CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207999Orig1s000

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:	October 26, 2015
Application Type and Number:	NDA 207999
Product Name and Strength:	Ocaliva (obeticholic acid) oral tablet 5 mg and 10 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Intercept
Panorama #:	2015-1120652
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Kendra Worthy, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ocaliva, 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 (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4)*** on August 18, 2014. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4)*** unacceptable (b) (4) in OSE Review #2014-26145, dated February 10, 2015.

Thus, the Applicant submitted the name, Ocaliva, for review on July 31, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 31, 2015 proprietary name submission.

- Intended Pronunciation: oh' kal i vah
- Active Ingredient: obeticholic acid
- Indication of Use: Treatment of primary biliary cirrhosis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.
- Route of Administration: Oral
- Dosage Form: Oral Tablet
- Strength: 5 mg and 10 mg
- Dose and Frequency: 5 to 10 mg/day: The recommended starting dose is 5 mg once daily. Based on the assessment of efficacy and tolerability after 3 months, the dose may be increased to 10 mg once daily, to improve response.
- How Supplied: OCA tablets are packaged in a 40cc high density polyethylene bottle containing 30 tablets closed with a polypropylene child resistant cap.
- Storage: Store (b) (4)
- Container and Closure Systems: See How Supplied

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 Gastroenterology & Inborn Error Products (DGIEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

83 practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 19, 2015 e-mail, the Division of Gastroenterology & Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

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

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1

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

[2] POCA search conducted on August 13, 2015.

Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	126
Low similarity name pair: combined match percentage score ≤49%	3

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

Our analysis of the 130 names contained in Table 1 determined that 130 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 Gastroenterology & Inborn Error Products (DGIEP) via e-mail on October 26, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DGIEP on October 26, 2015, they stated no additional concerns with the proposed proprietary name, Ocaliva.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 31, 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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

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
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.

APPEARS THIS WAY ON ORIGINAL

Appendix B: Prescription Simulation Samples and Results

Figure 1. Ocaliva Study (Conducted on August 21, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Ocaliva 10mg once daily	
Outpatient Prescription: Ocaliva 5mg Take 1 tablet once daily Disp #30	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Ocaliva

Total 33 23 27

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
OCABIA	1	0	0	1
OCABRIA	1	0	0	1
OCALAVA	0	7	0	7
OCALCIA	2	0	0	2
OCALIA	3	0	0	3
OCALICA	1	0	0	1
OCALIIA	1	0	0	1
OCALIUA	1	0	0	1
OCALIVA	2	4	27	33
OCALOVA	0	1	0	1
OCALRIA	13	0	0	13
OCALRIO	3	0	0	3
OCALVIA	2	0	0	2
OCALYVA	0	1	0	1
OCULIA	2	0	0	2
OCULIVA	1	0	0	1

OKALAVA	0	3	0	3
OKALEVA	0	3	0	3
OKALIBAR	0	1	0	1
OKELAVA	0	2	0	2
OKELEVA	0	1	0	1

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

No.	**Proposed name: Ocaliva** **Established name: Obeticholic Acid** **Dosage form: Oral Tablet** **Strength(s): 5 mg; 10 mg** **Usual Dose: 5-10 mg/day**	**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.	Ocaliva***	100%	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	(b) (4)***	64%
2.	(b) (4)***	63%
3.	Balziva	62%
4.	Balziva-21	62%
5.	Balziva-28	62%
6.	(b) (4)***	62%
7.	(b) (4)***	62%
8.	Calazem	58%
9.	(b) (4)**	56%
10.	Calcimar	54%
11.	Calube	54%
12.	Certiva	53%
13.	Ocrevus***	52%
14.	Ocuclear	52%
15.	Calan	52%
16.	Eskalith	52%
17.	Calagel	51%
18.	Onsolis	50%
19.	(b) (4)***	50%

No.	Name	POCA Score (%)
20.	Otoalgan	50%
21.	Boniva	50%
22.	Darcalma	50%

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: Ocaliva** **Established name: Obeticholic Acid** **Dosage form: Oral Tablet** **Strength(s): 5 mg; 10 mg** **Usual Dose: 5-10 mg/day**	**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.	Kariva	68%	This name contains fewer syllables. The first syllable of this name pair has sufficient phonetic differences. The infix of this name pair has sufficient orthographic differences.
2.	Focalin	65%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences as "F" and "O" differ along with "-lin" and "-liva."
3.	Castiva	63%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix of this name pair differs with the "O" and "C" as first letters. Additionally, the infix of this name pair differs with "-ast" and "-al." This name pair has a sufficient dosing difference: Castiva usual dosing is (b) (4) applications per day vs. Ocaliva usual dosing of 5-10 mg per day or 1 tablet per day.
4.	Onglyza	60%	This name contains fewer syllables. The second syllable of this name pair has sufficient phonetic differences. The infix of this name pair has sufficient orthographic differences.

No.	**Proposed name: Ocaliva** **Established name: Obeticholic Acid** **Dosage form: Oral Tablet** **Strength(s): 5 mg; 10 mg** **Usual Dose: 5-10 mg/day**	**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**
5.	One-Alpha	58%	This name contains fewer syllables. The first and third syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
6.	Ocu-Pred-A	57%	The second and third syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
7.	Lexiva	56%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
8.	Ultiva	55%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
9.	Calcilat	54%	This name contains fewer syllables. The second and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
10.	Calcitab	54%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.

No.	Proposed name: Ocaliva Established name: Obeticholic Acid Dosage form: Oral Tablet Strength(s): 5 mg; 10 mg Usual Dose: 5-10 mg/day	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
11.	Nucala***	54%	This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
12.	(b) (4) ***	52%	The second and third syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
13.	Opdivo	52%	This name contains fewer syllables. The second syllable of this name pair has sufficient phonetic differences. The prefix of this name pair has sufficient orthographic differences.
14.	Optivar	52%	This name contains fewer syllables. The second syllable of this name pair has sufficient phonetic differences. The prefix of this name pair has sufficient orthographic differences.
15.	Calcid	52%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
16.	Callergy	52%	This name contains fewer syllables. The third and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.

No.	Proposed name: Ocaliva Established name: Obeticholic Acid Dosage form: Oral Tablet Strength(s): 5 mg; 10 mg Usual Dose: 5-10 mg/day	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
17.	Otrivin	51%	This name contains fewer syllables. The second and third syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
18.	Oxilan	51%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences as “-an” differs from “-iva.”
19.	Oxilan-300	51%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences as “-an” differs from “-iva.”
20.	Oxilan-350	51%	This name contains fewer syllables. The first and second syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences as “-an” differs from “-iva.”
21.	Cala-Gen	51%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
22.	Calanif	51%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.

No.	Proposed name: Ocaliva Established name: Obeticholic Acid Dosage form: Oral Tablet Strength(s): 5 mg; 10 mg Usual Dose: 5-10 mg/day	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
23.	Alinia	50%	The second syllable of this name pair has sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
24.	Ascalix	50%	This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences, as "-lix" differs from "-liva."
25.	Ritalin LA	50%	This name contains fewer syllables. The first and last syllables of this name pair have sufficient phonetic differences. The prefix of this name pair has sufficient orthographic differences.
26.	Oscal	46%	This name contains fewer syllables. The last syllable of this name pair has sufficient phonetic differences. The suffix of this name pair has sufficient orthographic differences.
27.	Sustiva	42%	This name contains fewer syllables. The first syllable of this name pair has sufficient phonetic differences. The prefix of this name pair differs with the "S" and the "O." Additionally, this name contains a cross-stroke letter in the infix, while Ocaliva*** contains only an upstroke letter "l."
28.	Livalo	41%	This name contains fewer syllables. The second and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.

No.	Proposed name: Ocaliva Established name: Obeticholic Acid Dosage form: Oral Tablet Strength(s): 5 mg; 10 mg Usual Dose: 5-10 mg/day	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
29.	Ocuvite	41%	This name contains fewer syllables. The second and last syllables of this name pair have sufficient phonetic differences. The infix and suffix of this name pair have sufficient orthographic differences.
30.	Olysio	38%	The second and third syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
31.	Stevia	30%	This name contains fewer syllables. The first syllable of this name pair has sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.
32.	Octreotide	29%	The second and last syllables of this name pair have sufficient phonetic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
33.	Oleptro	25%	This name contains fewer syllables. The second and last syllables of this name pair have sufficient phonetic differences. The prefix and infix of this name pair have sufficient orthographic differences.

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

No.	Name	POCA Score (%)
1.	Eucalyptus	38%

No.	Name	POCA Score (%)
2.	Ocuflox	40%
3.	Ogen	22%

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.	Calimal	64%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4)***	56%	This name was found unacceptable by DMEPA (OSE# 2013-532). An alternate proposed proprietary name, Exondys 51***, was found acceptable by DMEPA (OSE# 2014-25473).
3.	Aviva***	54%	Product is not a drug. It is a name of a large volume parenteral container.
4.	(b) (4)***	51%	This name was found unacceptable by DMEPA (OSE# 2010-2608). An alternate proposed proprietary name, Bekyree***, was found acceptable by DMEPA (OSE# 2015-50245).

No.	Name	POCA Score (%)	Failure preventions
5.	Oxalate	51%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4)***	51%	This name was withdrawn by the sponsor (OSE# 2012-1132). The alternate proposed proprietary name, Qsymia, was found to be acceptable by DMEPA (OSE# 2012-1268).
7.	Oxalic Acid	50%	This product is not a drug. It is a compounding agent.
8.	Oxeladin	50%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	(b) (4)***	50%	This name was found unacceptable by DMEPA (OSE# 2008-1363). An alternate proposed proprietary name, Xgeva***, was found acceptable by DMEPA (OSE# 2010-1500).
10.	Baicalin	50%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	JOULEVA	61
2.	CELEVAC	60
3.	CO-LAV	58
4.	HEKLA LAVA	58
5.	KALETRA	58
6.	GAZYVA	57
7.	QOLIANA	57
8.	CAZAVI	56
9.	COLAZAL	56
10.	COLFED-A	56
11.	NELOVA	56
12.	STALEVO	56
13.	STALEVO 100	56
14.	STALEVO 125	56
15.	STALEVO 150	56
16.	STALEVO 200	56
17.	STALEVO 50	56
18.	STALEVO 75	56
19.	ALERA	54
20.	ASCLERA	54
21.	ATELVIA	54
22.	LOKELMA	54
23.	QUALUNA	54
24.	ZOLINZA	54
25.	ACOVA	53
26.	CELEXA	53
27.	DAKLINZA	53
28.	FALMINA	53

No.	Name	POCA Score (%)
29.	ALUVEA	52
30.	C10-36 OLEFIN	52
31.	C24-28 OLEFIN	52
32.	C30-45 OLEFIN	52
33.	CARLESTA	52
34.	CASIORA	52
35.	COLOVAGE	52
36.	CYCLESSA	52
37.	EUCRISA	52
38.	GOLCIMA	52
39.	INCLUZA	52
40.	SALKERA	52
41.	SYLEVIA	52
42.	TARCEVA	52
43.	ABLAVAR	51
44.	ATREZA	51
45.	CAMILA	51
46.	CETYLEV	51
47.	CLEEVEC	51
48.	CLINAC	51
49.	COMPLERA	51
50.	ACLACIN	50
51.	ASOLZA	50
52.	CHABELINA	50
53.	DOCULAX	50
54.	DULERA	50
55.	EPANOVA	50
56.	EPCLUSA	50
57.	EXCEL 3 IN 1	50
58.	HALAVEN	50

No.	Name	POCA Score (%)
59.	KYLEENA	50
60.	PALLADIA	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	N/A

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

/s/

MATTHEW J BARLOW
10/26/2015

KENDRA C WORTHY
10/26/2015

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 10, 2015
Application Type and Number:	IND 63307
Product Name and Strength:	(b) (4) (obeticholic acid) Oral Tablet 5 mg; 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Intercept Pharmaceuticals
Submission Date:	August 18, 2014
Panorama #:	2014-26145
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Kendra Worthy, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, M.S.
DMEPA Division Director:	Kellie Taylor, PharmD

19 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

---

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

/s/

MATTHEW J BARLOW
02/10/2015

KENDRA C WORTHY
02/11/2015

LUBNA A MERCHANT
02/11/2015

LUBNA A MERCHANT on behalf of KELLIE A TAYLOR
02/11/2015