CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206353Orig1s000

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:	June 04, 2014
Application Type and Number:	NDA 206353
Product Name and Strength:	Evotaz (Atazanavir and Cobicistat) Tablet 300 mg/150 mg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Bristol-Meyers Squibb
Submission Date:	April 4, 2014
Panorama #:	2014-17193
DMEPA Primary Reviewer:	James Schlick, MBA, RPh
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Evotaz, from a safety and promotional 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 for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the April 4, 2014 proprietary name submission.

- Intended Pronunciation: (ē - vō- tăz)
- Active Ingredient: Atazanavir and Cobicistat
- Indication of Use: For the treatment of HIV-1 infection in combination with other antiretroviral agents.
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 300 mg/150 mg
- Dose and Frequency: One tablet orally once daily
- How Supplied Container and Closure Systems: Bottle containing 30 tablets
- Storage: Room temperature

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anti-viral Products (DAVP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[1]USAN stem search conducted on May 5, 2014.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

One hundred twenty-two practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. One hundred three participants correctly interpreted the prescription. In the voice study, the letter 'v' was misinterpreted as the letter 'b'. In the written prescription, the letter 'v' was misinterpreted as the letter 'r'. 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, April 22, 2014 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 organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4)

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	142
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 146 names contained in Table 1 determined 146 names will not pose a risk for confusion as described in Appendices C through G.

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 May 28, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAVP on June 4, 2014, they stated no additional concerns with the proposed proprietary name, Evotaz.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further 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, Evotaz, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 4, 2014 submission are altered, 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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

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

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

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 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 (see Step 1 of the Moderately Similar Checklist).			
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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between 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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Evotaz Study (Conducted on April 18, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Evotaz 1 po daily with food	Evotaz Take 1 tablet by mouth once daily with food.
Outpatient Prescription: Evotaz Take 1 tablet by mouth once daily with food #30	Disp: #30

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Evotaz

As of Date 5/5/2014

275 People Received Study
122 People Responded

Study Name: Evotaz

Total	37	44	41	122

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BOTAZ	0	1	0	1
EBOTAZ	0	2	0	2
EBOTAZE	0	1	0	1
ECOTAZ	0	0	1	1
EMOTAZ	0	1	0	1
ENTAZ	1	0	0	1
EROTAZ	4	1	0	5
EVATAZ	0	0	1	1
EVOTAB	0	1	0	1
EVOTAQ	0	0	1	1
EVOTAS	0	1	0	1
EVOTAZ	31	36	36	103
EVOTAZG	0	0	1	1
EVOTEZ	1	0	0	1
EVOTOZ	0	0	1	1

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

No.	Proposed name: Evotaz (atazanavir and cobicistat) Strength(s): 300 mg/150 mg Usual Dose: 1 tablet orally once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	(b) (4)		

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

No.	Proposed Name	POCA Score (%)
1.	AVITA	64
2.	VITUZ	64
3.	CEFOTAN	58
4.	Estar	58
5.	IBU-TAB	58
6.	IBU-TAB 200	58
7.	ERY-TAB	57
8.	Xoten	55
9.	Duotan	54
10.	Vopac	54
11.	(b) (4)	
12.	Doctar	52
13.	Endodan	52
14.	Endotuss	52
15.	(b) (4)	
16.	EVEX	52
17.	EVOCLIN	52
18.	(b) (4)	
19.		
20.	TEVETEN	52
21.	(b) (4)	
22.	Vitabee 12	52
23.	(b) (4)	
24.	ERTACZO	51
25.	Ivocort	51

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No.	Proposed Name	POCA Score (%)
26.	KEFTAB	51
27.	TOVIAZ	51
28.	AVAGARD	50
29.	AVONEX	50
30.	AZASAN	50
31.	Entac	50
32.	(b) (4)	
33.		
34.		
35.	Iveegam	50
36.	LEVOPHED	50
37.	(b) (4)	
38.	TRAVATAN Z	50
39.	Xoten-C	50
40.	Zetar	50
41.	Zotex-12	50
42.	AMVAZ	56
43.	AXOTAL	56
44.	Estra-V 40	56
45.	Ethatab	56
46.	Evict	56
47.	REYATAZ	56
48.	VANTAS	56

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

No.	Proposed name: Evotaz (atazanavir and cobicistat) Strength(s): 300 mg/150 mg Usual Dose:	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.	FORTAZ	64	The infix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different. Evotaz contains three syllables versus two syllables in Fortaz
2.	CEPTAZ	63	The prefix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different. Evotaz contains three syllables versus two syllables in Ceptaz.
3.	Ed Spaz	62	The infix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different. Evotaz contains three syllables versus two syllables in Ed Spaz
4.	EVISTA	62	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different
5.	Levotabs	61	The prefix and suffix of this name pair have sufficient orthographic differences The first syllable of this name pair sounds different
6.	AVODART	60	The suffix of this name pair has sufficient orthographic differences The third syllable of this name pair sounds different
7.	EVOXAC	60	The suffix of this name pair has sufficient orthographic differences The third syllable of this name pair sound different
8.	Vazotab	58	The prefix and suffix of this name pair have sufficient orthographic differences The first syllable of this name pair sounds different

No.	Proposed name: Evotaz (atazanavir and cobicistat) Strength(s): 300 mg/150 mg Usual Dose:	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
9.	AMVAZ	56	The prefix and infix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different. Evotaz contains three syllables versus two syllables in Amvaz
10.	AXOTAL	56	The suffix of this name pair has sufficient orthographic differences The first and third syllable of this name pair sounds different.
11.	Estra-V 40	56	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllable of this name pair sound different
12.	Ethatab	56	The prefix and suffix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different
13.	Evict	56	The suffix of this name pair has sufficient orthographic differences The last syllable of this name pair sounds different. Evotaz contains three syllables versus two syllables in Evict.
14.	Alu-Tab	54	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sounds different
15.	Imotil	54	The suffix of this name pair has sufficient orthographic differences The third syllable of this name pair sounds different
16.	LEVO-T	54	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
17.	Dimotal	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different

No.	Proposed name: Evotaz (atazanavir and cobicistat) Strength(s): 300 mg/150 mg Usual Dose:	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
18.	DOPAR	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different. Evotaz contains three syllables versus two syllables in Dopar.
19.	Efasin	52	The prefix and suffix of this name pair have sufficient orthographic differences The third syllable of this name pair sounds different
20.	INVANZ	52	The suffix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different. Evotaz contains three syllables versus two syllables in Invanz.
21.	LEVATOL	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
22.	Yovital	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
23.	AVASTIN	51	The suffix of this name pair has sufficient orthographic differences The third syllable of this name pair sounds different
24.	Ed A-Ceph	51	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllable of this name pair sound different
25.	Ed-APAP	51	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllable of this name pair sound different
26.	Anaspaz	50	The suffix of this name pair has sufficient orthographic differences The first and third syllable of this name pair sound different

No.	Proposed name: Evotaz (atazanavir and cobicistat) Strength(s): 300 mg/150 mg Usual Dose:	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.	Delta D3	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllable of this name pair sound different
28.	Ed Cyte F	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllable of this name pair sound different
29.	EPITOL	50	The prefix and suffix of this name pair have sufficient orthographic differences The third syllable of this name pair sounds different
30.	No Doz	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and last syllables of this name pair sound different. Evotaz contains three syllables versus two syllables in No-Doz
31.	Vental	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and last syllables of this name pair sound different. Evotaz contains three syllables versus two syllables in Vental.
32.	Zebutal	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different

Appendix F: Low Similarity Names (i.e., combined POCA score is ≤49% from External Name Study)

No.	Name	POCA Score (%)
1.	Efavirenz	40
2.	Enablex	Less than 40
3.	Estrace	Less than 40

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	64	Name submitted under NDA 202022. The name Edurant was approved on May 20, 2011 under NDA 202022
2.	(b) (4) ***	62	Secondary name submitted to NDA 204242. The name Zubsolv was approved July 3, 2013 under NDA 204242.
3.	Evitex	62	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
4.	(b) (4) ***	61	Name submitted under NDA 201655 and found unacceptable. The name Opana ER was approved under NDA 201655 on December 9, 2011
5.	(b) (4) ***	60	Could not find information in DMEPA databases
6.	(b) (4) ***	59	The name was found unacceptable under ANDA 076563 because it contained the USAN (b) (4)
7.	Epimaz	58	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
8.	Ibutab	58	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
9.	(b) (4) ***	58	Name found unacceptable under NDA 022450. The name Ofirmev was approved on November 2, 2010 under NDA 022450

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No.	Name	POCA Score (%)	Failure preventions
10.	(b) (4)***	58	Secondary name submitted under NDA 022524. The name Zuplenz was approved on July 2, 2010 under NDA 022524
11.	(b) (4)***	57	Secondary name submitted under NDA (b) (4). The primary name (b) (4)*** was found acceptable under OSE review (b) (4)
12.	(b) (4)***	57	Secondary name submitted under NDA 022450. The name Ofirmev was approved on November 2, 2010 under NDA 022450
13.	amitraz	55	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
14.	(b) (4)***[***]	55	Name was found unacceptable under NDA 202342 under OSE review (b) (4) The product is currently marketed without a proprietary name
15.	(b) (4)***	54	Secondary name submitted under NDA 203312. The name Rytary*** was approved in OSE review 2012-2661 dated December 18, 2012
16.	Avitears	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
17.	Darpaz	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
18.	Espotabs	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
19.	Evacalm	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
20.	Evovist	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
21.	Evoxin	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
22.	EZ-Ox	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases

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No.	Name	POCA Score (%)	Failure preventions
23.	(b) (4) ***	54	Secondary name submitted under NDA 203858. The name Juxtapid was approved on December 21, 2012 under NDA 203858
24.	Ilopan	54	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
25.	(b) (4) ***	54	Secondary name submitted under NDA 021359. The name Rectiv was approved on June 21, 2011 under NDA 021359
26.	(b) (4) ***	54	Secondary name submitted under NDA 201739. The name Auvi-Q was approved on August 10, 2012 under NDA 201739
27.	(b) (4) ***	52	Could not find information in DMEPA databases
28.	Dilotab	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
29.	(b) (4) ***	52	The name was found unacceptable in OSE review (b) (4) due to (b) (4) in the name. The name is currently marketed without a proprietary name.
30.	Ecosave	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
31.	EDETOL	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
32.	(b) (4) ***	52	Secondary name under NDA 022532. The name BeYaz was approved on September 24, 2010 under NDA 022532
33.	Epogam	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
34.	(b) (4) ***	52	Could not find information in DMEPA databases
35.	Estra-D	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
36.	Evorel 100	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases

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No.	Name	POCA Score (%)	Failure preventions
37.	Evorel 25	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
38.	Evorel 50	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
39.	Evorel 75	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
40.	Neo-Tab	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
41.	potash	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
42.	Revitol	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
43.	(b) (4) ***	52	Tavita was found unacceptable in OSE review (b) (4) under NDA 022104. The product is currently marketed without a proprietary name
44.	Veta-K1	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
45.	Vita #12	52	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
46.	Acitak 200	51	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
47.	Acitak 400	51	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
48.	Acitak 800	51	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
49.	Ecopace	51	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
50.	Bio-Tab	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
51.	Ebufac	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases

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No.	Name	POCA Score (%)	Failure preventions
52.	edetate	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
53.	(b) (4)***	50	Secondary name submitted under ANA 202015. The name Yaela*** was found acceptable in OSE review 2011-521 dated September 18, 2013 under ANDA 202015
54.	Isocard	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
55.	Ivomec	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
56.	Ketotard	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
57.	Navoban	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
58.	Nefopam	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
59.	(b) (4)***	50	Secondary name submitted under NDA 203565. The name Injectafer was approved on July 25 2013 under NDA 203565
60.	(b) (4)***	50	Name found unacceptable under NDA 022387. The name Tyvaso was approved on July 30, 2009 under NDA 022387
61.	Zotex	50	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases
62.	Evict	56	Could not find information in Drugs@FDA, Redbook, or Facts and Comparisons databases

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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/

JAMES H SCHLICK
06/04/2014

LUBNA A MERCHANT on behalf of IRENE Z CHAN
06/04/2014