm for pain	58	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Percodan, which gives the names a different shape when scripted.Phonetic:Both root names have 3 syllables.First syllable share the letters 'er' in the same position.Second syllable 'ee' vs. 'co' sound different when spoken.Third syllable begin and end in the same letters 'd' and 'n'. The middle vowel sounds in the syllables 'a' vs. 'o' may sound different when spoken.Dose: Apply to affected nails or UAD vs. 1 tab
228.	Prodrin (Isometheptene mucate, caffeine, and acetaminophen) Tablets, 65 mg/20 mg/325 mg Dosage: 1 to 2 tablets orally at once, followed by one tablet every hour until relief, up to 5 tablets within a 12 hour period.	58	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Prodrin, which gives the names a different shape when scripted.Phonetic: The names have different number of syllables (3 vs. 2).The first two syllables in Ker-y-din sound different than the first syllable in Pro-drin.The last syllables in the names share the same letters 'd, i, n', with Pro-drin having an additional 'r' sound.Dose: Apply to affected nails or UAD vs. XX tab

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
229.	Teldrin (Chlorpheniramine Maleate) Tablets, 4 mg Dosage: ¹ / ₂ to 1 tablet orally every 4 to 6 hours (OTC)	58	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Teldrin, whereas Teldrin contains an additional up stroke letter, which gives the names a different shape when scripted.Phonetic: The names have different number of syllables (3 vs. 2).The first two syllables in Ker-y-din sound different than the first syllable in Tel-drin.The last syllables in the names share the same letters 'd, i, n', with Pro-drin having an additional 'r' sound.Dose: Apply to affected nails or UAD vs. XX tab
230.	Kadian (Morphine Sulfate) Extended-release capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, and 200 mg Dosage:	57	There is strength similarity between Kerydin 5% and Kadian 50 mg.	Orthographic:Kerydin contains a down stroke letter ('y') that is not present in Teldrin, whereas Teldrin contains an additional up stroke letter, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.The first two sounds of the first syllable 'Ker' vs 'Kay' may sound similar when spoken. The ending sounds 'r' vs. 'y' sound different.The second syllables 'ee' vs. 'dee' share the same 'ee' sound. However, there is an additional consonant sound 'd' in Kay-di-an.The last syllables 'din' vs. 'an' share the same ending sound 'n'; however, the beginning sounds differ 'di' vs. 'a'.Dose: Apply to affected pails or UAD vs. XX tab

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
231.	Desirudin Recombinant For Injection, 15 mg Dosage: 1.7 mg to 15 mg subcutaneously every 12 hours, with initial dose up to 5 to 15 minutes prior to surgery.	56	Both products are single strength. There is strength similarity between Kerydin 5% and Desirudin 15 mg	Orthographic:Both names begin with different letters ('K' vs.'D'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Desirudin, which gives the names a different shape when scripted. Finally, Desirudin has 9 letters vs. 7 letters in Kerydin, which help differentiate the names when scripted.Phonetic: The names have different number of syllables (3 vs. 4).Both names begin with a plosive sound 'K' vs. 'D', which may sound similar when spoken.The last syllable in both names is the same ('din'). However, the first three syllables in Desirudin sound different than the corresponding first two syllables in Kerydin.Dose: Apply to affected nails or UAD vs. XX mg

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
232.	Desitin Maximum Strength (Zinc oxide) Paste, 40% Multi Purpose (Petrolatum) Ointement, 70.3% Rapid Relief (Zinc Oxide) Cream, 13% Dosage: Apply liberally as often as necessary, with each diaper change Soothing Rash Bath Treatment (Colloidal Oatmeal) Powder, 43% Dosage: Soak affected area for 15- 30 minutes as needed (OTC)	56	Both products may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'D'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Desitin, which gives the names a different shape when scripted.Phonetic:Both names have three syllables.The first syllable begins with a plosive sound 'K' vs. 'D', which may sound similar when spoken. However, there are no reports of confusion between those letter pairs. The vowel sound 'e' is the same. The last sound in the syllable 's' (fricative) vs. 'r' (approximant) are different.The second syllable in both names sound the same ('i' vs. 'y').The third syllables in the names sound similar ('tin' vs. 'din').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
233.	Ferotrin (Ascorbic Acid, Cyanocobalamin, Folic Acid, Iron, Liver Stomach Concentrate) Capsules, 75 mg/15 mcg/0.5 mg/ 110 mg/240mg Dosage: Once capsule orally daily	56	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'F'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke ('y') and an up stroke ('d') that are not present in Ferotin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.The first syllable begins with different consonant sounds ('F' is labio-dental fricative vs. 'K' is plosive velar). The ending sounds are the same ('er').Second syllable in both names is a single vowel sound 'ee' vs. 'o', which may sound similar when spoken. One participant in the voice study misinterpreted these sounds.The first consonant sounds in the syllables 'd' vs. 't' may sound similar when spoken as they are both plosive alveolar. Two participants in the voice study misinterpreted these sounds. Both syllables end in the same letters 'in'. However, Ferotrin contains an additional 'r' sound in the last syllable.Dose: Apply to affected nails or UAD vs. 1 capsule

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
234.	Kedbumin (Albumin (human)) Injection, 25% Dosage: 25 mg to 100 g intravenously. Preparation, dosage, and infusion rate adjusted to patient's requirement and indication.	56	There is strength similarity between Kerydin 5% and Kedbumin 25%.	Orthographic:Kerydin contains a down stroke letter ('y') that is not present in Kedbumin, whereas Kedbumin contains an additional up stroke letter that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with the same sound 'Ke'. The ending sounds in the syllable 'r' vs. 'd' may sound different when spoken.Second syllable 'bu' vs. 'ee' sounds are different.Third syllables begin with different sounding 'm' vs. 'd' and end in the same sound 'in'.Dose: Apply to affected nails or UAD vs. XX mg or XX g

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
	Keralyt (Salicylic Acid) Gel. 6%			Orthographic:
	Dosage: Apply to the affected area and occlude the area at night and rinse in the			Keralyt contains an additional up stroke letter that is not present in Kerydin, and the down stroke letter 'y' are in different positions, which give the names a different shape when scripted.
	morning. Shampoo, 6%		Both products are	<u>Phonetic:</u> Both names have 3 syllables.
0.25	Dosage:	56	single strength and may be written as "apply to the affected area" or UAD.	Same first syllable 'Ker'.
235.	As concentrated scalp therapy. Do not wet hair. Apply to affected area of the scalp and leave on for			Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds.
	5 minutes, gradually increasing time up to one hour. Rinse.			Third syllables in the names sound different when spoken ('din' vs. lyt') due to the different consonants around the common vowel sound in the middle
	As medicated snampoo. Wet hair, apply and massage into lather, leave on for several minutes and rinse.			the initiale.
				Orthographic:
	Klor Con			Kerydin contains a down stroke letter ('y') that is not present in Klor-Con, and the up stroke letters are in different positions, which give the names a different shape when scripted.
	(Potassium Chloride)			Phonetic:
236.	Powder for solution, 20 mEq	56	Both products are single strength.	The names have different number of syllables (3 vs. 2).
	Dosage: 1 packet orally 1 to 5 times daily after meals			First syllable begins and end with the same sound 'K' and 'r'. Klor-Con has an additional sound 'lo' in the middle of the syllable.
				The second and third syllable in Kerydin sound different to the ending syllable in Klor-Con.
				<u>Dose</u> : Apply to affected nails or UAD vs. 1 packet

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
237.	Perdiem (Sennosides) Tablets, 15 mg Dosage: 1-2 tablets orally twice daily. Maximum daily dose is 4 tablets orally twice daily (OTC)	56	Both products are single strength. There is strength similarity between Kerydin 5% and Perdiem 15 mg.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Perdiem, which gives the names a different shape when scripted.Phonetic: The names have different number of syllables (3 vs. 2).The first syllables share the sound '-er'.The second syllable in Ker-y-din is not present in Perdiem.The last syllables in the names share the same letters 'di', with Per-diem having an additional 'm' sound.Dose: Apply to affected nails or UAD vs. XX tab
238.	Veregen (Sinecatechins) Ointment, 15% Dosage: Apply three times per day to all external genital and perianal warts.	56	Both products are single strength and may be written as "apply to the affected area" or UAD. There is strength similarity between Kerydin 5% and Veregen 15%.	Orthographic: Both names begin with different letters ('K' vs. 'V'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter 'd' that is not present in Veregen, which gives the names a different shape when scripted. <u>Phonetic</u> : Both names have 3 syllables The first syllables share the sound '-er'. The second syllables are single vowel sounds 'y' vs. 'e', which may sound similar when spoken. The last syllables in the names share the ending letter 'n'. The initial sound 'g' vs. 'd' may sound different when spoken.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
239.	Arestin (Minocycline hydrochloride) Microspheres, 1 mg Dosage: Variable dose product, dependent on the size, shape, and number of pockets being treated by the oral health care provider.	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'A'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (Kineret vs. Amikin and K-Phos Neutral vs. Neutra-Phos-K). Kerydincontains a down stroke letter 'y' that is notpresent in Arestin, which gives the names adifferent shape when scripted.Phonetic:Both names have 3 syllables.First syllable has the same consonant endingsound 'r'. However, the beginning of thesyllables is different ('Ke' vs. 'A').The second syllables sound different whenspoken ('y' vs. 'es').The third syllables in the names sound similar('tin' vs. 'din').Setting of Use:Kerydin is for home use by the patient vs.Arestin is for use by healthcare professionalduring oral procedure.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
240.	Asendin (Amoxapine) Capsules, 25 mg, 50 mg, 100 mg, 150 mg Dosage: Initial dose of 25 mg – 50 mg orally bid or tid. Increase to a maximum dose of 300 – 600 mg/day in divided doses.	54	There is strength similarity between Kerydin 5% and Asendin 50 mg	Orthographic:Both names begin with different letters ('K' vs.'A'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (Kineret vs. Amikin and K-Phos Neutral vs. Neutra-Phos-K). Kerydincontains a down stroke letter 'y' that is notpresent in Asendin, which gives the names adifferent shape when scripted.Phonetic:Both names have 3 syllables.First and second syllables in the names sounddifferent when spoken('Ker-' vs. 'As-' and '-y-' vs. '-en-').Same 3 rd syllables.Dose:Apply to affected nails or UAD vs. XX caps orXX mg

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
241.	Baridium (Phenazopyridine Hydrochloride) Tablets, 97.2 mg Dosage: 100 to 200 mg orally three times daily. (OTC)	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'V'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter 'd' that is not present in Veregen, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllablesThe first syllables begin with different sounds ('B' vs. 'K') and share the similar ending sound ('-er' vs. 'ar').Same 2 nd syllable sound 'y' vs. 'i'.The last syllables in the names share the same letters 'di' and similar ending letter 'n'. However, Baridium has an additional letter 'u' in the middle of the syllable which sounds different when spoken.Dose: Apply to affected nails or UAD vs. XX tabs or XX mg

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
242.	Cortan (Prednisone) Tablets, 20 mg Dosage: 5 to 60 mg orally per day depending of disease OR 200 mg daily for a week followed by 80 mg every other day for 1 month	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'C'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names. Kerydin contains a downstroke letter ('y') that is not present in Cortan,which gives the names a different shape whenscripted.Phonetic:The names have different number of syllables (3vs. 2).First syllable begins and ends with the samesounds 'K' vs. 'C' and 'r'. There are reports ofconfusion with names that begin with theseletters in ISMP's list of confused drug names.The middle vowel sound of the syllable differbetween the names ('e' vs. 'o').Although the names end in the same letter 'n',the second syllable in Cortan sound differentthan the second and third syllables in Kerydin.Dose:Apply to affected nails or UAD vs.XX tablet or XX mg

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
243.	Dryphen (Acetaminophen, Chlorpheniramine, and Phenylephrine) Tablets, 325 mg/2 mg/5 mg Dosage: 2 tablets orally every 4 hours (OTC)	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'D'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Dryphen contains an additional down stroke letter that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).Both names begin with a plosive sound 'K' vs. 'D', which may sound similar when spoken. The ending sound 'eye' in 'Dry' is different than the corresponding sound 'ee' in Kerydin.The last syllables sound different when spoken ('phen' vs. 'din').Dose: Apply to affected nails or UAD vs. XX tabs
244.	Eribulin Mesylate Injection, 1 mg/2 mL Dosage: 1.4 mg/m ² intravenously over 2 to 5 minutes on Days 1 and 8 of a 21-day cycle.	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'E'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter that is not present in Eribulin, and there is an additional up stroke letter in Eribulin, which gives the names a different shape when scripted.Phonetic: The names have different number of syllables (3 vs. 4).Kerydin begins with a plosive sound 'k' that is not present in Eribulin. The following 'ery' vs. 'Eri' sounds in both names are similar.The ending syllables 'din' vs. 'lin' sound similar. However, the additional syllable 'bu' in Eribulin makes the names sound different when spoken.Dose: Apply to affected nails or UAD vs.XX mg

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
245.	Fergon (Ferrous gluconate) Tablets, 27 mg Dosage: 27 mg orally once daily during the last 2 trimesters (OTC)	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'F'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Fergon, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 4).The first syllable begins with different consonant sounds ('F' is labio-dental fricative vs. 'K' is plosive velar). The ending sounds are the same ('er').The second and third syllables in Kerydin sound different than the corresponding syllable in Fergon.Dose: Apply to affected nails or UAD vs. 1 tablet
246.	Kariva (Desogestrel/ethinyl estardiol and ethinyl estradiol) Tablets 0.15 mg/0.02 mg and 0.01 mg Dosage: One tablet orally daily	54	Both products are single strengths and may be written as UAD.	Orthographic: Kerydin contains an up stroke and down stroke letter that is not present in Kariva, which give the names a different shape when scripted. <u>Phonetic:</u> Both names have 3 syllables. Similar sounding first syllable ('Ker' vs. 'Kar'. Same 2 nd syllable ('y' vs. 'i'). The last syllables sound different when spoken ('din' vs. 'va').

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
247.	Neo-Fradin (Neomycin Sulfate) Oral Solution, 125 mg/5 mL Dosage: 4 to 12 grams orally per day in divided doses for 5- 6 days	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'N'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (K-Phos Neutral vs.Neutra-Phos-K) However, these confusions arelikely due to the use of the prefix, infix andsuffix but in different positions in the name.Kerydin contains a down stroke letter that is notpresent in Neo-Fradin, which gives the names adifferent shape when scripted. In addition,Kerydin has 7 letters vs. 9 letters in Neo-Fradin,and looks shorter when scripted.Phonetic:Both names have 3 syllables.The first syllables in the name sound differentwhen spoken ('Ker' vs. 'Neo').The second syllables in the names sounddifferent when spoken ('y' vs. 'fra').Same 3 rd syllable 'din'.Dose:Apply to affected nails or UAD vs.XX mg orxx mL
248.	Panretin (Alitretinoin) Gel, 0.1% Dosage: Apply 2 to 4 times daily to cutaneous KS lesions.	54	Both products are single strengths and may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter that is not present in Panretin, which gives the names a different shape when scripted.Phonetic: Both names have 3 syllables.The first two syllables within the names sound different when spoken ('Kery' vs. 'Panre').The last syllables sound similar when spoken ('din' vs. 'tin').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
249.	Seromycin (Cycloserine) Capsules, 250 mg Dosage: 250 mg to 500 mg orally twice daily	54	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'S'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Seromycin, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 9 letters in Seromycin, and looks shorter when scripted.Phonetic: The names have different number of syllables (3 vs. 4).The first syllables in the name begin with a different sound ('K' vs. 'S'), followed by the similar sounding 'er' letters.The middle portions of the names sound different when spoken ('y' vs. 'omy').The last syllable in both names may sound similar when spoken ('din' vs. 'cin').Dose: Apply to affected nails or UAD vs. XX mg or xx tabs

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
250.	Del-mycin (Erythromycin) Topical Solution, 2% Dosage: Apply to affected area twice daily.	53	Both products are single strengths and may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'D'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Desirudin, which gives the names a different shape when scripted. Finally, Desirudin has 9 letters vs. 7 letters in Kerydin, which help differentiate the names when scripted.Phonetic: Both names have 3 syllables.Both names begin with a plosive sound 'K' vs. 'D', which may sound similar when spoken, followed by the 'e' sound.The second syllables sound different when spoken ('ee' vs. 'meye').The last syllable in both names may sound similar when spoken ('din' vs. 'cin').

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
251.	Paremyd (Hydroxyamphetamine hydrobromide, tropicamide) Ophthalmic Solution, 1%/0.25% Dosage: Instill 1 to 2 drops in the conjunctival sac 15 minutes before diagnostic procedure.	53	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Although both names contain the down stroke and up stroke letters 'yd', they are in different positions within the names, which give them a different shape when scripted.Phonetic:Both names have 3 syllables.The first syllables begin with a different sounding plosive consonant ('K' vs. 'P') and share the ending sound 'r'. The vowel sounds 'e' vs. 'a' may sound similar when spoken.The second syllables in the names may sound different when spoken ('ee' vs. 'e').The last syllables in the names share the middle vowel sound 'i' vs. 'y', but the beginning and ending sounds are different ('d' vs. 'm' and 'n' vs. 'd').
252.	Ak-tracin (Bacitracin) Ophthalmic Ointment, 500 Units/g Dosage: Apply a thin film to the conjunctiva of the affected eye(s) every 3 to 4 hours for 7 to 10 days	52	Both products are single strength.	Orthographic: Both names begin with different letters ('K' vs. 'A'). There are reports of confusion with names that begin with these letters in ISMP's list of confused drug names (Kineret vs. Amikin). Kerydin contains a down stroke letter 'y' that is not present in Ak-tracin, and there is an additional up stroke letter in Ak-tracin, which gives the names a different shape when scripted. <u>Phonetic</u> : Both names have 3 syllables. First syllables share the 'k' sound, but in opposite positions ('Ker' vs. 'Ak'). Second syllables sound different when spoken ('y' vs. 'tra'). Third syllables sound similar when spoken ('din' vs. 'cin').

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
253.	Alkeran (Melphalan) Tablets, 2 mg Dosage: 2 to 6 mg orally daily OR 0.2 mg/kg daily for 5 days	52	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'A'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (Kineret vs. Amikin and K-Phos Neutral vs. Neutra-Phos-K). Kerydincontains a down stroke letter 'y' that is notpresent in Alkeran, and there in an additional upstroke letter in Alkeran, which gives the names adifferent shape when scripted.Phonetic:Both names have 3 syllables.First syllables share the 'k' sound, but inopposite positions ('Ker' vs. 'Alk').Second syllables sound different when spoken('y' vs. 'er').Third syllables share the ending sound 'n' butdiffer in the beginning sound ('din' vs. 'an').Dose:Apply to affected nails or UAD vs.XX tablets or XX mg
254.	Keratol 45 Cream (Urea) 45% Keratol 45 Nail Gel (Urea) 45% Dosage: Apply to affected skin or nail twice per day.	52	Both products are single strength and may be written as "apply to the affected area" or UAD. There is strength similarity between Kerydin 5% and Keratol 45%.	Orthographic:Keralyt contains an additional up stroke letterthat is not present in Kerydin, and Kerydin has adown stroke letter not present in Keralyt, whichgive the names a different shape when scripted.Phonetic:Both names have 3 syllables.Same first syllable 'Ker'.Second syllable are single vowel sounds 'ee' vs'a' may sound similar when spoken. Thirteenparticipants in the voice study misinterpretedthese sounds.Third syllables in the names sound differentwhen spoken ('din' vs. tol').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these
	for 48 weeks			two names
255.	Keri Keri Original Keri Advanced Keri Shea Butter Keri Basic Essentials Over-the-counter product line of skin moisturizers Dosage: Apply all over the body daily.	52	Both products may be written as UAD.	Orthographic: Kerydin contains an up stroke and down stroke letter that is not present in Keri, which give the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 4 letters in Keri, which makes it look longer when scripted. <u>Phonetic:</u> The names have different number of syllables (3 vs. 2). Same first and second syllables ('Kery' vs. 'Keri'). Kerydin has an additional ending syllable that makes the names sound different when spoken ('din').
256.	Klaron (Sulfacetamide sodium) Lotion, 10% Dosage: Apply a thin film to the affected areas twice daily.	52	Both products are single strength and may be written as "apply to the affected area" or UAD.	<u>Orthographic:</u> Kerydin contains a down stroke letter that is not present in Klaron and the position of the up stroke letters within the names ('d' vs. 'l') is different, which give the names a different shape when scripted. <u>Phonetic:</u> The names have different number of syllables (3 vs. 2). The names share the same sounding letters 'K', 'r', and 'n'. However, the remaining sounds are different and Kerydin has an additional syllable ('din').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
257.	Neocidin (Neomycin sulfate, Polymyxin b sulfate, and bacitracin zinc) Ophthalmic Ointment, 3.5 mg/10,000 Units/400 Units Dosage: Apply into the affected eye every 3 or 4 hours for 7 to 10 days Neocidin (Neomycin sulfate, Polymyxin b sulfate, and Garamycin) Ophthalmic Solution, 1.75 mg/10,000 Units/ 0.025 mg Dosage: Instill 1 – 2 drops into the affected eye every 4 hours for 7-10 days.	52	Both products are single strength and may be written as UAD.	Orthographic:Both names begin with different letters ('K' vs.'N'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (K-Phos Neutral vs.Neutra-Phos-K). However, these confusions arelikely due to the use of the prefix, infix andsuffix but in different positions in the name.Kerydin contains a down stroke letter that is notpresent in Neocidin, which gives the names adifferent shape when scripted.Phonetic:Both names have 3 syllables.The first syllables in the name sound differentwhen spoken ('Ker' vs. 'Neo').The second syllables in the names share thesound 'y' vs. 'i', but Neocidin contain anadditional 's' sound in 'ci'.Same 3 rd syllable 'din'.Dosage Forms:Kerydin is available as a topical solution only vs.Neocin is available as ophthalmic ointment andophthalmic solution (with a differing activeingredient) and the prescription would need toinclude additional information to dispense thecorrect product.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
258.	Permapen (Penicillin G Benzathine) Injection, 1,200,000 Units Dosage: Single 900,000 or 1,200,000 Units by deep IM injection OR 2.4 million Units OR 3 million units at 7 day intervals OR 50,000 units/kg	52	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Permapen, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.The first syllables share the letters 'er'.The second syllables in the names sound different when spoken ('y' vs. 'ma').The last syllables in the names share the similar sounding letter 'in' vs. 'en', but they begin with different sounding letters ('d' vs. 'p').Dose: Apply to affected nails or UAD vs. XX Units

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
259.	Pre-pen (Benzylpenicilloyl polylsine) Injection, 6.0 X 10 ⁵ M Dosage: Perform skin test antigen intradermally following procedure OR by 'puncture testing'.	52	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Pre-pen, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).The first syllables share the letters 'e' and 'r' in alternate positions ('Ker' vs. 'Pre').The last syllables in the names share the similar sounding letter 'in' vs. 'en', but they begin with different sounding letters ('d' vs. 'p').Finally, Kerydin has an additional syllable 'y' that makes the name sound different when spoken.Setting of Use:Kerydin is for home use by the patient vs. Pre- pen is for use by healthcare professional during skin testing procedure for assessment of penicillin hypersensitivity.
260.	Serevent Diskus (Salmeterol Xinafolate) Inhalation Powder, 50 mcg Dosage: 1 oral inhalation twice daily OR 1 oral inhalation 30 minutes before exercise.	52	Both products are single strength. Both products may be written for UAD. There is strength similarity between Kerydin 5% and Serevent Diskus 50 mcg.	Orthographic:Both root names begin with different letters ('K'vs. 'S'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter that is not present in Serevent, which gives the names a different shape when scripted.Phonetic:Both root names have 3 syllables.The first syllables in the name begin with a different sound ('K' vs. 'S'), followed by the similar sounding 'er' letters.The middle and ending portions of the names sound different when spoken ('ydin' vs. 'event').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
261.	Teargen Eye Drops (Polyvinyl Alcohol) Ophthalmic Solution, 1.4% Dosage: Instill 1—2 drops into the affected eye(s) two to four times per day as needed (OTC)	52	Both products are single strength and may be written as UAD.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke that is not present in Teargen, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'r' sound at the end of the syllable.The last syllables in the names share a similar sounding ending ('in' vs. 'en'). However, the initial letters 'g' vs. 'd' may sound different when spoken. In addition, Kerydin has an additionl syllable in the middle of the name ('y') that makes the names sound different when spoken

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
262.	Tenormin (Atenolol) Tablets, 25 mg, 50 mg, 100 mg Dosage: 25 mg to 100 mg orally once daily	52	There is strength similarity between Kerydin 5% and Tenormin 25 mg and 50 mg.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke and a down stroke letter that are not present in Tenormin, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'e' sounds.Second syllables in the names sound different when spoken ('y' vs. 'or').Although the third syllables in the names share the ending sound ('in'), they a preceded by a different sounding consonant ('d' vs. 'm').Dose: Apply to affected nails or UAD vs. XX tablets or XX mg

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
263.	Terazosin Hydrochloride Capsules, 1 mg, 2 mg, 5 mg, 10 mg Dosage: Initial dose of 1 mg at bedtime. Increase dose up to 20 mg daily.	52	There is numerical overlap in strength between Keradyn 5% and Terazosin 5 mg.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Terazosin, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 9 letters in Terazosin, which makes it look shorter when scripted.Phonetic: The names have different number of syllables (3 vs. 4).First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'er' sounds.Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds.Last syllables in the names may sound similar ('din' vs. 'sin'). However, Terazosin and an additional syllable ('zo') in the middle of the name that make the names sound different when spoken.Dose: Apply to affected nails or UAD vs. XX tablets or XX mg

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
264.	Tridione (Trimethadione) Chewable Tablets, 150 mg Dosage: 150 mg to 600 mg orally 3 or 4 times daily	52	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke that is not present in Tridione, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'r' sound in different positions.Second syllable share the same sound ('y' vs. 'i'), but in Tridione it is preceded by an additional plosive consonant sound 'd'.Third syllable share the letter 'n' but sound different when spoken ('din' vs. 'on').Dose: Apply to affected nails or UAD vs. XX tablets or XX mg

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
265.	Aerodine (Povidone-Iodine) Topical Solution, 10% Dosage: Apply a small amount topically to affected area 1 to 3 times daily (OTC)	51	Both products are single strength and may be written as "apply to the affected area" or UAD.	Orthographic: Both names begin with different letters ('K' vs. 'A'). There are reports of confusion with names that begin with these letters in ISMP's list of confused drug names (Kineret vs. Amikin and K- Phos Neutral vs. Neutra-Phos-K). Kerydin contains a down stroke letter 'y' that is not present in Aerodine, which gives the names a different shape when scripted. <u>Phonetic</u> : Both names have 3 syllables. First syllables begin with a different sound ('a' vs. 'k'), but end in the same sound 'er'.l Second syllable in both names is a single vowel sound 'ee' vs. 'o', which may sound similar when spoken. One participant in the voice study misinterpreted these sounds. Third syllables sound similar when spoken ('din' vs. 'dine').
266.	Errin (Norethindrone) Tablets, 0.35 mg Dosage: 1 tablet orally daily	51	Both products are single strength and may be written as UAD.	Orthographic:Both names begin with different letters ('K' vs.'E'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke and an up stroke letter that is not present in Errin, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 5 letters in Errin, and looks longer when scripted.Phonetic: The names have different number of syllables (3 vs. 2).Kerydin begins with a plosive sound 'k' that is not present in Errin. The following 'ery' vs. 'Erri' sounds in both names are similar.The ending syllables 'din' vs. 'in' sound similar. However, the additional syllable 'y' in Kerydin makes the names sound different when spoken.

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
267.	Garamycin (Gentamycin sulfate) Ophthalmic Ointment, 3 mg Dosage: Apply a small amount to the affected eye 2 to 3 times a day. Ophthalmic Solution, 0.3% Dosage: Instill one or two drops every 4 hours into the affected eye	51	Both products are single strength and may be written as UAD.	Orthographic:Both names begin with different letters ('K' vs.'G'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Garamycin, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 9 letters in Garamycin, which makes it look shorter when scripted.Phonetic:The names have different number of syllables (3 vs. 4).Kerydin begins with a plosive sound 'k' that is not present in Garamycin. The first syllables 'Ker' vs. 'Ga' sound different when spoken.The middle syllables in the names ('y' vs. 'ra- my') sound different when spoken.The ending syllables 'din' vs. 'cin' sound similar.
268.	Korlym (Mifepristone) Tablets, 300 mg Dosage: 300 to 1,200 mg orally once daily	51	Both products are single strength.	Orthographic:Although both names have an up stroke and down stroke letter, the positions are inverted ('yd' vs. 'ly'), which gives the name a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).Similar sounding first syllables ('Ker' vs. 'Kor').Although the ending syllables ('din' vs. 'lym') sound similar, Kerydin has an additionl syllable in the middle of the name ('y') that makes the names sound different when spoken.Dose: Apply to affected nails or UAD vs. XX tablets or XX mg

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
269.	Anergan (Promethazine Hydrochloride) Injection, 50 mg/mL Dosage: 12.5 - 50 mg IM or IV every 4 - 6 hours as needed OR 0.25 – 1 mg/kg IM or IV	50	Both products are single strength. There is strength similarity between Kerydin 5% and Anergan 50 mg/mL	Orthographic:Both names begin with different letters ('K' vs.'A'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (Kineret vs. Amikin and K-Phos Neutral vs. Neutra-Phos-K). Kerydincontains an up stroke letter that is not present inAnergan, which gives the names a differentshape when scripted.Phonetic:Both names have 3 syllables.First syllables do not have any sounds incommon ('Ker' vs. 'An').Second syllables sound different when spoken('y' vs. 'er').Third syllables share the ending sound 'n' butdiffer in the beginning sound ('din' vs. 'gan').Dose:Apply to affected nails or UAD vs. XX mg
270.	Cerefolin (Cyanocobalamin, Levomefolate, Pyridoxine, Riboflavin) Tablets, 1 mg/5.635 mg/ 50 mg/5mg Dosage: 1 tablet orally daily	50	Both products are single strength and may be written as UAD.	Orthographic:Both names begin with different letters ('K' vs.'C'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names. Kerydin contains a downstroke letter ('y') that is not present in Cerefolin,and there is an additional up stroke letter inCerefolin, which gives the names a differentshape when scripted.Phonetic:The names have different number of syllables (3vs. 4).First syllable begins with a different sounds ('K'vs. 'S'). The ending of the syllables are the same('er').The second syllables are vowel sounding 'y' vs.'e', which may sound similar when spoken.Although both names end in similar soundingsyllables ('din' vs. 'lin'). The additional syllable'fo' in Cerefolin help differentiate the names.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
271.	Cervidil (Dinoprostone) Vaginal Insert, 10 mg Dosage: Place one vaginal insert transversely in the posterior fornix of the vagina. Remove upon onset of active labor or 12 hours after insertion.	50	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'C'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names. Kerydin contains a downstroke letter ('y') that is not present in Cervidil,and there is an additional up stroke letter inCerevidil, which gives the names a differentshape when scripted.Phonetic:Both names have 3 syllables.First syllable begins with a different sounds ('K'vs. 'S'). The ending of the syllables are the same('er').The second syllables share the vowel soundingletters 'y' vs. 'i', but Cervidil has an additionalsound 'v' in the syllable.Although the third syllables begin with the samesound 'di', they end with different sounds ('n' vs.'I').Setting of Use:Kerydin is for home use by the patient vs.Arestin is for use by healthcare professionalduring oral procedure.

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5%			In the conditions outlined below, the following
	Usual Dose: Apply to affected nails once daily for 48 weeks			combination of factors, are expected to minimize the risk of confusion between these two names
				Orthographic:
Formadon (Formaldehyde) Sol 10% 272. Dosage: Apply to feet twice weekly.	Formadon		Both products are single strength and may be written as "apply to the affected area' or UAD.	Both names begin with different letters ('K' vs. 'F'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter that is not present in Formadon, which gives the names a different shape when scripted.
	10%			Phonetic:
	Dosage: Apply to feet twice weekly.	50		Both names have 3 syllables.
				The first syllable begins with different consonant sounds ('F' is labio-dental fricative vs. 'K' is plosive velar). The ending sounds are similar ('er' vs. 'or').
				The second syllables in the name sound different when spoken ('y' vs. 'ma').
				The third syllables begin and end with the same sounds ('d' and 'n'), but the vowel sound in the middle is different ('i' vs. 'o').
				Orthographic:
				Keradyn contains a down stroke letter that is not present in Kerafoam, which give the names a different shape when scripted.
	Kerafoam		Both products are	Phonetic:
	(Urea) Foam, 30%		single strength and	Both names have 3 syllables.
273.	Dosage:	50	may be written as "apply to the affected	Same first syllable 'Ker'.
	Apply to affected area twice daily.		area' or UAD.	Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds.
				Third syllables in the names sound different when spoken ('din' vs. 'foam').

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
274.	Keralac (Urea) Topical Solution, 50% Cream, 50% Dosage: Apply to affected area twice daily.	50	Both products are single strength and may be written as "apply to the affected area' or UAD. There is strength similarity between Kerydin 5% and Keralac 50%	Orthographic: Keradyn contains a down stroke letter that is not present in Keralac, which give the names a different shape when scripted. Phonetic: Both names have 3 syllables. Same first syllable 'Ker'. Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds. Third syllables in the names sound different
275.	Kerasal (Natural Menthol) Lotion, 8.5% Dosage: Roll onto affected area no more than four times daily (OTC)	50	Both products are single strength and may be written as "apply to the affected area' or UAD.	Orthographic: Keradyn contains a down stroke letter that is not present in Kerasal and the position of the up stroke letters differ, which give the names a different shape when scripted. Phonetic: Both names have 3 syllables. Same first syllable 'Ker'. Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds. Third syllables in the names sound different when spoken ('din' vs. 'sal').

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
276.	Ketamine Hydrochloride Injection, 500 mg/10 mL Dosage: 1 to 4.5 mg/kg intravenously OR 6.5 to 13 mg/kg intramuscularly	50	Both products are single strength.	Orthographic:Keradyn contains a down stroke letter that is not present in Ketamine and the position of the up strokes letters differ, which give the names a different shape when scripted.Phonetic:Both names have 3 syllables.Similar sounding first syllables ('Ker' vs. 'Ket').Second syllable are single vowel sounds 'ee' vs 'a' may sound similar when spoken. Thirteen participants in the voice study misinterpreted these sounds.Although the third syllables in the names share the ending sound ('in' vs. 'ine'), they a preceded by a different sounding consonant ('d' vs. 'm').Dose: Apply to affected nails or UAD vs. XX mg
277.	Leukeran (Chlorambucil) Tablets, 2 mg Dosage: 2 to 10 mg orally daily	50	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'L'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter that is not present in Leukeran, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllables.The first syllables begin and end with different sounds ('K' vs. 'L' and 'r' vs. 'u'). The middle vowel sound 'e' may sound similar when spoken.The second syllables in the name sound different when spoken ('y' vs. 'ke').The third syllables end with the same sounds ('n'), but the beginning part sound different when spoken ('di' vs. 'ra').Dose: Apply to affected nails or UAD vs. XX mg or XX tabs

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
278.	Meperidine Hydrochloride Tablets, 50 mg, 100 mg Dosage: 50 mg to 150 mg orally every 3 or 4 hours as needed OR 1.1 to 1.8 mg/kg orally every 3 or 4 hours	50	There is strength similarity between Kerydin 5% and Meperidine 50 mg.	Orthographic:Both names begin with different letters ('K' vs.'M'). There are reports of confusion with namesthat begin with these letters in ISMP's list ofconfused drug names (Ketorolac vs. Methadone).Kerydin has 7 letters vs. 10 letters in Meperidine,which makes the name look shorter whenscripted.Phonetic:The names have different number of syllables (3vs. 4).The first syllable begins with different consonantsounds ('K' vs. 'M'), followed by the same 'e'sound.The second and third syllables in Meperidineshare the same sounds 'eri' with Kerydine, buthave an additional plosive 'p' sound that is notpresent in Kerydine.The last syllables have the same sound ('din' vs.<'dine').
No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
------	---	---------------	--	---
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
279.	Phenytoin Sodium Extended-release Capsules, 100 mg Dosage: 100 mg orally three times daily OR 300 mg orally once daily OR 5 mg/kg/day in 2 or 3 divided doses Injection, 100 mg/2 mL Dosage: Loading dose of 50 mg per minute intravenously OR 1-3 mg/kg/min OR 10-15 mg/kg intravenously	50	Both products are single strength.	Orthographic:Both root names begin with different letters ('K'vs. 'P'). There are no reports of confusion withnames that begin with these letters in ISMP's listof confused drug names. Phenytoin contains anadditional up stroke letter ('h') that is not presentin Kerydin, which gives the names a differentshape when scripted. Kerydin has 7 letters vs. 9letters in Pheytoin, which makes the name lookshorter when scripted.Phonetic:Both names have 3 syllables.The first syllables share the middle sound 'e',with different beginning and ending sounds ('K'vs. 'Ph' and 'r' vs. 'n').Same sounding 2 nd syllable 'y'.The last syllables may sound different whenspoken ('din' vs. 'toin').Dose:Apply to affected nails or UAD vs. XX caps orXX mg
280.	Polydine (Povidone-Iodine) Topical Solution, 10% Dosage: Apply a small amount topically to affected area 1 to 3 times daily (OTC)	50	Both products are single strength and may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Polydine contains an additional up stroke letter ('1') that is not present in Kerydin, which gives the names a different shape when scripted.Phonetic: Both names have 3 syllables.The first syllables sound different when spoken ('Ker' vs. 'Pol').Same sounding 2 nd syllable 'y'.The last syllables may sound different when spoken ('din' vs. 'dain').

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
281.	Prodium (Phenazopyridine Hydrochloride) Tablets, 95 mg Dosage: 100 to 200 mg orally three times daily. (OTC)	50	Both products are single strength. There is strength similarity between Kerydin 5% and Prodium 95 mg.	Orthographic:Both names begin with different letters ('K' vs.'P'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke letter ('y') that is not present in Prodium, which gives the names a different shape when scripted.Phonetic: The names have different number of syllables (3 vs. 2).The first two syllables in Ker-y-din sound different than the first syllable in Pro-dium.The last syllables in the names share the same letters 'di', and similar letters 'n' vs. 'm'; however, Pro-dium has an additional 'u' sound.Dose: Apply to affected nails or UAD vs. XX tab or XX mg
282.	Ry-tann (Chlorpheniramine tannate, Phenylephrine tannate) Tablets, 9 mg/25 mg Dosage: 1 – 2 orally every 12 hours	50	Both products are single strength.	Orthographic:Both names begin with different letters ('K' vs.'R'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. The location of the down stroke and up stroke letters in the names are different, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).The first syllables sound different when spoken ('Ker' vs. 'Ry').The second and third syllables in Kerydin sound different than the corresponding second syllable in Ry-tann ('ydin' vs. 'tann')The last syllables have the same sound ('din' vs. 'dine').Dose: Apply to affected nails or UAD vs. XX tabs

No.	Proposed name: Kerydin	POCA Score	Overlap in strength and/or Dose	Prevention of Failure Mode
	Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks			In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
283.	Serzone (Nefazodone Hydrochloride) Tablets, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg, 300 mg Dosage: 50 – 300 mg orally twice daily	50	There is strength similarity between Kerydin 5% and Serzone 50 mg.	Orthographic:Both names begin with different letters ('K' vs.'S'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains an up stroke letter that is not present in Serzone, which gives the names a different shape when scripted.Phonetic:Both names have 3 syllablesThe first syllables in the name begin with a different sound ('K' vs. 'S'), followed by the similar sounding 'er' letters.The second syllables in the names sound different when spoken ('y' vs. 'zo).The last syllables in the names sound different when spoken ('din' vs. 'ne').Dose: Apply to affected nails or UAD vs. XX mg or xx tabs
284.	Targretin (Bexarotene)Capsules, 75 mgDosage:300 mg to 750 mg orally dailyGel, 1%Dosage:Apply to cover the lesion once every other day for the first week. Increase application frequency at weekly intervals to once daily, then twice daily, then three times daily and finally four times daily.	50	There is strength similarity between Kerydin 5% and Targretin 75 mg. Both products may be written as "apply to the affected area" or UAD.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. The positions of the up stroke and down stroke letters within the names ('yd' vs. 'gret') are different, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 9 letters in Targretin, which makes it look shorter when scripted.Phonetic: Both names have 3 syllables.First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'r' sounds.The middle syllables in the names ('y' vs. 'gre') sound different when spoken.The ending syllables 'din' vs. 'tin' sound similar.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
285.	Theramycin Z (Erythromycin) Topical Solution, 2% Dosage: Apply to affected area twice daily.	50	Both products are single strengths and may be written as "apply to the affected area" or UAD.	Orthographic:Both root names begin with different letters ('K' vs. 'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. The positions of the up stroke letters within the names ('d' vs. 'h') are different, which gives the names a different shape when scripted. In addition, Kerydin has 7 letters vs. 10 letters in Theramycin, which makes it look shorter when scripted.Phonetic: The names have different number of syllables (3 vs. 4).First syllable share the 'er' sounds. The middle syllables in the names ('y' vs. 'ra- my') sound different when spoken.The ending syllables 'din' vs. 'cin' sound similar.

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Overlap in strength and/or Dose	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
286.	Tridil (Nitroglycerin) Injection, 5 mg/mL Dosage: 5 – 100 mcg/minute IV infusion OR 0.25 – 3 mcg/kg/min by IV infusion	50	Both products are single strength. There is numerical overlap in strength between Kerydin 5% and Tridil 5 mg/mL.	Orthographic:Both names begin with different letters ('K' vs.'T'). There are no reports of confusion with names that begin with these letters in ISMP's list of confused drug names. Kerydin contains a down stroke that is not present in Tridil, and there is an additional up stroke letter in Tridil, which gives the names a different shape when scripted.Phonetic:The names have different number of syllables (3 vs. 2).First syllable begins with a consonant plosive sound 'T' vs. 'K', and share the 'r' sound in a different position within the syllables. The 'e' sound in the middle of the syllable in Kerydin, make the names sound different when spoken.The last syllables in the names share the initial sound ('di'). However, the ending letters sound different when spoken ('n' vs. 'l').Dose: Apply to affected nails or UAD vs. XX mg

<u>Appendix G:</u> Highly Similar Names (i.e., combined POCA score is ≥70%).

No.	Proposed name: Kerydin Strength(s): 5% Usual Dose: Apply to affected nails once daily for 48 weeks	POCA Score	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
287.	Kerydin	100	Name under review

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

/s/

CARLOS M MENA-GRILLASCA 01/17/2014

LUBNA A MERCHANT 01/17/2014