CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208434Orig1s000

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 8, 2015
Application Type and Number:	NDA 208434
Product Name and Strength:	Alecensa (Alectinib) Capsules, 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Hoffmann La-Roche
Panorama #:	2015-960385
DMEPA Primary Reviewer:	Grace P. Jones, PharmD, BCPS
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Alecensa, 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 name study, conducted by [redacted] (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Alecensa, under IND 111723 on September 5, 2013. The proprietary name was found conditionally acceptable on December 10, 2015.[1]

1.2 PRODUCT INFORMATION

The following product information is provided in the July 9, 2015 proprietary name submission.

Intended Pronunciation	a le sen' sah
Active Ingredient	Alectinib
Indication of Use	Indicated for the treatment of patients with Anaplastic Lymphoma Kinase (ALK)-positive metastatic non-small cell lung cancer
Route of Administration	Oral
Dosage Form	Capsules
Strength	150 mg
Dose and Frequency	1200 mg/day [600 mg (4 x 150 mg capsules) twice daily]
How Supplied	To be determined
Storage	Store in the original container to protect from light and moisture, do not store above 30°C (86°F)

2 RESULTS

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

[1] Townsend, O. Proprietary Name Review for Alecensa IND 111723. Silver Spring (MD):FDA, CDER, OSE, DMEPA (US); 2013 12 10. RCM No. 2013-2041.

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 2 (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 name[2].

2.2.2 Components of the Proposed Proprietary Name

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

Seventy-nine (79) 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. Thirty-three (33) practitioners correctly interpreted the name Alecensa. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 24, 2015 e-mail, the Division of Oncology Products 2 (DOP2) did not have any concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[3] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4) Inc.

[2]USAN stem search conducted on July 20, 2015.

[3] POCA search conducted on July 20, 2015.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	213
Low similarity name pair: combined match percentage score ≤49%	12

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

Our analysis of the 228 names contained in Table 1 determined all 228 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 2 (DOP2) via e-mail on August 28, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP2 on August 31, 2015, they stated no additional concerns with the proposed proprietary name, Alecensa.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 9, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

[4] 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: ○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg

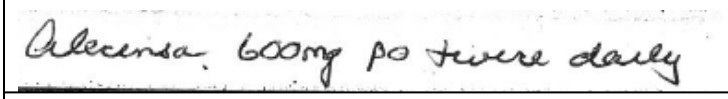
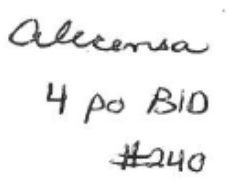
<table>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
Is there different number or placement of cross-stroke or dotted letters present in the names?
Do the infixes of the name appear dissimilar when scripted?
Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
Do the names have different number of syllables?
Do the names have different syllabic stresses?
Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Alecensa Study (Conducted on July 24, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Alecensa Take 4 capsules by mouth twice daily Dispense #240
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

245 People Received Study
79 People Responded

Study Name: Alecensa

Total	**28**	**26**	**25**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
AKCENSA	1	0	0	1
ALACENSA	0	2	0	2
ALACENSSA	0	1	0	1
ALASENSA	0	8	0	8
ALASENZA	0	1	0	1
ALECENDA	0	0	1	1
ALECENEA 4	1	0	0	1
ALECENIA	2	0	0	2
ALECENSA	14	0	19	33
ALECINSA	0	0	4	4
ALENCENSA	0	0	1	1
ALERCENSA	1	0	0	1
ALERENSA	2	0	0	2
ALESENSA	0	1	0	1
ALICENIA	1	0	0	1
ALICENSA	5	0	0	5
ALIRENSA	1	0	0	1
ALISENSA	0	2	0	2
ALLASENZA	0	1	0	1
ALLISENCIA	0	1	0	1
ALLISENSA	0	1	0	1
ALLOSENSA	0	2	0	2
ALOCENZA	0	1	0	1
ALOSENSA	0	4	0	4
ALOSENZA	0	1	0	1

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

No.	**Proposed name: Alecensa** **Established name: Alectinib** **Dosage form: Capsule** **Strength(s): 150 mg** **Usual Dose: 600 mg (4 capsules) twice daily**	**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.	ALFENTA	77	The infix and suffix of this name pair have sufficient orthographic differences. The name Alfenta contains one fewer syllable and the second and third syllables of this name pair sound different. Alfenta (alfentanil) Injection, 500 mcg/mL, is used during general surgery for anesthesia by an anesthetist or anesthesiologist. Alecensa is a capsule that may be taken orally by the patient. The different settings of use minimize the risk for confusion or the wrong drug being administered to a patient.
2.	LEVENTA	72	Veterinary Product
3.	ALBENZA	70	The infix of this name pair has sufficient orthographic differences, and there is an extra upstroke in the name Albenza. The name Albenza contains one fewer syllable and the second syllable of this name pair sounds different.

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

No.	Name	POCA Score (%)
1.	ACEPHEN	54
2.	ACETA	52
3.	ALIMTA	54
4.	ALINIA	52
5.	ALLEGRA	50
6.	ALLERMAX	51
7.	ALTINAC	52
8.	ALUPENT	62
9.	ALYACEN 7/7/7	63
10.	ARICEPT	50
11.	ARICIN	52
12.	AVINZA	52
13.	(b) (4) ***	58
14.	CELEXA	54
15.	LECITHIN	52
16.	LOTENSIN	58
17.	ULTRESA	50
18.	UNI-CENNA	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: Alecensa** **Established name: Alectinib** **Dosage form: Capsule** **Strength(s): 150 mg** **Usual Dose: 600 mg (4 capsules) twice daily**	**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.	Aflaxen	51	The prefix and infix of this name pair have sufficient orthographic differences. The name Aflaxen contains one fewer syllable and the second and third syllables of this name pair sound different.
2.	Ala seb	52	The suffix of this name pair has sufficient orthographic differences. The name Ala Seb contains one fewer syllable and the third syllable of this name pair sounds different.
3.	Ala-tet	50	The suffix of this name pair has sufficient orthographic differences. The name Ala-Tet contains one fewer syllable and the third syllable of this name pair sounds different.
4.	Alcortin a	52	The infix of this name pair has sufficient orthographic differences. The second, third, and fourth syllables of this name pair sound different.
5.	Aldex an	56	The infix and suffix of this name pair have sufficient orthographic differences. The name Aldex an contains one fewer syllable and the second and third syllables of this name pair sound different.
6.	Aldex gs	54	The infix and suffix of this name pair have sufficient orthographic differences. The second, third, and fourth syllables of this name pair sound different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	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
7.	Alefacept	54	The infix and suffix of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
8.	Alenic alka	50	The infix and suffix of this name pair have sufficient orthographic differences. The name Alenic Alka contains one more syllable and the second, third, and fourth syllables of this name pair sound different.
9.	Aler-tab	52	The suffix of this name pair has sufficient orthographic differences. The name Aler-tab contains one fewer syllable and the third syllable of this name pair sounds different.
10.	Alesse	50	The infix of this name pair has sufficient orthographic differences. The name Alesse contains one fewer syllable and the third syllable of this name pair sounds different.
11.	Alevazol	53	The suffix of this name pair has sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
12.	Aleve pm	52	The suffix of this name pair has sufficient orthographic differences. The second, third, and fourth syllables of this name pair sound different.
13.	Aleve-d	56	The suffix of this name pair has sufficient orthographic differences. The name Aleve-D contains one fewer syllable and the second and third syllables of this name pair sound different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	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
14.	Alfentanil	54	The infix and suffix of this name pair have sufficient orthographic differences. The second, third, and fourth syllables of this name pair sound different.
15.	Aliclen	55	The suffix of this name pair has sufficient orthographic differences. The name Aliclen contains one fewer syllable and the third syllable of this name pair sounds different.
16.	Alkets	56	The infix and suffix of this name pair have sufficient orthographic differences. The name Alkets contains two fewer syllables and the second syllable of this name pair sounds different.
17.	Alkums	50	The infix and suffix of this name pair have sufficient orthographic differences. The name Alkums contains two fewer syllables and the second syllable of this name pair sounds different.
18.	Allercon	53	The prefix of this name pair has sufficient orthographic differences. The name Allercon contains one fewer syllable and the third syllable of this name pair sounds different.
19.	Allerest	56	The prefix and suffix of this name pair have sufficient orthographic differences. The name Allerest contains one fewer syllable and the third syllable of this name pair sounds different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
20.	Allerest pe	54	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The name Allerrest PE contains one more syllable and the third, fourth, and fifth syllables of this name pair sound different.
21.	Allerfed	54	The prefix and suffix of this name pair have sufficient orthographic differences. The name Allerfed contains one fewer syllable and the third syllable of this name pair sounds different.
22.	Allerfrin	52	The prefix and suffix of this name pair have sufficient orthographic differences. The name Allerfrin contains one fewer syllable and the third syllable of this name pair sounds different.
23.	Allernaze	51	The prefix of this name pair has sufficient orthographic differences. The name Allernaze contains one fewer syllable and the third syllable of this name pair sounds different.
24.	Allerphed	53	The prefix and suffix of this name pair have sufficient orthographic differences. The name Allerphed contains one fewer syllable and the third syllable of this name pair sounds different.
25.	Aller-tec d	51	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
26.	Allfen	53	The prefix and suffix of this name pair have sufficient orthographic differences. The name Allfen contains two fewer syllables and the second syllable of this name pair sounds different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	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
27.	Allfen dm	54	The prefix and suffix of this name pair have sufficient orthographic differences. The second, third and fourth syllables of this name pair sound different.
28.	Allfen jr	54	The prefix and suffix of this name pair have sufficient orthographic differences. The second, third and fourth syllables of this name pair sound different.
29.	Alocane	54	The name Alocane contains one fewer syllable and the third syllable of this name pair sounds different. Alocane (Lidocaine HCl) Gel, 4% is an OTC topical product that's applied to affected area not more than 3 to 4 time daily; versus Alecensa is dosed as 4 capsules by mouth twice daily. The different sig on prescriptions minimizes the risk of confusion between these two names.
30.	Aloe vesta	63	The infix and suffix of this name pair have sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
31.	Aloemint	54	The suffix of this name pair has sufficient orthographic differences. The name Aloemint contains one fewer syllable and the third syllable of this name pair sounds different.
32.	Alophen	57	The suffix of this name pair has sufficient orthographic differences. The name Alophen contains one fewer syllable and the third syllable of this name pair sounds different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
33.	Alosetron	51	The suffix of this name pair has sufficient orthographic differences. The fourth syllable of this name pair sounds different.
34.	Alphanate	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
35.	Alsuma	53	The name Alsuma contains one fewer syllable and the second and third syllables of this name pair sound different. Alsuma (Sumatriptan succinate) Injections, 6 mg/0.5 mL, is an auto-injector; versus Alecensa is a capsule dosed as 4 capsules by mouth twice daily. Given the totality of the information (POCA 53% and difference in product characteristics), the risk of confusion between these two names are minimized.
36.	Altace	50	The infix of this name pair has sufficient orthographic differences. The name Altace contains two fewer syllables and the second syllable of this name pair sounds different.
37.	Altavera	52	The infix of this name pair has sufficient orthographic differences. The second, third, and fourth syllables of this name pair sound different.
38.	Alustra	56	The suffix of this name pair has sufficient orthographic differences. The name Alustra contains two fewer syllables and the third syllable of this name pair sounds different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	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
39.	Aluvea	52	The infix of this name pair has sufficient orthographic differences. The third and fourth syllables of this name pair sound different.
40.	Alyacen 1/35	63	The infix and suffix of this name pair have sufficient orthographic differences. The second and fourth syllables of the name pair sound different.
41.	Amlactin	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The name Amlactin contains one fewer syllable and the first, second, and third syllables of the name pair sound different.
42.	Aptensio	52	The prefix and infix of this name pair have sufficient orthographic differences. The first, second, third, and fourth syllables of the name pair sound different.
43.	Aquatensen	51	The prefix and infix of this name pair have sufficient orthographic differences. The first, second, and fourth syllables of the name pair sound different.
44.	Argesic-sa	54	The prefix and infix of this name pair have sufficient orthographic differences. The name Argesic-SA contains one more syllable and the first, second, third, and fourth syllables of the name pair sound different.
45.	(b) (4) ***	56	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of the name pair sound different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
46.	(b) (4)***	58	The prefix and infix of this name pair have sufficient orthographic differences. The name (b) (4)*** contains one fewer syllable and the first and second syllables of the name pair sound different.
47.	Dalvance	58	The prefix and infix of this name pair have sufficient orthographic differences. The name Dalvance contains two fewer syllables and the first and second syllables of the name pair sound different.
48.	Halls defense	58	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The name Halls Defense contains one fewer syllable and the first, second, and third syllables of the name pair sound different.
49.	Lucentis	60	The prefix and suffix of this name pair have sufficient orthographic differences. The name Lucentis contains one fewer syllable and the first and third syllables of the name pair sound different.
50.	Opalescence pf	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The name Opalescence PF contains many more syllables, and none of the syllables sound alike.
51.	(b) (4)***	56	The prefix and infix of this name pair have sufficient orthographic differences. The name (b) (4)*** contains one fewer syllable and the first, second, and third syllables of the name pair sound different.

No.	Proposed name: Alecensa Established name: Alectinib Dosage form: Capsule Strength(s): 150 mg Usual Dose: 600 mg (4 capsules) twice daily	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
52.	Prolensa	58	The prefix and infix of this name pair have sufficient orthographic differences. The name Prolensa contains one fewer syllable and the first syllable of the name pair sounds different.
53.	Quasense	55	The prefix of this name pair has sufficient orthographic differences. The name Quasense contains two fewer syllables and the first and second syllables of the name pair sound different.
54.	Relenza	56	The prefix and infix of this name pair have sufficient orthographic differences. The name Relenza contains one fewer syllable and the first syllable of the name pair sounds different.

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

No.	Name	POCA Score (%)
1.	Acetasol	48
2.	Alendronate	42
3.	Alfacalcidol	31
4.	Alfuzosin	43
5.	Aliskiren	46
6.	Alka Seltzer	42
7.	Alli	<20
8.	Aredia	46
9.	Aspirin	<20

No.	Name	POCA Score (%)
10.	Atacand	44
11.	Augmentin	<20
12.	Iressa	<20

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.	ABLETEX	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	ABLETEX PSE	50	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.
3.	(b) (4) ***	52	Proposed proprietary name found unacceptable due to overstating efficacy (OSE# 2009-1457, NDA 022450). Product approved under new name Ofirmev on 11/2/2010.
4.	ACLACIN	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	ACNEFREE SA	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	ADIZEM-SR	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	(b) (4) ***	52	This is a secondary proposed proprietary name and the primary name was found acceptable (OSE# (b) (4), IND (b) (4)). Sponsor submitted application inactivation request on (b) (4).

No.	Name	POCA Score (%)	Failure preventions
8.	ALBAMYCIN	51	Name identified in Drugs At FDA, RxNorm, and Redbook databases. Product is discontinued and deactivated, and no generic alternatives are available.
9.	ALBUMINS	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	ALCLOXA	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	ALDIOXA	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	ALENAZE-D	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	ALERTNESS AL	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	ALEXAN	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	ALEXAN-100	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	ALI FLEX	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	ALIBENDOL	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	ALLENT	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
19.	ALLERGEN EAR	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	(b) (4) ***	55	Proposed proprietary name found unacceptable due to containing a USAN stem (OSE# 2008-631). Product approved under new name Allernaze (NDA 020120, 2/4/2000).
21.	ALLERSOL A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	ALLERX AM	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	ALLERX DF AM	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	ALLETHRIN	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	ALLFEN C	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	ALLFEN CD	54	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.
27.	ALLFEN CDX	50	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.
28.	ALLFEN CX	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	ALPHEN	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
30.	ALTENOL	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	ALTEX PSE	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
32.	ALTRESYN	50	Veterinary Product
33.	AMYLASES	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	ANACIN AF	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	ANTATENS	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	APSIFEN F	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	ATENSINE	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	(b) (4)***	52	This proposed proprietary name is the root name of a proposed proprietary name which was found unacceptable due to overstating efficacy (OSE# (b) (4), IND (b) (4)). Sponsor has yet to submit a new proprietary name for review.
39.	BELLAPHEN-S	60	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.
40.	DALACIN T	66	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
41.	DECONSAL C	54	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.

No.	Name	POCA Score (%)	Failure preventions
42.	DECONSAL L.A.	55	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.
43.	DIATENSEC	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	(b) (4)***	55	Proposed proprietary name withdrawn on (b) (4) (IND (b) (4)). New proprietary name (b) (4)*** was requested for review.
45.	EPHENSIN-LA	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	ILETIN NPH	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	(b) (4)***	52	Proposed proprietary name found acceptable (OSE# (b) (4), NDA (b) (4)), however, the application withdrawal request was submitted on (b) (4).
48.	LIDOSENSE	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	LOFENSAID	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	(b) (4)***	58	Name and application withdrawn by the Sponsor.
51.	ORAL DEFENSE	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
52.	ORO CLENSE	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	(b) (4)***	60	Proposed proprietary name found unacceptable (OSE# (b) (4), ANDA (b) (4)). Subsequent proposed proprietary name, (b) (4)***, was found acceptable.

No.	Name	POCA Score (%)	Failure preventions
54.	SALUTENSIN	56	Name identified in Drugs At FDA, RxNorm, and Redbook databases. Product is discontinued and deactivated, and no generic alternatives are available.
55.	TALACEN	62	Name identified in Drugs At FDA, RxNorm, and Redbook databases. Product is discontinued and deactivated, and no generic alternatives are available.
56.	(b) (4)***	50	This is a proposed alternate proprietary name, but the primary proposed proprietary name (b) (4)*** (OSE# (b) (4)) was found conditionally acceptable under IND (b) (4).
57.	(b) (4)***	64	This is a proposed proprietary name that was withdrawn and the product was approved under the proprietary name Ibrance.
58.	VALERTEST	50	Name identified in RxNorm and Redbook databases. Product is deactivated, and no generic alternatives are available.

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

No.	Name	POCA Score (%)
1.	BALACET	52
2.	BALANCED SALT	54
3.	BALANTA	57
4.	CALCITAB	50
5.	(b) (4)***	52
6.	(b) (4)***	50
7.	(b) (4)***	57
8.	CLEOCIN T	52
9.	CLEOCIN-T	52

No.	Name	POCA Score (%)
10.	CRESEMBA	53
11.	(b) (4) ***	53
12.	DEFEN-LA	62
13.	DELAZINC	50
14.	DESENEX	52
15.	DE-SONE LA	53
16.	DEXAPHEN SA	60
17.	(b) (4) ***	56
18.	DILZEM SR	50
19.	DIPHENTANN	50
20.	DIXLANTA	52
21.	DOLACET	50
22.	DURA-VENT/A	54
23.	(b) (4) ***	60
24.	ECONTRA	50
25.	ELANTAN	53
26.	ELANTAN LA	58
27.	ELEPSIA	54
28.	ELESTAT	52
29.	ELESTRIN	50
30.	ELIFEMME***	52
31.	ELLENCE	56
32.	ELOCON	50
33.	(b) (4) ***	56
34.	(b) (4) ***	50
35.	EULEXIN	51
36.	FLEET ENEMA	52
37.	FLOVENT HFA	50

No.	Name	POCA Score (%)
38.	FOLACIN	50
39.	HALAVEN	52
40.	HALOTEX	50
41.	HELICIN	56
42.	(b) (4)***	52
43.	ILETIN I	52
44.	ILETIN II	50
45.	IRCON-FA	50
46.	(b) (4)***	52
47.	(b) (4)***	59
48.	LAZANDA	59
49.	LEGEND	53
50.	LENVIMA	50
51.	LESSINA	58
52.	LESSINA-21	58
53.	LESSINA-28	58
54.	LEVITRA	52
55.	LEVODOPA	52
56.	LICE MD	52
57.	LICE-NIL	52
58.	LUDEN'S	56
59.	LUSEDRA	55
60.	MACITENTAN	50
61.	MIRAPHEN LA	51
62.	NALACET	52
63.	NUCYNTA	51
64.	NUELIN S.A.	54
65.	(b) (4)***	50

No.	Name	POCA Score (%)
66.	ORLENTA	58
67.	(b) (4) ***	52
68.	(b) (4) ***	53
69.	PARACETS	53
70.	(b) (4) ***	52
71.	POLYCIN-B	51
72.	POLYCITRA	51
73.	SALACYN	56
74.	SALICIN	57
75.	SAXENDA	56
76.	(b) (4) ***	52
77.	SELFEMRA	52
78.	SILICONES	52
79.	SILTUSSIN SA	59
80.	SUFENTA	52
81.	ULESFIA	51
82.	WAL-ITIN D	50
83.	WAL-PHED PE	51

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

/s/

GRACE JONES
09/08/2015

CHI-MING TU
09/08/2015