CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208261Orig1s000

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)

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Date of This Review:	September 25, 2015
Application Type and Number:	NDA 208261
Product Name and Strength:	Zepatier (elbasvir and grazoprevir) Tablets 50 mg/100 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp.
Panorama #:	2015-992881
DMEPA Primary Reviewer:	Mónica Calderón, PharmD, BCPS
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Zepatier, 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 PRODUCT INFORMATION

The following product information is provided in the July 16, 2015 proprietary name submission.

- Intended Pronunciation: zeh pah TEER
- Active Ingredient: elbasvir and grazoprevir
- Indication of Use: treatment of chronic hepatitis C (CHC) genotypes 1, 4, (b) (4) infection in adults
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 50 mg/100 mg
- Dose and Frequency: one tablet once daily
- How Supplied: a carton containing two (2) 14-count child-resistant dose packs for a total of 28 tablets
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (between 59°F to 86°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 Antiviral Products (DAVP) 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].

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[1]USAN stem search conducted on August 14, 2015.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Zepatier 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 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. Forty-nine participants interpreted the name correctly (outpatient n=25; voice n=3, inpatient n=21). 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 10, 2015 e-mail, the Division of Antiviral Products (DAVP) 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. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	149
Low similarity name pair: combined match percentage score ≤49%	0

[2] POCA search conducted on August 14, 2015.

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

Our analysis of the 149 names contained in Table 1 determined no names will 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 Antiviral Products (DAVP) via e-mail on September 17, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAVP on September 25, 2015, they stated no additional concerns with the proposed proprietary name, Zepatier.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 16, 2016 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Zepatier Study (Conducted on August 7, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Zepatier one tabled po once daily	Zepatier 1 tab by mouth daily Disp #84
Outpatient Prescription: Zepatier 1 tab by mouth daily Disp # 84	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

244 People Received Study
70 People Responded

Study Name: Zepatier

Total	26	20	24	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTA
CEPATIER	0	1	0	1
SEPATERE	0	2	0	2
SEPATIR	0	1	0	1
ZAPATEER	0	2	0	2
ZAPATERE	0	1	0	1
ZAPATIER	0	3	3	6
ZAPATIR	0	1	0	1
ZEPATERE	0	3	0	3
ZEPATIER	25	3	21	49
ZEPATIES	1	0	0	1
ZEPATIR	0	2	0	2
ZEPATRIR	0	1	0	1

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

No.	Proposed name: Zepatier Established name: elbasvir and grazoprevir Dosage form: tablets Strength(s): 50 mg/100 mg Usual Dose: 1 tablet once 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.	N/A		

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 (%)
2.	ZADITOR	64
3.	ZENATANE	62
4.	ZANAMIVIR	56
5.	SEBUCARE	54; Phonetic: 74
6.	ZYKADIA	52
7.	ZEMAIRA	52
8.	ZACLIR	52
9.	(b) (4) ***	52
10.	CEPROTIN	50
11.	SEPTISOL	50
12.	ZNP BAR	50
13.	ZADITEN	50
14.	VIBatiV	50
15.	LApatiNIB	50

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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: Zepatier Established name: elbasvir and grazoprevir Dosage form: tablets Strength(s): 50 mg/100 mg Usual Dose: 1 tablet once 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
16.	ZETAR	60; phonetic 70	The infixes of this name pair have sufficient orthographic differences Zepatier contains an extra syllable.
17.	DepaKOTE ER	66	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
18.	ZIPSOR	62	The suffixes of this name pair have sufficient orthographic differences. Zepatier contains and extra syllable.
19.	ZELAPAR	62	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
20.	ZEMPLAR	59	The infixes of this name pair have sufficient orthographic differences. Zepatier contains an extra syllable.
21.	BETAPAR	59; phonetic 71	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
22.	VESICARE	58; phonetic 76	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
23.	CETADERM	58; phonetic 70	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	Proposed name: Zepatier Established name: elbasvir and grazoprevir Dosage form: tablets Strength(s): 50 mg/100 mg Usual Dose: 1 tablet once 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
24.	ZETACET	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
25.	TepaNIL	56	The suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
26.	TepaDINA	56	The suffixes of this name pair have sufficient orthographic differences. Tepadina contains an extra syllable.
27.	DepaKENE	56	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
28.	DepaKOTE	54	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
29.	ZEBUTAL	53	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
30.	ZINOTIC ES	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
31.	ZETAMINE	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	Proposed name: Zepatier Established name: elbasvir and grazoprevir Dosage form: tablets Strength(s): 50 mg/100 mg Usual Dose: 1 tablet once 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
32.	ZESTRIL	52	The infixes of this name pair have sufficient orthographic differences. Zepatier contains an extra syllable.
33.	ZEBETA	52	The infixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
34.	ZANOSAR	52	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
35.	ZYMAFLUOR	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
36.	ZINECARD	51	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
37.	ZETIA	50	The infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
38.	CepaCOL	50	The prefixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound. Different.

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

No.	Name	POCA Score (%)
39.	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
40.	(b) (4) ***	65	Proprietary name found acceptable under IND (b) (4); however Applicant submitted a new name under the same IND and (b) (4) *** was found conditionally acceptable.
41.	ZIPEPROL	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
42.	ZERIT XR	54	Withdrawn 2/10/05 pending FR notice due to manufacturing issues that prevented marketing of the drug.
43.	ZEFAZONE	54	Withdrawn FR effective 9/17/2001. No generics available.
44.	(b) (4) ***	54	Application Withdrawn by Applicant on 6/25/2012. Application not approvable under section 505 (d) and the Act and 21 CFR 314.125(b).

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No.	Name	POCA Score (%)	Failure preventions
45.	ZEatiN	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	ZYBAN SR	52	Zyban is currently marketed and is a sustained-release drug; however, SR is not a part of the approved proprietary name. The name with the added modifier is not in commonly used databases.
47.	ZINC CatiON	52	Not a drug, it's a metal cation.
48.	(b) (4) ***	52	Secondary name proposed for NDA 018066, name not officially submitted for evaluation. Application approved without proprietary name. Approved as Unisom tablets over-the-counter.
49.	BepaDIN	52	Withdrawn pending FR notice 8/17/05.
50.	SepaSOOTHE	50	Discontinued, no generics available.
51.	DepaNDRO 100	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
52.	(b) (4) ***	60
53.	XENADERM	60
54.	TRECATOR	60
55.	SEPTICARE	59
56.	LIPITOR	59
57.	RIFATER	58
58.	METADATE ER	58
59.	DEPINAR	58
60.	CEFACLOR	58
61.	PREDATOR	56
62.	OPANA ER	56
63.	DEPODUR	56
64.	DENTICARE	56
65.	DENTI CARE	56
66.	DECADERM	56
67.	BETADERM	56
68.	CEFTIOFUR	55
69.	XTAMPZA ER***	54
70.	VETALAR	54
71.	TRITUSS ER	54
72.	SENSIPAR	54
73.	RETISERT	54
74.	PASER	54
75.	EPICARE	54
76.	DEXAIR	54
77.	CEFOTIAM	54
78.	CEFDINIR	54

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No.	Name	POCA Score (%)
79.	CAPSTAR	54
80.	BETAPACE	54
81.	VEPESID	53
82.	TESTOMAR	53
83.	TAPAZOLE	53
84.	REPIDERM	53
85.	RENESE-R	53
86.	(b) (4)***	53
87.	XIPAMIDE	52
88.	TETRADURE	52
89.	TELADAR	52
90.	TEGAFUR	52
91.	TAFINLAR	52
92.	SLEEP-ETTES	52
93.	(b) (4)***	52
94.	SERPASIL	52
95.	RECTICARE	52
96.	PINE TAR	52
97.	MITIGARE	52
98.	METI-DERM	52
99.	LEADER	52
100.	HIBTITER	52
101.	FOTOTAR	52
102.	FENESIN IR	52
103.	EPIKLOR	52
104.	(b) (4)***	52
105.	DIGITER	52
106.	DENAVIR	52

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No.	Name	POCA Score (%)
107.	CETACORT	52
108.	CEFACLOR ER	52
109.	CEBATROL	52
110.	VETADRYL	51
111.	VERTAB SR	51
112.	VERACUR	51
113.	TEMODAR	51
114.	TAXOTERE	51
115.	SOTACOR	51
116.	SHEA BUTTER	51
117.	RENAKARE	51
118.	OPTIVAR	51
119.	ISOTRATE ER	51
120.	GENTAFAIR	51
121.	ENTEX ER	51
122.	BENEFIBER	51
123.	X-SEB T PEARL	50
124.	XATRAL SR	50
125.	VOSPIRE ER	50
126.	VENOFER	50
127.	VALSTAR	50
128.	TRESADERM	50
129.	TOPOSAR	50
130.	TOPICALE	50
131.	THERATEARS	50
132.	THERA TEARS	50
133.	TERAMINE ER	50
134.	STRATTERA	50
135.	OTICAIR	50
136.	NEXAVIR	50

No.	Name	POCA Score (%)
137.	NEPHRO-FER	50
138.	NATRECOR	50
139.	NAFAZAIR	50
140.	MEVACOR	50
141.	(b) (4) ***	50
142.	LEDIPASVIR	50
143.	LACTICARE	50
144.	KETOTARD	50
145.	KEEP ALERT	50
146.	DERMAPHOR	50
147.	DEPOTEST	50
148.	DEMSER	50
149.	DELLA CARE	50
150.	CETAPRED	50
151.	BENICAR	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

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

/s/

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09/25/2015

BRENDA V BORDERS-HEMPHILL
09/25/2015