

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207953Orig1s000

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:	February 4, 2015
Application Type and Number:	NDA 207953
Product Name and Strength:	Yondelis (trabectedin) for Injection, 1 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen
Submission Date:	December 16, 2014
Panorama #:	2014-45599
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Yondelis, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Yondelis, on November 25, 2008 under NDA (b) (4)

This time, the Applicant submitted the name, Yondelis, for review on December 16, 2014 under NDA 207953 Trabectedin for injection (lyophilized powder) with the proposed indication (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the December 16, 2014 proprietary name submission.

- Intended Pronunciation: Yon DELiss
- Active Ingredient: trabectedin
- Indication of Use: (b) (4)
(b) (4)
- Route of Administration: intravenous infusion
- Dosage Form: for injection
- Strength: 1 mg/vial
- Dose and Frequency: 1.5 mg/m² body surface area as a 24-hour intravenous infusion, every 3 weeks
- How Supplied: 1 mg of trabectedin, as a sterile lyophilized white powder in a 25 mL glass vial
- Storage: 2°C to 8°C (36°F to 46°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products II (DOP2) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Yondelis 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

Ninety-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.

In the outpatient written study, 28 of 32 respondents correctly interpreted the name. In the inpatient written study, 22 of 29 respondents correctly interpreted the name. Common misinterpretations in the written studies included misinterpretation of the letter '-o-' as '-a-', and misinterpretation of the letter string '-lis' as '-liz', '-lie', and '-lia'. In the verbal study, 11 of 30 respondents correctly interpreted the name. Common misinterpretations included misinterpretation of the letter string 'Yon-' as 'Ya-', 'Yan-', and 'Yun-', and misinterpretation of the letter string '-elis' as '-alis', '-ellis', '-allis', '-alus', '-ellis' and '-ulas'.

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, December 29, 2014 e-mail, the Division of Oncology Products II (DOP2) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

¹USAN stem search conducted on January 7, 2015.

2.2.4 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search² organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	73
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 76 names contained in Table 1 determined 76 names will not pose a risk for confusion as described in Appendices C through H.

2.2.6 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Oncology Products II (DOP2) via e-mail on January 22, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP2 on February 2, 2015, they stated no additional concerns with the proposed proprietary name, Yondelis.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 16, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

² POCA search conducted on December 18, 2014.

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/about/MedErrors.html>. Last accessed 10/11/2007.

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

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

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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

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

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

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

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

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

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

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

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

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

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

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

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

<p>Step 1</p>	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</p>

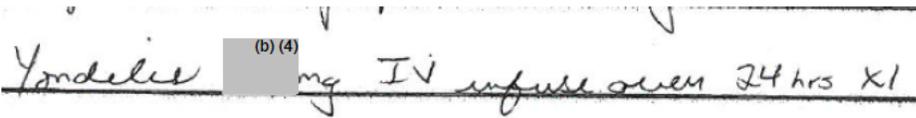
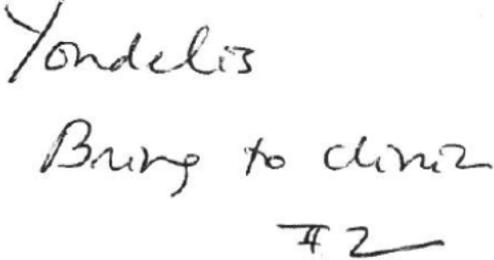
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none">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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Yondelis Study (Conducted on January 7, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Yondelis Bring to clinic Dispense #2</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Yondelis

As of Date 1/20/2015

253 People Received Study

91 People Responded

Total	32	30	29	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
YADALIS	0	1	0	1
YADELIS	0	2	0	2
YADELLIS	0	1	0	1
YANDALIS	0	2	0	2
YANDALLIS	0	1	0	1
YANDALUS	0	1	0	1
YANDELIE	0	0	1	1
YANDELIS	0	2	2	4
YODELIS	1	0	0	1
YONDALIS	0	2	0	2
YONDALLIS	0	1	0	1
YONDELES	0	1	0	1
YONDELIA	0	0	2	2
YONDELIE	0	0	1	1
YONDELIS	28	11	22	61
YONDELISS	0	1	0	1
YONDELIZ	3	0	0	3
YONDELLIS	0	2	0	2
YONDILIS 2.5MG	0	0	1	1
YONDULAS	0	1	0	1
YUNDELIS	0	1	0	1

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

No.	Proposed name: Yondelis Established name: trabectedin Dosage form: Powder, for Injection Strength(s): 1 mg/vial Usual Dose: 1.5 mg/m ² as a 24 hour intravenous infusion every 3 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Yondelis	100	Name is the subject of this review.
2.	ONSOLIS	72	<p>NDA 022266 Onsolis (fentanyl buccal soluble film) was approved in 2009 but is discontinued according to Drugs@FDA. No generic equivalents are available.</p> <p>Yondelis contains a letter ‘Y’ at the beginning of the name, whereas Onsolis begins with the letter ‘O’.</p> <p>Yondelis contains an upstroke letter in the fourth position, which is absent in Onsolis.</p> <p>Although Onsolis is available in strength of 1200 mcg (or 1.2 mg) film, a dose of 1.2 mg for Yondelis is unlikely. Therefore, there are no overlaps in strength or dose between Yondelis and Onsolis.</p> <p>Additionally, Onsolis has a REMS program that consists of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. It is part of the single shared system REMS, the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access Program. Prescribers and pharmacists must enroll in the TIRF REMS Access program to prescribe, dispense, or distribute TIRF medicines (including Onsolis).</p>
3.	Rendells	70	International product marketed in Portugal

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

No.	Proposed Name	POCA Score (%)
1.	CONDYLOX	55
2.	Inderide	50
3.	INDERIDE-40/25	50
4.	INDERIDE-80/25	50
5.	Jinteli	56
6.	KYPROLIS	50
7.	Mandelay	50
8.	Tandem Plus	54
9.	Undelenic	56
10.	VICTRELIS	50
11.	(b) (4)***	51

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

No.	Proposed name: Yondelis Established name: trabectedin Dosage form: Powder, for Injection Strength(s): 1 mg/vial Usual Dose: 1.5 mg/m ² as a 24 hour intravenous infusion every 3 weeks	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.	ANGELIQ	59	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	Proposed name: Yondelis Established name: trabectedin Dosage form: Powder, for Injection Strength(s): 1 mg/vial Usual Dose: 1.5 mg/m ² as a 24 hour intravenous infusion every 3 weeks	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
2.	ANTHELIOS 20	57	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different.</p> <p>ANTHELIOS 20 contains extra syllables from the modifier '20'.</p>
3.	ANTHELIOS 40	57	<p>The prefix and infix of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different.</p> <p>ANTHELIOS 40 contains extra syllables from the modifier '40'.</p>
4.	Andehist	54	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different.</p>
5.	Rondex	53	<p>The prefix and suffix of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different.</p> <p>Yondelis has 3 syllables whereas Rondex has 2 syllables.</p>
6.	(b) (4) ***	52	<p>(b) (4)</p>
7.	(b) (4) ***	52	

No.	Proposed name: Yondelis Established name: trabectedin Dosage form: Powder, for Injection Strength(s): 1 mg/vial Usual Dose: 1.5 mg/m ² as a 24 hour intravenous infusion every 3 weeks	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.	INDERAL	51	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
9.	CLINDESSE	50	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
10.	CLINDETS	50	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair sound different. And Yondelis has an extra syllable.
11.	ZYDELIG	50	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair sound different.

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

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	64	Name identified in Name entered by Safety Evaluator database. Name is not a proprietary name (according to RCM 2007-1457). NDA 022103 is approved and marketed under proprietary name Sanctura XR.
2.	(b) (4) ***	58	This is a proposed proprietary name for IND (b) (4) found unacceptable in OSE 2014-16881. This application is active in DARRTS.
3.	condoliase	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. A Google search of this product name indicates that it is an enzyme drug product that is currently being studied in Phase III Clinical Trial for the treatment of lumbar disc herniation. However, no product information was available.
4.	Brondelate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Flanders	56	No drug is marketed under only the root name "Flanders". A Google search did identify the product Flanders Buttocks Ointment, which is an over-the-counter product used to treat diaper rash. However, this product lacks orthographic and phonetic similarity since it was not retrieved from our POCA search. Thus, Flanders Buttocks Ointment will not be evaluated.
6.	(b) (4) ***	54	Name identified in Name Entered by Safety Evaluator database. This appears to be a misspelling of Zydelig (NDA 205858) in AIMS, and NDA 205858 is approved with the proprietary name Zydelig on July 23, 2014. Zydelig is evaluated in Appendix E.
7.	Brondil	52	International product marketed in Philippines

No.	Name	POCA Score (%)	Failure preventions
8.	Propolis	52	Product is not a drug. It is a dietary supplement. No overlap in dose or strength (1000 mg, 600 mg, 70%, 500 mg)
9.	undeceth-7	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Condylone	51	International product marketed in United Kingdom, France, Italy, Poland, New Zealand, Russia, Denmark, India, Norway, Sweden, and Hungary.
11.	(b) (4)***	50	Proposed name found unacceptable by DMETS in OSE RCM #2006-864 under IND (b) (4). No new proprietary name submitted.
12.	Condasin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	(b) (4)***	50	Proposed name found unacceptable by DMEPA in OSE RC 2011-2416, 2011-2417 (ANDA 200910) (b) (4). NDA 200910 is approved under new proprietary name, Xulane.
14.	Ponderax	50	International product marketed in Australia, Austria, Germany, Ireland, South Africa, and United Kingdom
15.	Tanderil	50	International product name for chloramphenicol that was formerly manufactured in United Kingdom, Switzerland, and Germany. Chloramphenicol is not available in the United States because chloramphenicol causes aplastic anemia.

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

No.	Name	POCA Score (%)
1.	ADCETRIS	50
2.	Antacid DS	50

No.	Name	POCA Score (%)
3.	Bion Tears	51
4.	Bonjela	52
5.	BRINTELLIX	51
6.	C Tan D Plus	50
7.	Denta 5000 Plus	55
8.	Doptelet	50
9.	Drontal Plus	52
10.	Endal D	52
11.	Endolor	50
12.	End-Zit	50
13.	ENLON-PLUS	54
14.	Handclens	52
15.	Indoflex	50
16.	Indolar	52
17.	Indolar SR	54
18.	Insulase	53
19.	INTELENCE	50
20.	Iodides	54
21.	Ionil Plus	55
22.	Ionil T Plus	50
23.	Ionosol-T	50
24.	MYTELASE	54
25.	OMNARIS	58
26.	Ontepix	52
27.	Onzeald	50
28.	Optilast	55
29.	Pronto Plus	52
30.	Renaplus	52
31.	Ron Acid Plus	50
32.	SenoSol-SS	50

No.	Name	POCA Score (%)
33.	Syndros	50
34.	Syntaris	58
35.	VENTAVIS	58
36.	VENTOLIN	50

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/s/

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02/04/2015

CHI-MING TU
02/04/2015