

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203093Orig1s000

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:	June 11, 2014
Application Type and Number:	NDA 203093
Product Name and Strength:	Vitekta (elvitegravir) Tablets, 85 mg and 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gilead Sciences, Inc.
Submission Date:	April 9, 2014
Panorama #:	2014-17202
DMEPA Primary Reviewer:	Mónica Calderón, PharmD, BCPS
DMEPA Team Leader:	Irene Chan, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Vitekta, 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 re-submitted a previously evaluated external name study by [REDACTED] (b) (4).

1.1 REGULATORY HISTORY

The Sponsor previously submitted the proposed proprietary name, Vitekta on March 28, 2012, and September 14, 2012 for IND 72177 and NDA 203093, respectively. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Vitekta, acceptable in OSE Review #2012-762 and 2012-2142, dated September 20, 2012, under both the IND and the NDA.

NDA 203093 was given a Complete Response April 26, 2013 due to facility inspection and product quality deficiencies. Thus, the sponsor re-submitted the name, Vitekta, under NDA 203093 as a part of the Class 2 resubmission for review on April 9, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the April 9, 2014 proprietary name submission.

- Intended Pronunciation: vye-TEK-tuh
- Active Ingredient: elvitegravir
- Indication of Use: Coadministered with a ritonavir-boosted protease inhibitor and with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults.
- Route of Administration: Oral
- Dosage Form: Tablet
- Strength: 85 mg or 150 mg
- Dose and Frequency: 150 mg once daily. If given in combination with HIV-1 protease inhibitors lopinavir/ritonavir or atazanvir/ritonavir, dose should be decreased to 85 mg once daily.
- How Supplied: 30-count bottles
- Storage: Controlled room temperature of 25°C (77°F); excursions are permitted between 15°C and 30°C (57°F and 86°F, respectively).

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 Antiviral 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 name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Vitakta 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 and twenty one 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. Thirty-six participants interpreted the name correctly (outpatient n=27, voice n=5, inpatient n=4). Twenty-six participants misinterpreted the letter 'k'; two for 'ch' (voice n=2), three for 'ck' (outpatient n=1, voice n=2), and 21 for 'c' (voice n=20, outpatient n=1). Seven participants misinterpreted the letter 'i' for 'y' (voice n=7). Four participants misinterpreted 'ekt' for 'ikl' (inpatient n=4). Twenty participants misinterpreted the letter 'e' for 'i' (inpatient n=20) and seven participants misinterpreted the letter 'i' for 'e' (voice n=1, inpatient n=6). 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 28, 2014, 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

¹USAN stem search conducted on April 14, 2014.

or low similarity for further evaluation. Two hundred and sixty two names were initially identified; however, 22 names were excluded as they were previously identified and evaluated in prior review (OSE Review # 2012-762 and 2012-2142).

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	237
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

Our analysis of the 240 names contained in Table 1 determined none of the names will 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 23, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAVP on June 6, 2014, they stated no additional concerns with the proposed proprietary name, Vitekta.

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, Vitekta, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your April 9, 2014 submission are altered, the name must be resubmitted for review.

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

² 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**

	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?

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

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 49\%$.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. 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 $\geq 70\%$).

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).			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as z and f), is there a different	Y/N	Do the syllables have different phonologic processes, such vowel

	number or placement of upstroke/downstroke letters present in the names?		reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ Alternative expressions of dose: 5 mL may be listed in the
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	<p>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.</p> <ul style="list-style-type: none">○ 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	<p>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 <u>with</u> overlapping or similar strengths or doses.</p>

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

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where 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. Proposed Name Study (Conducted on date of study)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Vitekta 85mg T po once daily with food</i></p>	<p>Vitekta 85 mg</p> <p>One tablet daily with food</p> <p>Disp #30</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Vitekta 85mg</i></p> <p><i>Take one tablet daily with food</i></p> <p><i># 30</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

274 People Received Study
121 People Responded

Study Name: Vitekta

Total	36	44	41	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
DIRECTA	0	1	0	1
VETEBLA	0	0	1	1

VETEBTA	0	0	1	1
VETEKTA	0	1	3	4
VETEKTAN	0	0	1	1
VIETEKTA	0	0	1	1
VITACTA	0	1	0	1
VITAKTA	0	1	0	1
VITCHTA	1	0	0	1
VITE_TA	1	0	0	1
VITECHTA	0	2	0	2
VITECKTA	1	2	0	3
VITECTA	1	20	0	21
VITEICTA	1	0	0	1
VITEIETA	1	0	0	1
VITEIKTA	1	0	0	1
VITEITA	1	0	0	1
VITEKTA	27	5	4	36
VITELETA	1	0	0	1
VITIBTA	0	0	1	1
VITIKBA	0	0	1	1
VITIKLA	0	0	4	4
VITIKTA	0	0	20	20
VITIKTAN	0	0	1	1
VITIRTA	0	0	1	1
VITIRTO	0	0	1	1
VITKBA	0	0	1	1
VYKECTA	0	1	0	1
VYKETA	0	1	0	1
VYTECHTA	0	1	0	1
VYTECTA	0	3	0	3
VYTEKA	0	1	0	1
VYTEKTA	0	4	0	4

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

No.	Proposed name: Vitekta Strength(s): 85 mg and 100 mg Usual Dose: 150 mg once daily. If given in combination with lopinavir/ritonavir or atazanvir/ritonavir, dose should be decreased to 85 mg once daily.	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Vitekta***	100	Proposed proprietary name of this review.
2.	(b) (4) ***	80	Name was found unacceptable under IND 72177. New name Vitekta*** currently under review.
3.	Bidex-A	72	<ul style="list-style-type: none"> The names do not appear orthographically similar due to the two additional upstrokes 'k', and 't' in Vitekta that are not present in Bidex-A, which gives the names a different shape when scripted. Phonetically, the third syllable in Vitekta does not sound similar to that of Bidex-A when spoken.

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

No.	Proposed Name	POCA Score (%)
4.	Vitrax	66
5.	Bitex	62
6.	FORTESTA	62
7.	Vistacot	62
8.	Vita-Respa	62
9.	Vaqta	60
10.	VASCEPA	60

11.	Veta-K1	60
12.	Viactiv***	60
13.	Zebeta	60
14.	Fenex-LA	59
15.	VIVACTIL	59
16.	Zyrtec-D	59
17.	Uritact	58
18.	Viekira***	58
19.	Vitabee 12	58
20.	Vitadye	58
21.	Bidex	56
22.	Evista	56
23.	LUNESTA	56
24.	VEETIDS	56
25.	VEETIDS '125'	56
26.	VEETIDS '250'	56
27.	VEETIDS '500'	56
28.	ZYTIGA	56
29.	Duetact	55
30.	Natesto***	55
31.	(b) (4)***	55
32.	Bionect	54
33.	DYMISTA	54
34.	OXECTA	54
35.	RAVICTI	54
36.	Sufenta	54
37.	TOTECT	54
38.	VANIQA	54
39.	VI-DOM-A	54
40.	VISINE-A	54

41.	Vistacon	54
42.	ZAVESCA	54
43.	MYTREX A	53
44.	Vienva***	53
45.	Bicitra	52
46.	Diabeta	52
47.	FLUTEX	52
48.	Fostex	52
49.	Gentex LA	52
50.	Photrexa***	52
51.	Povidex	52
52.	THIOTEPA	52
53.	UVADEX	52
54.	VAGISTAT-1	52
55.	VECTICAL	52
56.	VINCREX	52
57.	Vistaject-50	52
58.	(b) (4) ***	52
59.	ZETONNA	52
60.	(b) (4) ***	52
61.	Dasetta 1/35	51
62.	Dasetta 7/7/7	51
63.	Del-Beta	51
64.	Fototar	51
65.	LIDEX	51
66.	RANEXA	51
67.	Vyfemla	51
68.	ZOMETA	51
69.	Zyrtec	51
70.	AVITA	50

71.	BEXTRA	50
72.	Celexa	50
73.	Centex	50
74.	Cydectin	50
75.	Feridex	50
76.	FINACEA	50
77.	LEVITRA	50
78.	Menactra	50
79.	MENTAX	50
80.	NIPENT	50
81.	NUDEXTA	50
82.	PreNexa	50
83.	PYTEST	50
84.	RITUXAN	50
85.	(b) (4) ***	50
86.	Vestura***	50
87.	Viscoat	50
88.	VITAMIN D	50
89.	vitamin D3	50
90.	VITRASERT	50
91.	Zetia	50
92.	ZIBA-RX	50
93.	Zilactin	50
94.	ZIOPTAN	50

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

No.	Proposed name: Vitekta Strength(s): 85 mg and 150 mg Usual Dose: 150 mg once daily. If given in combination with lopinavir/ritonavir or atazanvir/ritonavir, dose should be decreased to 85 mg 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
95.	(b) (4) ***	55	<ul style="list-style-type: none"> The prefixes, infixes, and suffixes of the names have sufficient orthographic differences. The first and second syllables in the names sound different when spoken.
96.	Zerbaxa***	53	<ul style="list-style-type: none"> The prefixes and infixes of the names have sufficient orthographic differences. The first and second syllables in the names sound different when spoken.
97.	(b) (4) ***	52	<ul style="list-style-type: none"> The prefixes and suffixes have sufficient orthographic differences. The second and third syllables in the names sound different when spoken. No new name has been proposed for review.
98.	Vasotec	52	<ul style="list-style-type: none"> The infixes and suffixes of the names have sufficient orthographic differences. The second and third syllables in the names sound different when spoken.
99.	Vimpat	50	<ul style="list-style-type: none"> The prefixes of the names have sufficient orthographic differences. The first and second syllables in the names sound different when spoken. Vitekta has three syllables whereas Vimpat has two

syllables.

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
100.	(b) (4) ***	68	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-799). Product was approved under the proprietary name Tyvaso.
101.	Evitex	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
102.	(b) (4) ***	64	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1092). Product approved under new proprietary name (b) (4)
103.	(b) (4) ***	64	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-1165). Product approved under new proprietary name Atralin.
104.	Vitapap	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Zotex LA	64	Name identified in RxNorm database. Unable to find product characteristics in commonly

			used drug databases.
106.	(b) (4) ***	63	Proposed Proprietary Name found unacceptable by DMEPA ((b) (4)). Application has been given a Complete Response (b) (4)
107.	Vanex-LA	62	Name identified in RxNorm database. Product withdrawn from the market for safety reasons. No brand or generic equivalents available.
108.	Vortex	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
109.	(b) (4) ***	60	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-537). Product was approved under the proprietary name Fanapt.
110.	(b) (4) ***	60	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-1298). Product approved under new proprietary name Gilenya.
111.	(b) (4) ***	60	Proposed Proprietary Name found conditionally acceptable by DMEPA (OSE# 2008-1123); however, product approved under Venlafaxine Hydrochloride.
112.	(b) (4) ***	60	Proposed Proprietary Name

			found unacceptable by DMEPA (OSE# 2010-44). Product approved under new proprietary name (b) (4)
113.	Vitaped	60	NDA 20176 was withdrawn FR effective 6/16/2006. There are no generic equivalents available.
114.	XPECT-AT		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
115.	Ami-Tex LA	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
116.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-799). Product approved under the established name Diltiazem hydrochloride.
117.	Uritact	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
118.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA ((b) (4)). Name withdrawn by the Applicant.
119.	(b) (4) ***	58	Proposed Proprietary Name submitted by Applicant, but not reviewed.

			Application given Complete Response ^{(b) (4)} and application subsequently withdrawn ^{(b) (4)} .
120.	VioNex	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
121.	Vita #12	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
122.	Vitadil 2A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
123.	Vitadil 5A	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
124.	Zotex	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
125.	Zotex-12	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
126.	Dacex A	57	Name identified in RxNorm database. Unable to find product

			characteristics in commonly used drug databases.
127.	Depakota	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
128.	(b) (4) ***	57	Secondary name proposed for NDA 203585, name not officially submitted for evaluation. Product was approved under the proprietary name Synribo.
129.	Zetacet	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	(b) (4) ***	57	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1539). Product was approved under the proprietary name Caprelsa.
131.	Fentex	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
132.	Genexa	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
133.	Leventa	56	Name identified in RxNorm database. Unable to find product

			characteristics in commonly used drug databases.
134.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA ((b) (4)). The proposed name (b) (4) *** was found conditionally acceptable.
135.	(b) (4) ***	56	Secondary name proposed for NDA 203491, name not officially submitted for evaluation. Product was approved under the proprietary name Ilevro.
136.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-2142). Product was approved under the proprietary name Latuda.
137.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA ((b) (4)). The proposed name (b) (4) *** was found conditionally acceptable.
138.	Vistra	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
139.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1029). Product was approved under the proprietary name Lastacraft.

140.	Zit Stick	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
141.	Femtest	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
142.	(b) (4) ***	55	Secondary Proprietary Name withdrawn by Applicant (b) (4). Application given a Complete Response (b) (4).
143.	Tri-TEX	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
144.	Uni-TEX	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
145.	Viractin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
146.	Visqid AA	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
147.	Vita-E	55	Name identified in RxNorm

			<p>database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
148.	Ami-Tex	54	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
149.	Expecta	54	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
150.	(b) (4) ***	54	<p>Secondary name proposed for NDA 22192, name not officially submitted for evaluation.</p> <p>Product was approved under the proprietary name Fanapt.</p>
151.	Fiber Tab	54	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
152.	(b) (4) ***	54	<p>Secondary name proposed for IND (b) (4), name not officially submitted for evaluation.</p> <p>The proposed name (b) (4) *** was found conditionally acceptable.</p>
153.	Neotect***	54	<p>Name identified in 'Name entered by safety evaluator' database.</p> <p>Unable to find this name in any internal database.</p>

154.	(b) (4) ***	54	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
155.	Phentex LA	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
156.	Sil Tex	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
157.	Sitrex	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
158.	(b) (4) ***	54	Proposed Proprietary Name withdrawn by Applicant (b) (4) . Application given a Complete Response (b) (4) .
159.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-1122). Product was approved under the established name Venlafaxine Hydrochloride.
160.	Telcyta***	54	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.

161.	(b) (4) ***	54	<p>Secondary name proposed for NDA 203567.</p> <p>The proposed name Jublia*** was found conditionally acceptable..</p>
162.	(b) (4) ***	54	<p>Name identified in 'Name entered by safety evaluator' database.</p> <p>Unable to find this name in any internal database.</p>
163.	(b) (4) ***	54	<p>Name identified in 'Name entered by safety evaluator' database.</p> <p>Unable to find this name in any internal database.</p>
164.	Vitoxapap	54	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
165.	(b) (4) ***	54	<p>Secondary name proposed for IND (b) (4), name not officially submitted for evaluation.</p> <p>Product was approved under the proprietary name Kuvan.</p>
166.	Zotex PE	54	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
167.	Mytrex A	53	<p>ANDA 62598 was withdrawn FR effective 7/21/1999. There are no generic equivalents available.</p>
168.	Umecta***	53	<p>Name identified in 'Name</p>

			entered by safety evaluator' database. Unable to find this name in any internal database.
169.	Zotex C	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
170.	Zotex-D	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
171.	Betastat	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
172.	Betatan	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
173.	Bicitra	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
174.	Bimectin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
175.	Binaca	52	Name identified in RxNorm database. Unable to find product

			characteristics in commonly used drug databases.
176.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-377). Product was approved under the proprietary name Cenestin.
177.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (b) (4) Name withdrawn by the Applicant.
178.	Entex LA	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
179.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1196). Product was approved under the proprietary name Nucynta.
180.	(b) (4) ***	52	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
181.	Pri-Dextra	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
182.	Purtect	52	Name identified in RxNorm database. Unable to find product characteristics in commonly

			used drug databases.
183.	Santex LA	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
184.	Tavist DA	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
185.	Vagistat	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
186.	Valpax	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
187.	Vasaten	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
188.	VetStarch	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
189.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-50). Applicant submitted the name Vitekta for review.
190.	Viden	52	Name identified in RxNorm

			<p>database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
191.	Vidopen	52	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
192.	Visonex	52	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
193.	Vitacilina	52	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
194.	(b) (4) ***	52	<p>Proposed Proprietary Name found acceptable by DMEPA ((b) (4)).</p> <p>Application was given a Complete Response (b) (4) .</p>
195.	(b) (4) ***	52	<p>Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-929).</p> <p>Product was approved under the proprietary name Generess Fe.</p>
196.	(b) (4) ***	52	<p>Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-179).</p> <p>Product was approved under the proprietary name Zenpep.</p>
197.	Zida-Co	52	<p>Name identified in RxNorm</p>

			<p>database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
198.	(b) (4) ***	51	<p>Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2006-1004).</p> <p>Product was approved under the proprietary name Vimpat.</p>
199.	Fototar	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
200.	Guiatex LA	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
201.	Medex-LA	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
202.	Vanatab	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
203.	(b) (4) ***	51	<p>Proposed Proprietary Name found acceptable by DMEPA (b) (4)</p> <p>Application given a Complete Response (b) (4).</p>
204.	(b) (4) ***	51	<p>Name identified in 'Name entered by safety evaluator'</p>

			<p>database.</p> <p>Unable to find this name in any internal database.</p>
205.	(b) (4) ***	51	<p>Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2006-903).</p> <p>Product was approved under the proprietary name Performomist.</p>
206.	(b) (4) ***	51	<p>Product approved under established name Sodium Chloride 0.9%.</p>
207.	Visage	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
208.	Visine Extra	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
209.	(b) (4) ***	51	<p>Secondary name proposed for NDA 21359, name not officially submitted for evaluation.</p> <p>Product was approved under the proprietary name Rectiv.</p>
210.	Zaditen	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
211.	Zinc-DTPA	51	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly</p>

			used drug databases.
212.	(b) (4) ***	51	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
213.	Bentex	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
214.	BEXTRA	50	NDA 21341 was withdrawn FR effective on 8/2/2013. There are no generic equivalents available.
215.	(b) (4) ***	50	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
216.	Centex	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
217.	Cylectin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
218.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2006-12). Product was approved under the proprietary name Folutyn.
219.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by

			DMEPA (b) (4) Application has been given a Complete Response (b) (4). Applicant subsequently withdrew the application (b) (4).
220.	(b) (4) ***	50	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
221.	Lantex-LA	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
222.	Latex	50	Not a drug product. Latex is a milky substance harvested from rubber tree plants.
223.	Mintex	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
224.	Phentex	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
225.	(b) (4) ***	50	Tertiary name proposed for NDA 200045, name not officially submitted for evaluation. Product was approved under the proprietary name Amturnidine.
226.	ReFacto	50	Name identified in RxNorm

			<p>database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
227.	Sinex	50	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
228.	(b) (4) ***	50	<p>Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-572).</p> <p>(b) (4) was withdrawn and Aptiom*** was found conditionally acceptable.</p>
229.	Tisept	50	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
230.	(b) (4) ***	50	<p>Name identified in 'Name entered by safety evaluator' database.</p> <p>Unable to find this name in any internal database.</p>
231.	(b) (4) ***	50	<p>Secondary name proposed for IND (b) (4), name not officially submitted for evaluation.</p> <p>(b) (4) *** found conditionally acceptable as proprietary name under IND.</p>
232.	Vetalar	50	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>

233.	Vetribute	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
234.	(b) (4) ***	50	Secondary name proposed for IND (b) (4), name not officially submitted for evaluation (b) (4) *** was found conditionally acceptable as proprietary name under IND.
235.	Vicotuss	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
236.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1586). Product was approved under the proprietary name Jetrea.
237.	(b) (4) ***	50	Name identified in 'Name entered by safety evaluator' database. Unable to find this name in any internal database.
238.	(b) (4) ***	50	Secondary name proposed for IND (b) (4), name not officially submitted for evaluation. Prolensa*** found conditionally acceptable as proprietary name under IND.
239.	Zita	50	Name identified in RxNorm

			<p>database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>
240.	Zymecot	50	<p>Name identified in RxNorm database.</p> <p>Unable to find product characteristics in commonly used drug databases.</p>

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/s/

MONICA M CALDERON
06/11/2014

LUBNA A MERCHANT on behalf of IRENE Z CHAN
06/11/2014

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review--Final

Date: March 13, 2013

Reviewer: Morgan Walker, Pharm.D., MBA
Division of Medication Error Prevention and Analysis

Team Leader: Jamie Wilkins Parker, Pharm.D.
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Vitekta (Elvitegravir) Tablets, 85 mg and 150 mg

Application Type/Number: NDA 203093

Applicant/sponsor: Gilead Sciences

OSE RCM #: 2012-2226

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Vitekta (Elvitegravir) Tablets, 85 mg and 150 mg is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, *Vitekta*, acceptable in OSE Review # 2012-2142 dated September 20, 2012. We also found the name Vitekta acceptable for IND 072177 (OSE Review # 2012-762). Both the IND and NDA requests for proprietary name review were evaluated in the same review, as there were overlapping submission timelines.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review # 2012-2142. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Vitekta and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 1, 2013. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on November 8, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Vitekta, did not identify any vulnerabilities that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Vitekta, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Anti-Viral Products (DAVP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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

4 REFERENCES

1. **OSE Reviews: 2012-2142 (NDA 203093); 2012-762 (IND 072177) (combined review)**
2. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved 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](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. ***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.
4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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/s/

MORGAN A WALKER
03/13/2013

JAMIE C WILKINS PARKER
03/13/2013

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: September 20, 2012

Reviewer: Morgan Walker, Pharm.D., MBA
Division of Medication Error Prevention and Analysis

Acting Team Leader: Jamie Wilkins Parker, Pharm.D.
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh.
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Vitekta (Elvitegravir) 85 mg and 150 mg Tablet

Application Type/Number: IND 072177 and NDA 203093

Applicant/Sponsor: Gilead Sciences, Inc.

OSE RCM #: 2012-762 for IND 072177
2012-2226 for NDA 203093

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Vitekta, 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.

1.1 REGULATORY HISTORY

DMEPA completed a proprietary name review in OSE Review # 2011-2498 for the proposed primary proprietary name (b) (4) and alternate name (b) (4). On December 22, 2011, the Agency found the proposed proprietary name (b) (4) unacceptable because it is orthographically similar to and shares overlapping product characteristics with the marketed product (b) (4). Although it had not been officially submitted for review, the Agency's preliminary evaluation of the proposed secondary name, (b) (4) determined that it too is vulnerable to name confusion with (b) (4).

Gilead submitted a Request for Proprietary Name Review for IND 072177 on March 28, 2012, and September 14, 2012 for NDA 2030903 for the proposed name Vitekta, the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 28, 2012 proprietary name submission.

- Proprietary Name: Vitekta
- Established Name: Elvitegravir
- Indication of Use: Elvitegravir, coadministered with a ritonavir-boosted protease inhibitor and with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 85 mg and 150 mg
- Dose: 1 tablet once daily
- How Supplied: 30-count bottles
- Storage: This product should be stored at a controlled room temperature of 25°C (77°F); excursions are permitted between 15°C and 30°C (57°F and 86°F, respectively)

2. RESULTS

The following sections provide the 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 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

The April 9, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

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. The Applicant did not submit a derivation of the name with this submission.

2.2.3 FDA Name Simulation Studies

Thirty-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Twenty-five participants interpreted the inpatient and outpatient prescriptions correctly. All of the voice study participants (n=10) misinterpreted the proposed name. The most common misinterpretation was replacing the 'k' in Vitekta with the letter 'c'. The misinterpretations did not overlap with or appear or sound similar to any currently marketed products. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, April 6, 2012 e-mail, the Division of Anti-Viral Products (DAVP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Vitekta. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Vitekta identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by ^{(b) (4)} not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study)

Look Similar					
	<i>Name</i>	<i>Source</i>		<i>Name</i>	<i>Source</i>
1	Vitamin A	FDA	27	Byetta	External name study
2	Vitalets	FDA	28	Krystexxa	External name study
3	Vibativ	FDA	29	Lidex-E	External name study
4	Velivet	FDA	30	Tekturna	External name study
5	Vectibix	FDA	31	Viagra	External name study
6	Veletri	FDA	32	Vidaza	External name study
7	Vivitrol	FDA	33	Videx	External name study
8	Xeloda	FDA	34	Videx EC	External name study
9	Velcade	FDA	35	Viracept	External name study
10	Vitellin	FDA	36	Vitamin K	External name study
11	Nitrek	FDA	37	Vitec	External name study
12	Relistor	FDA	38	Vytorin	External name study
13	(b) (4) ***	FDA	39	Zyprexa	External name study
14	(b) (4) ***	FDA	40	Vosol HC	FDA
15	Vtreta	FDA			
16	(b) (4) ***	FDA			
17	Vitrase	FDA			
18	Valstar	FDA			
19	Valtrex	FDA			
20	Vitazol	FDA			
21	Votrient	FDA			
22	Vi-Dan D.C.	FDA			
23	Rilutek	FDA			
24	Vitafol	FDA			
25	Ritalin	FDA			
26	Nitrodur	FDA			

Look Similar			
41	Vibra Tabs	FDA	
42	Venastat	FDA	
43	Vental	FDA	
44	Viatexx-60	FDA	
45	Vibal LA	FDA	
Look and Sound Similar			
46	Victoza	Both FDA and External Name Study	

Our analysis of the 46 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 40 names will not pose a risk for confusion as described in Appendix D and E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Anti-Viral Products via e-mail on July 9, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Anti-Viral Product on July 13, 2012, they stated no additional concerns with the proposed proprietary name, Vitekta.

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, Vitekta, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your September 14, 2012 submission are altered, the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

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

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. ***Access Medicine*** (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. ***Red Book*** (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. ***Lexi-Comp*** (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations*** (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy*** (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP 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 provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

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.

4. 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.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'V'	U	F
Lower case 'v'	r, u, x	f
Lower case 'i'	e	Any vowel
Lower case 't'	r, f, x, A	d
Lower case 'e'	a, i, l, o, u, p	Any vowel
Lower case 'k'	x, h, la	c, g
Lower case 't'	r, f, x, A	d
Lower case 'a'	el, ci, cl, d, o, u	Any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Vitakta Study (Conducted on April 6, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> <i>Vitakta 150mg 1 tablet daily</i></p> <p><u>Outpatient Prescription:</u> <i>Vitakta 85mg #30 1 po daily</i></p>	<p>Vitakta 85 mg Take 1 tablet by mouth daily Disp: #30</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study

38 People Responded

Study Name: Vitakta

Total	13	10	15		
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL	
VILEKTA	2	0	0	2	
VITECTA	0	9	0	9	
VITEKTA	10	1	14	25	
VITEKTRA	0	0	1	1	
VITELETA	1	0	0	1	

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

	Proprietary Name	Active Ingredient	Similarity to Vitekta	Failure preventions
1	Velivet	Ethinyl Estradiol and Desogestrel	Look Alike	The pair have sufficient orthographic and/or phonetic differences
2	Vivitrol	Naltrexone	Look Alike	The pair have sufficient orthographic and/or phonetic differences
3	Vitrase	Hyaluronidase	Look Alike	The pair have sufficient orthographic and/or phonetic differences
4	Valtrex	Valacyclovir	Look Alike	The pair have sufficient orthographic and/or phonetic differences
5	Venastat	Horse Chestnut	Look Alike	The pair have sufficient orthographic and/or phonetic differences
6	Vental	Guaifenesin/ Phenylpropanolamine Hydrochloride	Look Alike	The pair have sufficient orthographic and/or phonetic differences
7	Vitazol	Metronidazole	Look Alike	The pair have sufficient orthographic and/or phonetic differences
8	Vi Dan D.C.	Danthron/Docusate Calcium	Look Alike	The pair have sufficient orthographic and/or phonetic differences
9	Vitafol	Multiple Vitamins	Look Alike	The pair have sufficient orthographic and/or phonetic differences
10	Vibral LA	Cyanaocobalamin	Look Alike	The pair have sufficient orthographic and/or phonetic differences
11	Vosol HC	Acetic Acid, Propylene Glycol Diacetate, and Hydrocortisone	Look Alike	The pair have sufficient orthographic and/or phonetic differences
12	Victoza	Liraglutide	Look Alike and Sound Alike	The pair have sufficient orthographic and/or phonetic differences
13	Byetta	Exenatide	Look Alike	The pair have sufficient orthographic and/or phonetic differences
14	Krystexxa	Pegloticase	Look Alike	The pair have sufficient orthographic and/or phonetic differences
15	Videx	Didanosine	Look Alike	The pair have sufficient orthographic and/or phonetic differences
16	Videx EC	Didanosine	Look Alike	The pair have sufficient orthographic

	Proprietary Name	Active Ingredient	Similarity to Vitakta	Failure preventions
				and/or phonetic differences
17	Vitamin K	N/A	Look Alike	The pair have sufficient orthographic and/or phonetic differences
18	Vitamin A	N/A	Look Alike	The pair have sufficient orthographic and/or phonetic differences
19	Vytorin	Ezetimibe/Simvastatin	Look Alike	The pair have sufficient orthographic and/or phonetic differences
20	Tekturna	Aliskiren Fumarate	Look Alike	The pair have sufficient orthographic and/or phonetic differences
21	Viagra	Sildenafil Citrate	Look Alike	The pair have sufficient orthographic and/or phonetic differences
22	Vidaza	Azacitidine	Look Alike	The pair have sufficient orthographic and/or phonetic differences
23	Viracept	Nelfinavir Mesylate	Look Alike	The pair have sufficient orthographic and/or phonetic differences
24	Vitec	Vitamin E	Look Alike	The pair have sufficient orthographic and/or phonetic differences
25	Zyprexa	Olanzapine	Look Alike	The pair have sufficient orthographic and/or phonetic differences
26	Lidex E	Fluocinonide	Look Alike	The pair have sufficient orthographic and/or phonetic differences
27	Nitrodur	Nitroglycerin	Look Alike	The pair have sufficient orthographic and/or phonetic differences
28	Vtreta	Isotretinoin	Look Alike	The pair have sufficient orthographic and/or phonetic differences
29	Vibra Tabs	Doxycycline	Look Alike	The pair have sufficient orthographic and/or phonetic differences
30	Viatexx 60	Nutriceutical	Look Alike	The pair have sufficient orthographic and/or phonetic differences
31	(b) (4)	Elvitegravir	Look Alike	RCM # 2011-2498; this name was submitted as an alternate name to (b) (4), however was not formally submitted to the Agency as a proposed proprietary name
32	Vitellin	Lecithin	Look Alike	Not a drug product; a protein found in egg yolk

	Proprietary Name	Active Ingredient	Similarity to Vitakta	Failure preventions
33	(b) (4)	Alcaftadine	Look Alike	NDA 22134; Name denied by DMEPA on 1/26/2010 and name withdrawn on 5/7/2010
34	(b) (4)	Brivaracetam	Look Alike	IND (b) (4); Name denied my DMEPA on (b) (4); new proposed proprietary name, (b) (4), submitted on (b) (4)
35	Votrient	Pazopanib	Look Alike	The pair have sufficient orthographic and/or phonetic differences

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

	Proposed name: Vitakta Dosage Form: Tablet Strength(s): 85 mg and 150 mg Usual Dose: 1 tablet once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
36	Vibativ (Telavancin) Strength: 250 mg, 750 mg Dosage Form: Powder for injection Dose: 10 mg/kg every 24 hours for 1-2 weeks Route of administration: Intravenous	<u>Orthographic similarity:</u> Both names begin with 'Vi' and have an upstroke in the third and fifth positions. <u>Overlapping product characteristics:</u> Frequency: Daily	<u>Orthographic differences:</u> Vitekta has an extra upstroke 't' in the sixth position whereas Vibativ does not, therefore giving the names different appearances when scripted. <u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. 250 mg and 750 mg Dose: 1 tablet vs. 10 mg/kg (average dose: 72 kg patient = 720 mg)

37	<p>Vectibix (Panitumumab)</p> <p>Strength: 20 mg/mL (5 mL, 10 mL)</p> <p>Dosage Form: Solution for injection</p> <p>Dose: 6 mg/kg every 2 weeks</p> <p>Route of administration: Intravenous</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with the letter ‘V’.</p> <p>Both names contain upstrokes in the sixth position.</p> <p><u>Overlapping product characteristics:</u></p> <p>None</p>	<p><u>Orthographic differences:</u></p> <p>The prefix in Vectibix ‘Vect’ appears longer than Vitekta ‘Vit’ when scripted.</p> <p><u>Differentiating product characteristics:</u></p> <p>Strength: 85 mg and 150 mg vs. single strength which would not be required to be written on a prescription.</p> <p>Dose: 1 tablet vs. 6 mg/kg (average dose: 72 kg patient = 432 mg)</p>
38	<p>Veletri (Epoprostenol)</p> <p>Strength: 1.5 mg</p> <p>Dosage Form: Powder for injection</p> <p>Dose: 2 ng/kg/minute</p> <p>Route of administration: Intravenous</p>	<p><u>Orthographic similarity:</u></p> <p>Both names begin with ‘V’ and have an upstroke in the third and fifth positions.</p> <p><u>Overlapping product characteristics:</u></p> <p>Numerical strength similarity: 150 vs. 1.5</p>	<p><u>Orthographic differences:</u></p> <p>The upstroke in the third position in the name Vitekta is a cross stroke whereas the upstroke in the same position in the name Veletri is not.</p> <p>Vitekta has an extra upstroke ‘t’ in the sixth position whereas Veletri does not.</p> <p><u>Differentiating product characteristics:</u></p> <p>Dose: 1 tablet vs. 2 ng/kg/minute</p> <p>Frequency: Once daily vs. continuous infusion</p>

39	<p>Xeloda (Capecitabine) Strength: 150 mg, 500 mg Dosage Form: Tablet Dose: 1000 mg/m² to 1250 mg/m² twice daily for 2 weeks, every 21 days Route of administration: Oral</p>	<p><u>Orthographic similarity:</u> ‘X’ and ‘V’ may look similar when scripted. Both names have an upstroke in the third and fifth positions. Both names end with the letter ‘a’. <u>Overlapping product characteristics:</u> Strength: 150 mg Route of administration: Oral Dosage form: Tablet</p>	<p><u>Orthographic differences:</u> Vitekta has an extra upstroke ‘t’ in the sixth position whereas Xeloda does not. <u>Differentiating product characteristics:</u> Dose: 1 tablet vs. 1000 mg/m² (2 tablets) to 1250 mg/m² (2 and a half tablets)</p>
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40	<p>Velcade (Bortezomib) Strength: 3.5 mg Dosage Form: Powder for injection Dose: 1.3 mg/m² days 1, 4, 8, 11, 22, 25, 29, and 32 of a 42-day treatment cycle for 4 cycles, followed by 1.3 mg/m² days 1, 8, 22, and 29 of a 42-day treatment cycle for 5 cycles Route of administration: Intravenous and subcutaneous</p>	<p><u>Orthographic similarity:</u> Both names begin with ‘V’ and have an upstroke in the third position.</p> <p><u>Overlapping product characteristics:</u> None</p>	<p><u>Orthographic differences:</u> The upstroke in the third position in the name Vitakta is a cross stroke whereas the upstroke in the same position in the name Velcade is not. Vitekta has an upstroke in the fifth position whereas Velcade does not.</p> <p><u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. 3.5 mg Dose: 1 tablet vs. 1.3 mg/m² (for a 1.72 m² patient, the dose is 2.236 mg) days 1, 4, 8, 11, 22, 25, 29, and 32 of a 42-day treatment cycle for 4 cycles, followed by 1.3 mg/m² days 1, 8, 22, and 29 of a 42-day treatment cycle for 5 cycles Route of administration: Oral vs. intravenous and subcutaneous</p>
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41	<p>Nitrek (Nitroglycerin)</p> <p>Strength: 0.2 mg/hr, 0.4 mg/hr, 0.6 mg/hr</p> <p>Dosage Form: Transdermal patch</p> <p>Dose: 0.2-0.4 mg/hour initially and titrate to doses of 0.4-0.8 mg/hour</p> <p>Route of administration: Transdermal</p>	<p><u>Orthographic similarity:</u></p> <p>‘N’ and ‘V’ may look similar when scripted.</p> <p>Both names have an upstroke in the third position and have the letter ‘k’.</p> <p><u>Overlapping product characteristics:</u></p> <p>Frequency: Once daily</p>	<p><u>Orthographic differences:</u></p> <p>Vitekta has a cross stroke is the sixth position and ends with the letter ‘a’ whereas Nitrek does not.</p> <p>Vitekta has an upstroke in the fifth position whereas Nitrek does not.</p> <p><u>Differentiating product characteristics:</u></p> <p>Strength: 85 mg and 150 mg vs. 0.2 mg/hr, 0.4 mg/hr, 0.6 mg/hr</p> <p>Dose: 1 tablet once daily vs. 0.2-0.4 mg/hour initially and titrate to doses of 0.4-0.8 mg/hour</p> <p>Product is deactivated in Redbook; no information available about the product in DARRTS. However, prescribers could still use this name to reference existing similar products currently marketed.</p>
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42	<p>Relistor (Methylnaltrexone)</p> <p>Strength: 8 mg/0.4 mL; 12 mg/0.6 mL prefilled syringe; 12 mg/0.6 mL vial</p> <p>Dosage Form: Solution for injection</p> <p>Dose: <38 kg: 0.15 mg/kg (round dose up to nearest 0.1 mL of volume)</p> <p>38 to <62 kg: 8 mg</p> <p>62-114 kg: 12 mg</p> <p>>114 kg: 0.15 mg/kg (round dose up to nearest 0.1 mL of volume)</p> <p>Route of administration: Subcutaneous</p>	<p><u>Orthographic similarity:</u></p> <p>‘R’ and ‘V’ can look similar when scripted.</p> <p>Both names have an upstroke in the third position.</p> <p><u>Overlapping product characteristics:</u></p> <p>None</p>	<p><u>Orthographic differences:</u></p> <p>Vitekta has a cross stroke in the third position whereas Relistor does not.</p> <p>Vitekta has an upstroke in the fifth position whereas Relistor does not.</p> <p>The end of Relistor ‘tor’ appears longer when scripted compared to the end of Vitekta ‘ta’.</p> <p><u>Differentiating product characteristics:</u></p> <p>Strength: 85 mg and 150 mg vs. 8 mg/0.4 mL; 12 mg/0.6 mL prefilled syringe; 12 mg/0.6 mL vial</p> <p>Dose: : 1 tablet vs.</p> <p><38 kg: 0.15 mg/kg (round dose up to nearest 0.1 mL of volume)</p> <p>38 to <62 kg: 8 mg</p> <p>62-114 kg: 12 mg</p> <p>>114 kg: 0.15 mg/kg (round dose up to nearest 0.1 mL of volume)</p> <p>Frequency: Once daily vs. once every other day</p>
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43	<p>Valstar (Valrubicin) Strength: 40 mg/mL Dosage Form: Solution for injection Dose: 800 mg once weekly (retain for 2 hours) for 6 weeks Route of administration: Intravesical</p>	<p><u>Orthographic similarity:</u> Both names begin with ‘V’ and have an upstroke in the third and fifth positions. <u>Overlapping product characteristics:</u> None</p>	<p><u>Orthographic differences:</u> Vitekta has an extra upstroke ‘t’ in the sixth position whereas Valstar does not. <u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. single strength which would not be required to be written on a prescription. Dose: 1 tablet vs. 800 mg Frequency: Once daily vs. weekly</p>
44	<p>Rilutek (Riluzole) Strength: 50 mg Dosage Form: Tablet Dose: 50 mg every 12 hours Route of administration: Oral</p>	<p><u>Orthographic similarity:</u> ‘R’ and ‘V’ can look similar when scripted. Both names have an upstroke in the third position. <u>Overlapping product characteristics:</u> None</p>	<p><u>Orthographic differences:</u> Vitekta has an extra upstroke ‘t’ in the sixth position whereas Rilutek does not. Rilutek has an upstroke in the 7th position whereas Vitekta does not. <u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. single strength which would not be required to be written on a prescription. Dose: 1 tablet once daily vs. 1 tablet every 12 hours</p>

45	<p>Ritalin (Methylphenidate)</p> <p>Strength/Dosage Form: Sustained-release (SR) formulation: 20 mg; Immediate- release formulation: 5 mg, 10 mg, 20 mg; Long-acting (LA) formulation: 10 mg, 20 mg, 30 mg, 40 mg</p> <p>Dose: Sustained-release formulation: Once daily dosing; Long-acting formulation: 20 mg once daily; Immediate- release formulation for narcolepsy: 10 mg 2 to 3 times/day</p> <p>Route of administration: Oral</p>	<p><u>Orthographic similarity:</u> ‘R’ and ‘V’ can look similar when scripted.</p> <p>Both names have an upstroke in the third and fifth position.</p> <p><u>Overlapping product characteristics:</u> Dose: One tablet once daily Route of administration: Oral Dosage form: Tablet</p>	<p><u>Orthographic differences:</u> Vitekta has a cross stroke ‘t’ in the sixth position whereas Ritalin does not.</p> <p><u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. SR formulation: 20 mg; Immediate- release formulation: 5 mg, 10 mg, 20 mg; LA formulation: 10 mg, 20 mg, 30 mg, 40 mg</p>
46	<p>Vitalets (Children’s Vegan Multivitamin)</p> <p>Dosage Form: Tablet</p> <p>Dosing: Children under 4 years old take 1 tablet daily; children 4 years old and older take 2 tablets daily</p> <p>Route of administration: Oral</p>	<p><u>Orthographic similarity:</u> Both names begin with ‘Vit’ and have an upstroke in the third and fifth positions.</p> <p><u>Overlapping product characteristics:</u> Dosing: 1 tablet once daily Route of administration: Oral</p>	<p><u>Differentiating product characteristics:</u> Strength: 85 mg and 150 mg vs. single strength which would not be required to be written on a prescription.</p>

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/s/

MORGAN A WALKER
09/20/2012

CAROL A HOLQUIST
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