CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206143Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	September 22, 2014
Application Type and Number:	NDA 206143
Product Name and Strength:	Corlanor (ivabradine) Tablets, 5 mg and 7.5 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Amgen
Submission Date:	June 27, 2014
Panorama #:	2014-25714
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the June 27, 2014 proprietary name submission.

- Intended Pronunciation: core' lan ore
- Active Ingredient: Ivabradine
- Indication of Use: To reduce the risk of [redacted] (b) (4) hospitalizations for worsening heart failure in patients with chronic heart failure [redacted] (b) (4) in sinus rhythm with heart rate ≥ 70 bpm, [redacted] (b) (4) including maximally tolerated doses of beta blockers, or when beta blocker therapy is contraindicated [redacted] (b) (4).
- Route of Administration: Oral
- Dosage Form: Film-coated tablets
- Strength: 5 mg and 7.5 mg
- Dose and Frequency: 1 tablet twice daily with food. [redacted] (b) (4) Maximum daily dose is 15 mg.
- How Supplied: 30-day and 90-day supply bottles [redacted] (b) (4)
- Storage: Store at or below 30˚C
- Container and Closure Systems: High Density Polyethylene Bottles with 2-piece foil induction seal and a [redacted] (b) (4) closure. [redacted] (b) (4).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) 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

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Corlanor, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

One hundred one practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. The most common verbal misinterpretations included mistaking the 'Cor' for 'Kor' and the 'nor' for 'ndor', 'nore', and 'nur'. The most common written misinterpretation was the 'nor' being mistaken for 'non', 'ner', 'ver', and 'vor'. Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 14, 2014 e-mail, the Division of Cardiovascular and Renal Products (DCRP) forwarded the following comments relating to the proposed proprietary name at the initial phase of the review:

1. The name is reminiscent of Cordarone.
2. The "lano" mid-section of this name might suggest to someone that this is a cardiac-lanoxin preparation (cor-lano(r)).

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation and by (b) (4) Proprietary Name Safety Summary.

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[1]USAN stem search conducted on July 17, 2014.

[2] POCA search conducted on August 1, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	213
Low similarity name pair: combined match percentage score ≤49%	5

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

Our analysis of the 219 names contained in Table 1 determined 219 names would not pose a risk for confusion as described in Appendices C through G.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on September 5, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DCRP on September 10, 2014, they stated no additional concerns with the proposed proprietary name, Corlanor.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Cherye Milburn, OSE project manager, at 301-796-2084.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 27, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

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

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

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

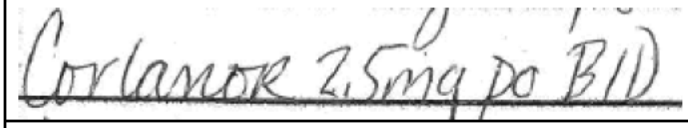
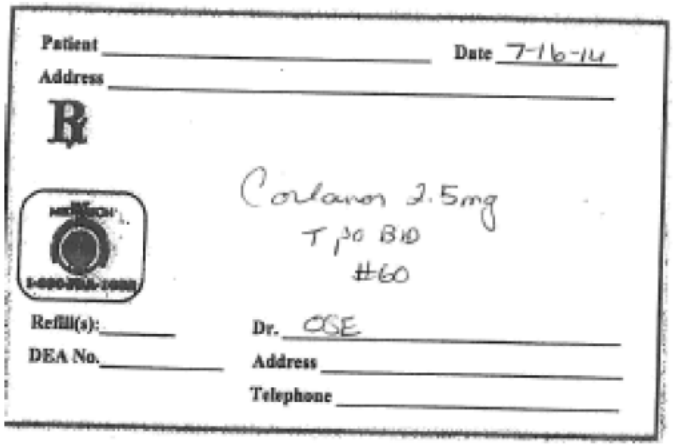
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Corlanor Study (Conducted on July 17, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Corlanor 2.5 mg One tablet BID Dispense # 60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

264 People Received Study
101 People Responded

Study Name: Corlanor

Total	37	30	34	
	OUTPATIENT	VOICE	INPATIENT	TOTAL
CLORANOR	0	0	1	1
COLAVER	1	0	0	1
CORELANORE	0	1	0	1
CORLAMOR	0	0	1	1
CORLANDOR	0	1	0	1
CORLANER	1	0	1	2
CORLANON	4	0	0	4
CORLANOR	26	23	31	80
CORLANUR	0	1	0	1
CORLAVEN	1	0	0	1
CORLAVOR	3	0	0	3
CORLENDOR	0	1	0	1
CORLOUNOR	1	0	0	1
KORLANDOR	0	1	0	1
KORLANOR	0	1	0	1
QUORLANOR	0	1	0	1

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

No.	Proposed name: Corlanor Strength(s): 5 mg & 7.5 mg Usual Dose: 1 Tablet BID	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Corlanor	100	The subject of this review

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

No.	Proposed Name	POCA Score (%)
1.	1-PropANOl	50
2.	ARRANON	50
3.	ButorphANOl	50
4.	Calaclear	52
5.	Caladryl	53
6.	Calagel	50
7.	Cala-Gen	50
8.	Calamine	53
9.	CALAN	55
10.	Calcidol	50
11.	CALCIMAR	58
12.	CalCORt	52
13.	CaldeCORt	50
14.	CALDOLOR	56
15.	Calimal	50
16.	Calmol	52
17.	Calmol 4	52
18.	Camphor	50
19.	Caraderma	52
20.	CARBACHOL	52
21.	Carbomer	62
22.	Carbomer 1342	62

No.	Proposed Name	POCA Score (%)
23.	carbomer-934	62
24.	Carbomer-940	62
25.	Carbomer-974P	53
26.	Carbomer-980	62
27.	CARDENE SR	63
28.	Carlesta	54
29.	Carlson D	59
30.	Carmol	52
31.	Carmol 10	52
32.	Carmol-20	52
33.	Carmol-40	52
34.	CARNITOR	64
35.	CEFDINIR	52
36.	CERADON	50
37.	CeraSport	52
38.	Chlordrine SR	50
39.	Chlor-Tan A 12	50
40.	ChoLAN	51
41.	CHOLYBAR	54
42.	Chromonar	52
43.	CLAFORAN	50
44.	ClinaCORt	50
45.	CLOLAR	54
46.	clorsulon	50
47.	Coal Tar	58
48.	Cobolin-M	50
49.	Codar AR	55
50.	COLAZAL	53
51.	Coldamine	50
52.	Coldec-TR	52

No.	Proposed Name	POCA Score (%)
53.	Coldonyl	52
54.	Colicon	50
55.	Collagen	52
56.	COLOCORT	59
57.	Cologel	50
58.	COLONAID	54
59.	Colyte 4 Flavor	54
60.	CORdilox MR	52
61.	CORDRAN	61
62.	CORDRAN SP	55
63.	CORDRAN-N	59
64.	COREG CR	56
65.	CORGARD	56
66.	CORicidin	51
67.	CORLOPAM	59
68.	CORn Oil	58
69.	CORtAlo	54
70.	CORtamox	60
71.	CORTAN	60
72.	CORtane	56
73.	CORtane-B	62
74.	CORTENEMA	52
75.	CORTONE	52
76.	CORVERT	53
77.	CORzall	51
78.	CotaCORt	54
79.	crofelemer	54
80.	Curaler	62
81.	Curasore	60
82.	CUROSURF	51

No.	Proposed Name	POCA Score (%)
83.	DilaCOR	52
84.	KELNOR	62
85.	KORLYM	55
86.	MAZANOR	56
87.	MICRONOR	56
88.	NORPLANT	50
89.	PARACORT	52
90.	PramCORt	51
91.	PRIMACOR	52
92.	PursLANe oil	50
93.	ScalaCORt	54
94.	SILENOR	65
95.	sooLANtra ***	58
96.	SotaCOR	54
97.	SPORANOX	52

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

No.	**Proposed name: Corlanor** **Strength(s): 5 mg & 7.5 mg** **Usual Dose: 1 Tablet BID**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Calabren	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
2.	CALAN SR (Orthographic: 76%)	68	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Calan SR contains an extra syllable.
3.	Calsynar	64	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	Carbacot	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
5.	CARBATROL	52	The suffix of this name pair has sufficient orthographic. The second and third syllables of this name pair sound different.
6.	Cardec TR	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different differences and the name Cardec TR contains an extra syllable.
7.	Cardene IV	50	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Cardene IV contains an extra syllable.

No.	Proposed name: Corlanor Strength(s): 5 mg & 7.5 mg Usual Dose: 1 Tablet BID	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8.	CARDURA	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
9.	CIRCANOL	58	The infix and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
10.	CLINORIL	58	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
11.	CORDARONE	54	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
12.	CORdarone I.V.	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different, and Cordarone IV contains two extra syllables.
13.	CORdarone X	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and Cordarone X contains an extra syllable.
14.	CORdron NR (Phonetic: 70%)	68	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Cordron NR contains an extra syllable.

No.	Proposed name: Corlanor Strength(s): 5 mg & 7.5 mg Usual Dose: 1 Tablet BID	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
15.	CORdron-12 D	56	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Cordron 12-D contains extra syllables.
16.	CORdron-D	56	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different.
17.	CORdron-D NR	55	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Cordron D-NR contains two extra syllables.
18.	CORdron-DM NR	50	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Cordron DM-NR contains three extra syllables.
19.	CORfen-DM	52	The suffix of this name pair has sufficient orthographic differences. The second and third syllables of this name pair sound different and the name Corfen-DM contains an extra syllable.
20.	CORTALONE	56	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	CORticool	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	Proposed name: Corlanor Strength(s): 5 mg & 7.5 mg Usual Dose: 1 Tablet BID	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
22.	CORtilone	54	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
23.	Cotolone	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
24.	COZAAR	56	The prefix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and the name Corlanor contains an extra syllable.
25.	CRESTOR	52	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and the name Corlanor contains an extra syllable.

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

No.	Name	POCA Score (%)
1.	Coreg	42
2.	Cortisone	46
3.	Dilacor XR	38
4.	Natrecor	40
5.	Panadol	32

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

No.	Name	POCA Score (%)	Failure preventions
1.	afoxoLANer	56	Veterinary product.
2.	BaLANcer	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
3.	CaLANif	58	International nifedipine product marketed in several countries.
4.	cangrelor ***	53	Name identified in Names Entered by SE database. This is an established name. The product (b) (4) Kengreal*** in OSE RCM# (b) (4).
5.	Caplenal	54	International allopurinol product marketed in several countries.
6.	Carbadox	52	Veterinary product.
7.	Carbinox	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
8.	carbromal	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
9.	Cardilate MR	57	International nifedipine product marketed in several countries.

No.	Name	POCA Score (%)	Failure preventions
10.	Cardinol	63	International propranolol hydrochloride product marketed in several countries.
11.	Carles	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
12.	carvone	50	Terpenoid ketone found in essential oils.
13.	Carylderm	56	International carbaryl product marketed in the UK for head lice.
14.	carzenide	52	Chemical Compound.
15.	Choragon	51	International chorionic gonadotropin product marketed in several countries.
16.	Clinitar	56	International coal tar shampoo product marketed in the UK.
17.	(b) (4) ***	56	Name identified in Names Entered by SE database. This was a secondary name never reviewed. The product was approved under the name Nexiclon XR granted in OSE RCM# 2010-224.

No.	Name	POCA Score (%)	Failure preventions
18.	(b) (4) ***	54	Name identified in Names Entered by SE database. Unable to find product characteristics in internal and commonly used drug databases (L drive, AIMs legacy data, Panorama, and DARRTS).
19.	(b) (4) ***	53	Name identified in Names Entered by SE database. This was a secondary name never reviewed. The product was approved under the name (b) (4) *** granted in OSE RCM# (b) (4)
20.	(b) (4) ***	54	Name identified in Names Entered by SE database. This was a secondary name never reviewed. The product was approved under the name Procomp granted in OSE RCM# 2009-121.
21.	CORdon D	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
22.	CORdon DM	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
23.	CORiander oil	50	Essential oil.

No.	Name	POCA Score (%)	Failure preventions
24.	CORisin	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
25.	CORLUX ***	56	Name identified in Names Entered by SE database. This name was never reviewed. The product was approved under the name Korlym granted in OSE RCM# 2011-2647.
26.	CORLuxin ***	55	This name was found unacceptable in OSE RCM# 2011-1353. The product was approved under the name Korlym granted in OSE RCM# 2011-2647.
27.	CORoday MR	61	International nifedipine product marketed in the UK.
28.	CORo-Nitro	58	International nitroglycerin spray product marketed in the UK.
29.	CORsodyl	54	International chlorhexidine gluconate product marketed in the Czech Republic.
30.	CORtinide	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
31.	CORtivazol	52	International glucocorticoid product marketed in several countries.

No.	Name	POCA Score (%)	Failure preventions
32.	(b) (4) ***	50	This name was found unacceptable in OSE RCM# (b) (4). The application, NDA (b) (4) was deemed 'Not Approvable".
33.	CORwin	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
34.	curdLAN	62	A gelling agent used in food, construction, and pharmaceuticals.
35.	fluraLANer	60	Veterinary product.
36.	KelocyANOR	58	International edetic acid dicobalt product marketed in France and Greece.
37.	(b) (4) ***	56	This name was found unacceptable in OSE RCM# (b) (4) for NDA 22573. NDA 22573 was later approved under the established name and now marketed by a labeler under (b) (4)
38.	SuroLAN	54	Veterinary product.
39.	TerfeNOR (Phonetic: 73%)	64	Hoechst Marion Roussel voluntarily removed this product form the market for safety concerns.
40.	(b) (4) ***	50	Name identified in Names Entered by SE database. This name was withdrawn by the Applicant in OSE RCM# (b) (4). The application ANDA (b) (4) was also withdrawn.

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

No.	Name	POCA Score (%)
1.	Acoflam SR	58
2.	Adalat AR	50
3.	argan oil	50
4.	Bellamor	58
5.	Dermazor	54
6.	Duramorph	54
7.	Fiormor	53
8.	Florastor	53
9.	KALBITOR	54
10	Kaochlor	52
11	Karbinal	50
12	KARBINAL ER	50
13	(b) (4) ***	52
14	Kera Nail	50
15	Keratol	50
16	Keratol 40	50
17	KERLONE	58
18	Kolorz	50
19	NOVOLIN R	56
20	Oramorph	55
21	Organ-1 NR	58
22	(b) (4) ***	52
23	Paramol	52
24	PARLODEL	54
25	Polytar	52
26	(b) (4) ***	57
27	PREDAIR	50
28	Predator	58

No.	Name	POCA Score (%)
29	Prevnar	53
30	Prevnar 13	53
31	Primor	56
32	Primor 120	56
33	Primor 1200	56
34	Primor 240	56
35	Primor 600	56
36	PROKLAR	50
37	Purklenz	54
38	Salamol	53
39	Selenos	51
40	sevelamer	53
41	Sochlor	52
42	Solganal	50
43	Solostar	50
44	Sore No More	53
45	Teladar	52
46	TORADOL	54
47	(b) (4) ***	56
48	(b) (4) ***	56
49	TYLENOL	50
50	(b) (4) ***	52
51	Zerlor	53

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/s/

JANINE A STEWART
09/22/2014

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09/22/2014