CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206099Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	October 22, 2015
Application Type and Number:	NDA 206099
Product Name and Strength:	Onzetra Xsail (Sumatriptan) Nasal Powder 11 mg per nosepiece
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Avanir Pharmaceuticals
Panorama #:	2015-1595257
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onzetra Xsail, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Avanir previously submitted the proposed proprietary name, Onzetra on May 26, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Onzetra acceptable in OSE Review # 2015-546766, dated August 13, 2015.

Subsequently, on September 22, 2015, Avanir submitted an amendment to request for proprietary name review to include the device related modifier Xsail in the proprietary name, i.e. Onzetra Xsail.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 22, 2015 proprietary name submission.

- Intended Pronunciation: On ze trah X-sail
- Active Ingredient: Sumatriptan
- Indication of Use: Acute migraine with or without aura
- Route of Administration: Nasal
- Dosage Form: Nasal powder formulation for intranasal deposition to be used with Xsail Breath Powered Delivery Device
- Strength: 11 mg Sumatriptan base per nosepiece
- Dose and Frequency: Two nosepieces (each 11 mg) for a total of a 22 mg dose. 11 mg is delivered nasally into each nostril via the delivery technology at the first sign of a migraine; if a second dose is needed it can be repeated after 2 hours. Not to exceed more than 44 mg in a 24 hour period.
- How Supplied:
    - Commercial: Available in kits containing 8 doses. Each kit contains 8 pouches containing two one-time use nosepieces per pouch (each nosepiece contains 11 mg sumatriptan, equivalent to 15.4 mg of sumatriptan succinate) and 2 Xsail reusable devices
    - Professional Sample: Each carton contains Xsail reusable device and 2 one-time use nosepieces (one dose) contained in 1 pouch
- Storage: Store at room temperature between 20° C to 25° C (68° F to 77° F), with excursions permitted between 15° C to 30° C (59° F to 86° F). Do not store in the

refrigerator or freezer. Use nosepiece immediately after removing from foil pouch.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product, however they noted that the name Xsail "easily evokes the word 'exhale'" and expressed concern that the name could lead to medication errors since "the drug product is to be administered via nasal inhalation". DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's misbranding assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Onzetra Xsail, in their submission. This proprietary name is comprised of two words, a root name 'Onzetra' and a modifier 'Xsail'. The root name and the modifier do not contain any components (i.e., route of administration, numbers, etc.) that are misleading or can contribute to medication errors.

The root name, Onzetra, was reviewed and conditionally approved in a previous review[2] and is not further evaluated in this review. Our evaluation of the modifier is discussed in Section 2.2.5.

2.2.3 FDA Name Simulation Studies

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

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[1]USAN stem search conducted on September 15, 2015.

[2] Myers D. Proprietary Name Review for ONZETRA (NDA 206099). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Aug 13. 25 p. OSE RCM No.: 2015-546766.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 8, 2015 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 FMEA of Modifier Xsail

The Applicant proposes to use the modifier 'Xsail' for this product and indicated that the modifier, 'Xsail,' represents the device that is used with the medication but has no intended meaning. They did not provide data to support that the proposed modifier is understood by health care practitioners and patients; however, the naming convention to use a modifier to represent a specific device has been used before (e.g. Advair Diskus and Flovent Diskus). The Xsail device is not available on its own and we do not anticipate that the modifier 'Xsail' will be written on its own without the root name.

OPDP determined that the proposed name would not misbrand the proposed product, however they noted that the modifier "Xsail" easily evokes the word, "exhale" and since this drug product is to be administered via nasal inhalation, OPDP is concerned that the name "Xsail" could lead to medication errors. Although this product is administered via nasal inhalation, the device is breath powered and the user must exhale (blow) into the mouthpiece to propel the medication into the nostrils. Thus, the modifier "Xsail", and the meaning it may evoke, is consistent with the use of the product. Additionally, the modifier may help users identify that this is a unique method of delivery of drug for intranasal administration. Furthermore, "Xsail" should help to differentiate this inhaler from other nasal inhalers which do not rely on exhalation to deliver the dose. Therefore, we consider the use of this modifier appropriate for this product.

We note that the modifier "Xsail" is phonetically similar to the modifier "XL". This was seen in our prescription simulation study, where 5 participants misinterpreted the modifier "Xsail" for "XL" in the verbal study. The modifier "XL" has been commonly used to convey a modified dosage formulation for extended release products which are formulated to make the drug substance available over an extended period of time following ingestion. Since Onzetra Xsail is only available as an immediate release product and is not for oral use, it is unlikely that the modifier "Xsail", if misinterpreted, would result in a medication error.

We note that modifiers may sometimes be omitted. If the modifier Xsail is omitted, there is no other Onzetra product currently marketed from which Onzetra Xsail will need to be distinguished. Additionally, we did not identify any names that can be confused with 'Xsail' during our review of the ISMP's List of Products with Drug Name Suffixes[3]. Therefore, we do not find the modifier, Xsail, misleading or vulnerable to confusion and find it acceptable for this product.

[3] Institute for Safe Medication Practices. ISMP's List of Products with Drug Name Suffixes. 2010.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on October 14, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on October 16, 2015, they stated no additional concerns with the proposed proprietary name, Onzetra Xsail.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-496-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 22, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***ISMP's List of Products with Drug Name Suffixes***

APPENDICES

Appendix A

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

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

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.

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

Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. 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.

c. 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Onzetra Xsail Study (Conducted on September 18, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Onzetra Xsail administer 22mg intranasally	Onzetra Xsail Use As Directed Disp #1
Outpatient Prescription: Onzetra Xsail Use as Directed Disp #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Onzetra Xsail

243 People Received Study
70 People Responded

Study Name: Onzetra Xsail

Total	22	23	25	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ANZETIAX HAIL	0	0	1	1
ANZETRA EXHALE	0	1	0	1
ANZETRA XSAIL	0	0	5	5
HUNZETRA XL	0	1	0	1
ONCENTRA XL	0	1	0	1
ONEZTRA XSUIL	1	0	0	1
ONSETRA EXHALE	0	1	0	1
ONSETRA-XHALE	0	1	0	1
ONZECTRA X-ALE	0	1	0	1
ONZENTRA EXHALE	0	3	0	3
ONZENTRA EXSAIL	0	1	0	1
ONZENTRA XSAIL	1	0	1	2
ONZETHRA XSAIL	0	0	1	1
ONZETRA EXHALE	0	6	0	6
ONZETRA XALE	0	1	0	1
ONZETRA XCUIT	1	0	0	1
ONZETRA XL	0	3	0	3
ONZETRA XRNIL	0	0	1	1
ONZETRA XSAID	0	0	1	1
ONZETRA XSAIL	18	0	14	32
ONZETRA XSAIL ADMINISTER	0	0	1	1
ONZETRA XSUIL	1	0	0	1
ONZETRAXCEL	0	1	0	1
UNZETRA EXSALE	0	1	0	1
UNZETRA XAL	0	1	0	1

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

/s/

JUSTINE HARRIS
10/22/2015

DANIELLE M HARRIS
10/22/2015

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 13, 2015
Application Type and Number:	NDA 206099
Product Name and Strength:	Onzetra (Sumatriptan) Nasal Powder 11 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Avanir Pharmaceuticals
Panorama #:	2015-546766
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onzetra, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4) *** on January 27, 2014. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) *** unacceptable from a misbranding perspective in OSE Review #2014-16850, dated March 4, 2014.

Thus, the Applicant submitted the name, Onzetra, for review on May 6, 2014. In OSE Review# 2014-17318, dated July 14, 2014, this name was granted conditional acceptance. The Agency provided a Complete Response Letter on November 26, 2014. On April 15, 2015 The Agency held a teleconference with Avanir Pharmaceuticals to inform the Applicant that the proposed proprietary name, Onzetra, could result in medication errors due to confusion with another pending proprietary name, (b) (4) ***. The Applicant submitted a complete response on May 6, 2015 and on May 26, 2015, Avanir submitted a re-request for review of the proposed proprietary name Onzetra.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 26, 2015 proprietary name submission.

- Intended Pronunciation: On ze' trah
- Active Ingredient: Sumatriptan Succinate
- Indication of Use: Acute migraine with or without aura
- Route of Administration: Nasal
- Dosage Form: Nasal powder formulation for intranasal deposition to be used with Xsai® Breath Powdered Delivery Device
- Strength: 11 mg per nosepiece
- Dose and Frequency: 22 mg delivered nasally (11 mg in a disposable nosepiece, one for each nostril; two nosepieces equals one does) as needed at the first sign of a migraine; may repeat after 2 hours if needed; not to exceed more than 44 mg in 24 hour period
- How Supplied: One device body with protective lid and a total of 16 nose pieces (2 nosepieces per dose; 8 total doses per pack). Nosepieces are packaged in a foil pouch containing disposable nosepieces. There will not be a refill pack, but rather a patient will get a new device and disposable nosepieces with each prescription.
- Storage: Controlled room temperature

- Container and Closure Systems: Foil (b) (4) pouch

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 30, 2015, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation.

[1] USAN stem search conducted on June 1, 2015.

[2] POCA search conducted on June 1, 2015.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	110
Low similarity name pair: combined match percentage score ≤49%	0

2.2.5 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Onzetra will be available in strength of 11 mg. Since this is not a commonly marketed strength, we searched the (b) (4) (b) (4) database to identify any names with potential orthographic, spelling, and phonetic similarities with Onzetra that were not identified in POCA, and found to have an overlap in strength with Onzetra.

Table 1A. (b) (4) Search Results	POCA score
none	

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

Our analysis of the 111 names contained in Table 1 determined that none of these names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA contacted the Division of Neurology Products (DNP) via e-mail on July 17, 2015. At that time we requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on July 27, 2015, they stated no additional concerns with the proposed proprietary name, Onzetra.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact CDR Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 26, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or 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. [3]

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

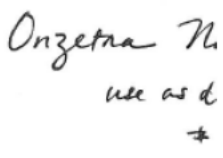
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Onzetra Nasal Powder Study (Conducted on June 12, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Onzetra Nasal Powder Use as directed. Dispense #1
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

245 People Received Study
73 People Responded

Study Name: Onzetra Nasal Spray

Total	22	21	30	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
`ONJETRA NASAL POWDER	1	0	0	1
ONSETRA NASAL POWDER	0	1	0	1
ONZATRA NASAL POWDER	1	0	0	1
ONZENTRA	1	0	0	1
ONZETNA NASAL POWDER	11	0	0	11

ONZETNA NASLA POWDER	1	0	0	1
ONZETRA	0	4	0	4
ONZETRA NASAL POWDER	7	12	9	28
ONZITRA	0	0	1	1
ONZITRA NASAL POWDER	0	0	20	20
UNZETRA NASAL POWDER	0	4	0	4

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

No.	**Proposed name:** Onzetra **Established name:** Sumatriptan **Dosage form:** Nasal powder formulation for intranasal deposition to be used with Xsai® Breath Powdered Delivery Device **Strength(s):** 11 mg **Usual Dose:** 22 mg nasally as needed at the first sign of a migraine; may repeat after 2 hours if needed; not to exceed more than 44 mg in 24 hour period	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Onzetra	100	Name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Inspra	62 (Phonetic score 71)
2.	Zetran	62
3.	Ontinua***	56
4.	Oxecta	55
5.	Oleptro	54
6.	Orenitram	53
7.	(b) (4)***	52
8.	Ondansetron	52
9.	Otezla	51
10.	Anzemet	50
11.	Orgatrax	50

12.	Zenzedi	50

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

No.	**Proposed name:** Onzetra **Established name:** Sumatriptan **Dosage form:** Nasal powder formulation for intranasal deposition to be used with Xsai® Breath Powdered Delivery Device **Strength(s):** 11 mg **Usual Dose:** 22 mg nasally as needed at the first sign of a migraine; may repeat after 2 hours if needed; not to exceed more than 44 mg in 24 hour period	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Sunvepra***	66	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllable of this name pair sound different.
2.	(b) (4)***	64	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different. Dose: 22 mg intranasally or UAD for Onzetra vs. (b) (4) (b) (4)
3.	Benzepro	62	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
4.	Inflectra***	58	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
5.	Tetra 500	58	The prefixes of this name pair (Onzetra vs the root name Tetra) have sufficient orthographic differences. The first syllables of this name pair sound different, and Onzetra contains an extra syllable. In addition, Tetra

			500 contains a modifier making the pair sound different when spoken, if included.
6.	Levitra	57	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
7.	Bicitra	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
8.	Jetrea	56	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
9.	Kcentra	56	The prefixes and infixed of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
10.	Tuzistra***	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different.
11.	Zetia	56	The prefixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
12.	Hizentra	55	The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
13.	Kaletra	55	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
14.	Omidria	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Omidria contains an extra syllable.
15.	Omnitrope	55	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound

			different.
16.	Menactra	54	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
17.	Omedia	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and Omedia contains an extra syllable.
18.	Onzeald***	54	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different.
19.	Adcetris	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
20.	Cometriq	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
21.	Concentraid	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
22.	Cytra 2	52	The prefixes of this name pair (Onzetra vs the root name Cytra) have sufficient orthographic differences. The first syllables of this name pair sound different, and Onzetra contains an extra syllable. Cytra 2 contains a modifier making the pair sound different when spoken, if included.
23.	Cytra-3	52	The prefixes of this name pair (Onzetra vs the root name Cytra) have sufficient orthographic differences. The first syllables of this name pair sound different, and Onzetra contains an extra syllable. Cytra-3 contains a modifier making the pair sound different when spoken, if included.
24.	Minitran	52	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.

			The first, second, and third syllables of this name pair sound different.
25.	Omnipred	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
26.	Opsiria***	52	The infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different and Ospiria contains an additional syllable.
27.	Oxytrol	52	The suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
28.	Septra	52	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
29.	Tums Ultra	52	The prefixes of this name pair (Onzetra vs. Tums Ultra) have sufficient orthographic differences. The first syllables of this name pair (Onzetra vs. Tums Ultra) sound different.
30.	Benzedrex	51	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
31.	(b) (4)***	51	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
32.	Abstral	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Onzetra contains an extra syllable.
33.	(b) (4)***	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound

			different.
34.	Oby-trim	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
35.	Oncaspar	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
36.	Onivyde***	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
37.	Ortho Evra	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and the name Ortho Evra contains an extra syllable.
38.	Oxymeta-12	50	The infixes and suffixes of this name pair (Onzetra vs the root name Oxymeta) have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Oxymeta contains an extra syllable, as well as a modifier making the pair sound different when spoken, if included.
39.	Polycitra	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and Polycitra contains an extra syllable.

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

No.	Name	POCA Score (%)

1.	n/a	

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	64	Proposed proprietary name found unacceptable by DMEPA (OSE# 2013-2242). New proprietary name, Xadago*** (OSE# 2015-47065 for NDA (b) (4) and 2014-26128 for IND (b) (4)), was found conditionally acceptable.
2.	Metra	62	Product withdrawn from the market due to safety concerns.
3.	Oncet	62	International product marketed in India.
4.	Andec-TR	58 (Phonetic score 70)	Brand discontinued with no generic equivalent available (per RedBook).
5.	Z-Xtra	58	Brand discontinued with no generic equivalent available (per RedBook).
6.	Econtra***	56	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Levonorgestrel.
7.	ODT Levitra***	56	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, (b) (4).
8.	(b) (4)***	56	Proposed proprietary name withdrawn by the Applicant. Alternate name,

			(b) (4)***, was found conditionally acceptably in 2013-1782. However, the Applicant withdrew NDA (b) (4) on 12/3/2014.
9.	Onsior	55	Veterinary product.
10.	(b) (4)***	55	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
11.	(b) (4)***	54	Proposed proprietary name found unacceptable by DMEPA (OSE# 2013-16332). Product approved under new proprietary name Norethindrone Acetate and Ethinyl Estradiol Tablets, USP 0.5 mg / 0.0025 mg.
12.	Benzepril	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Bextra	54	Product withdrawn from the market due to safety concerns.
14.	(b) (4)***	54	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Xtoro.
15.	(b) (4)***	54	Proposed proprietary name found unacceptable due to conflict with another pending name (OSE# 2014-40634). Applicant has submitted an alternate name for review.
16.	Orbexa	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug

			databases.
17.	Amitraz	50	Veterinary product.
18.	Vistra	50	International product marketed in Philippines.

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

No.	Name	POCA Score (%)
1.	Arzerra	57
2.	Rondec-TR	57
3.	Concerta	56
4.	Uni-Tren	56
5.	Linjeta***	55
6.	Antara	54
7.	Bonjela	54
8.	Bosatria***	54
9.	Convenia	54
10.	Integra F	54
11.	Congess SR	53
12.	(b) (4)***	53
13.	Invega	53
14.	Antepar	52
15.	Conceptrol	52
16.	Entex LA	52
17.	Inderal	52
18.	Lusedra	52
19.	Natroba	52
20.	(b) (4)***	52
21.	Sanctura	52
22.	Sonata	52
23.	Zometa	52

24.	Encora	51
25.	Myzilra	51
26.	Natpara	51
27.	Sanfed A	51
28.	Atripla	50
29.	Bendeka***	50
30.	Covera	50
31.	Ignatia	50
32.	Inlyta	50
33.	Ixempra	50
34.	(b) (4)***	50
35.	Nitrek	50
36.	(b) (4)***	50
37.	Renvela	50
38.	Rovera	50
39.	Sonapram	50
40.	Uni-cenna	50
41.	Zonegran	50

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/s/

DEBORAH E MYERS
08/13/2015

DANIELLE M HARRIS
08/13/2015

IRENE Z CHAN
08/13/2015

MEMORANDUM

REVIEW OF PROPRIETARY NAME

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)

Date of This Memorandum:	September 25, 2014
Requesting Office or Division:	Division of Neurology Products (DNP)
Application Type and Number:	NDA 206099
Product Name and Strength:	Onzetra (Sumatriptan) Nasal Powder, 11 mg
Submission Date:	May 6, 2014
Applicant/Sponsor Name:	Avanir Pharmaceuticals
OSE RCM #:	2014-17318-01
DMEPA Primary Reviewer:	Jacqueline Sheppard, PharmD
DMEPA Acting Team Leader:	Tingting Gao, PharmD
DMEPA Associate Director:	Lubna Merchant, M.S., PharmD

1 PURPOSE OF MEMO

This memorandum is to re-assess, the proposed proprietary name, Onzetra. The proposed name, Onzetra, was found acceptable in OSE review #2014-17318 dated July 14, 2014[1]. The product was originally presented with the strength (b) (4) and is now being presented with the strength of 11 mg. All other product characteristics remain the same.

[1] Sheppard J. Proprietary Name Review for Onzetra (NDA 206099). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Jul 14. 34 p. OSE RCM No.: 2014-17318.

2 METHODS AND MATERIALS REVIEWED

We evaluated the previous review dated July 14, 2014 to assess whether the change in strength would alter our previous conclusion regarding the acceptability of the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

3 CONCLUSIONS

We have completed the re-evaluation of the proposed proprietary name, Onzetra, and have concluded that this name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE Project Manager, at 301-796-0097.

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/s/

JACQUELINE E SHEPPARD
09/25/2014

TINGTING N GAO
09/25/2014

LUBNA A MERCHANT
09/25/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	July 14, 2014
Application Type and Number:	NDA 206099
Product Name and Strength:	Onzetra (Sumatriptan) Nasal Powder (b) (4)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Avanir Pharmaceuticals
Submission Date:	May 6, 2014
Panorama #:	2014-17318
DMEPA Primary Reviewer:	Jacqueline Sheppard, PharmD
DMEPA Acting Team Leader:	Tingting Gao, PharmD
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Onzetra, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [redacted](b) (4)., for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, Promtiva on January 27, 2014. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, Promtiva unacceptable from a promotional perspective in OSE Review 2014-16850, dated March 4, 2014.

Thus, the sponsor submitted the name, Onzetra, for review on May 6, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 6, 2014 proprietary name submission.

- Intended Pronunciation: On ze trah
- Active Ingredient: Sumatriptan
- Indication of Use: Acute migraine with or without aura
- Route of Administration: Nasal
- Dosage Form: Nasal powder formulation for intranasal deposition to be used with Xsail Breath Powered Delivery Device
- Strength: [redacted](b) (4) (11 mg in a disposable nosepiece, one for each nostril; two nosepieces equals one dose)
- Dose and Frequency: 22 mg as needed as migraine occurs; may repeat after 2 hours; not to exceed more than 44 mg in 24 hour period
- How Supplied: [redacted](b) (4) [redacted](b) (4)
- Storage: Controlled room temperature
- Container and Closure Systems: [redacted](b) (4) pouch

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 Neurology

Products (DNP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Onzetra in their submission. This proprietary name is comprised of a single word with a descriptor 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

101 practitioners participated in DMEPA's prescription studies. One interpretation overlapped with a foreign product, Onsetron. This misinterpretation is further evaluated in Section 2.2.6. The other interpretations did not overlap with any currently marketed products or any products in the pipeline. In the verbal prescription study, 19 of the 34 participants correctly interpreted the prescription. Common misinterpretations include misinterpreting the letter string "zet" as "cent," "cet," "sent," "set," and "zent." In the written prescription study, 38 of 67 participants correctly interpreted the prescription. Common misinterpretations include misinterpreting the letter string "on" as "om," "an," and "pn," and the letter string "ze" as "gi," "zi,"and "si." 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, May 6, 2014 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study or by Drug Safety Institute.

[1]USAN stem search conducted on June 6, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	144
Low similarity name pair: combined match percentage score ≤49%	2

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

We evaluated the potential for confusion between Onzetra and Onsetron in detail due to the misinterpretation in the FDA prescription study (see section 2.2.3 and Appendix B). Onsetron is the foreign proprietary name in New Zealand for Ondansetron. Although Onzetra and Onsetron share similar orthographic characteristics, Onsetron is not available in the United States. Additionally, ondansetron, the established name for Onsetron, was evaluated independently and determined to have sufficient orthographic differences and no overlap in strength or dose with Onzetra.

Our analysis of the 148 names contained in Table 1 determined that 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 Neurology Products (DNP) via e-mail on June 20, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on June 20, 2014, they stated no additional concerns with the proposed proprietary name, Onzetra.

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 Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 6, 2014 submission are altered, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

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

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

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

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

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

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

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (See Table 3)
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4)
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist (See Table 5).

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names **with** overlapping or similar strengths or doses.

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product in a prescription simulation study). In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Onzetra Study (Conducted on May 16, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Onzetra Dmg intranasally x1	Onzetra Use as directed Dispense #1
Outpatient Prescription: Onzetra UAD #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

OUTPATIENT	VOICE	INPATIENT
OMZETRA (4)	ONCENTRA (2)	ANGITRA (1)
ONZETRA (30)	ONCETRA (1)	ANZETRA (1)
ONZETTRA (1)	ONSENTRA (1)	ANZITHRA DMG (1)
	ONSETRA (6)	ANZITRA (4)
	ONSETRON (1)	ANZITRA DMG (1)

	ONZENTRA (2)	OMZITRA (1)
	ONZETRA (19)	ONSITRA (1)
	ONZETTRA (2)	ONZETRA (8)
		ONZITHO (1)
		ONZITRA (11)
		PNZETRA (1)
		PNZITRA (1)

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

No.	**Proposed name: Onzetra** **Strength:** (b) (4) **Usual Dose: Inhale 22 mg at the start of a headache; May repeat once 24 hours.**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Or** **Failure prevention reasons**
1.	Onsetron	70	The "a" and "on" sounds at the end of the name pairs give sufficient phonetic difference. Onsetron is a foreign proprietary name for ondansetron in New Zealand. Onsetron is not available in the United States. Thus, there is no risk that a patient in the United States will receive Onsetron instead of the intended Onzetra.
2.	Novitra	70	The letter strings "Nov" and "Onz" look different when scripted. The "No" and "On" sounds at the beginning of the name pairs and "vi" and "ze" sounds in the middle of the name pair give sufficient phonetic differences. Novitra is a homeopathic topical cream that is no longer currently marketed and the product characteristics are not found in the commonly used databases.

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

No.	Name	POCA Score (%)
1.	Inspra	62
2.	Metra	62
3.	Zetran	62
4.	Concerta	56
5.	Ontinua ***	56
6.	Orenitram	55
7.	Oxecta	55
8.	Antara	54
9.	Oleptro	54

No.	Name	POCA Score (%)
10.	Onglyza	54
11.	Invega	53
12.	Orenitram	53
13.	Arixtra	52
14.	(b) (4) ***	52
15.	Inderal	52
16.	Ondansetron	52
17.	Otezla	51
18.	Anzemet	50
19.	Covera	50
20.	Inlyta	50
21.	Ixempra	50
22.	Orgatrax	50
23.	Zenzedi	50
24.	Zonegran	50

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

No.	**Proposed name: Onzetra** **Strength:** (b) (4) **Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Sunvepra ***	66	The prefix and infix of this name pair have sufficient orthographic differences The first syllables of this name pair sound different.
2.	(b) (4) ***	64	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
3.	Benzepro	62	The prefix of this name pair has sufficient orthographic differences The first and third syllables of this name pair sound different.
4.	Z-Xtra	58	The prefix of this name pair has sufficient orthographic differences The first syllable of this name pair sounds different.
5.	Arzerra	57	The infix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
6.	Levitra	57	The first and second syllables of this name pair sound different. Onzetra is available in a single strength and therefore strength may be omitted from the prescription. Levitra is available in multiple strengths and therefore strength needs to be specified on a prescription. There is no overlap within the strengths.
7.	Ostera	57	The infix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.

No.	**Proposed name: Onzetra** **Strength:** (b) (4) **Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.**	**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**
8.	Rondec	57	The prefix, infix, and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
9.	Bicitra	56	The prefix and infix of this name pair have sufficient orthographic differences The first syllables of this name pair sound different.
10.	Jetrea	56	The prefix of this name pair has sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
11.	Kcentra	56	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
12.	(b) (4) ***	56	The infix of this name pair has sufficient orthographic differences The second syllable of this name pair sounds different. (b) (4)
13.	Zetia	56	The prefix of this name pair has sufficient orthographic differences. Onzetra has 7 letters whereas Zetia has 5 letters. The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
14.	Hizentra	55	The prefix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
15.	Kaletra	55	The prefix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
16.	Omidria	55	The infix and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
17.	Omnitrope	55	The prefix, infix, and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
18.	(b) (4) ***	54	The infix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
19.	Bosatria ***	54	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
20.	(b) (4) ***	54	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
21.	Integra F	54	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
22.	Menactra	54	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
23.	Omedia	54	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
24.	Onset Forte	54	The suffix of this name pair has sufficient orthographic differences The third syllables of this name pair sound different and Onset Forte contains an extra syllable with the modifier.
25.	Zeftera ***	54	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
26.	Congess SR	53	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different, and Onzetra contains an extra syllable.
27.	Adcetris	52	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
28.	Cometriq	52	The infix and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
29.	Concentraid	52	The infix and suffix of this name pair have sufficient orthographic differences. Concentraid has 11 letters whereas Onzetra has 7 letters. The first, second, and third syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
30.	Conceptrol	52	The infix and suffix of this name pair have sufficient orthographic differences. Conceptrol has 11 letters whereas Onzetra has 7 letters. The first, second, and third syllables of this name pair sound different.
31.	Cytra-2	52	The prefix of this name pair has sufficient orthographic differences The first syllable of this name pair sound different and Onzetra contains an extra syllable.
32.	Cytra -3	52	The prefix of this name pair has sufficient orthographic differences The first syllable of this name pair sound different and Onzetra contains an extra syllable.
33.	Entex LA	52	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllable of this name pair sound different and Onzetra contains an extra syllable.
34.	Lusedra	52	The infix of this name pair has sufficient orthographic differences The first and third syllables of this name pair sound different.
35.	Minitran	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
36.	Natroba	52	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
37.	Omnipred	52	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
38.	Opsiria ***	52	The infix of this name pair has sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
39.	Oxytrol	52	The suffix of this name pair has sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
40.	Sanctura	52	The prefix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
41.	Septra	52	The prefix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
42.	Sonata	52	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
43.	Tums Ultra	52	The prefix of this name pair has sufficient orthographic differences. If the modifier 'Ultra' is dropped, Tums only has 4 letters whereas Onzetra has 7 letters. The first and second syllables of this name pair sound different.
44.	Zometa	52	The suffix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
45.	Benzedrex	51	The prefix and suffix of this name pair have sufficient orthographic differences. Benzedrex has 9 letters whereas Onzetra has 7 letters. The first and third syllables of this name pair sound different.
46.	Myzilra	51	The prefix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
47.	(b) (4) ***	51	The infix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different.
48.	Natpara ***	51	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
49.	(b) (4) ***	51	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
50.	Abstral	50	The suffix of this name pair has sufficient orthographic differences The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
51.	Atripla	50	The infix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.
52.	(b) (4) ***	50	The prefix and infix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different.

No.	Proposed name: Onzetra Strength: (b) (4) Usual Dose: Inhale 22 mg at the start of headache. May repeat once in 24 hours.	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
53.	Nitrek	50	The prefix and suffix of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different and Onzetra contains an extra syllable.
54.	Oby-Trim	50	The infix and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
55.	Oncaspar	50	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
56.	Onivyde ***	50	The infix and suffix of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different.
57.	Ortho-Evra	50	The infix and suffix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different, and Ortho-Evra contains an extra syllable.
58.	Polycitra	50	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
59.	(b) (4) ***	50	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.
60.	Renvela	50	The prefix and infix of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Onsolis	≤49%
2.	Zarnestra	≤49%

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

No.	Name	POCA Score (%)	Failure preventions
1.	Onzetra	100	Subject of this review.
2.	(b) (4) ***	68	This is a proposed secondary name and the primary name Astragraf XL was granted.
3.	(b) (4) ***	63	Name and entire application withdrawn by the Applicant
4.	(b) (4) ***	62	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-11367). Product approved under new proprietary name Diclegis.
5.	Oncet	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	61	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-1510). Product approved under new proprietary name Tradjenta

No.	Name	POCA Score (%)	Failure preventions
7.	Ostora ***	59	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-4101). No new proprietary name requests were received for this product.
8.	Andec-TR	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Lodotra ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE # 2009-1440). Product approved under new proprietary name Zelboraf.
10.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1510). Product approved under new proprietary name Otezla.
11.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-696). Product approved under new proprietary name Omacor.
12.	Tetra 500	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3165). Product approved under established name Esomeprazole strontium.

No.	Name	POCA Score (%)	Failure preventions
14.	Uni-Tren	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Linjeta ***	55	Proposed Proprietary Name found unacceptable by DMEPA (OSE # 2012-1369). Application received complete response.
16.	Onsior	55	Veterinary product
17.	Uni-Tris	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-1084). Product approved under new proprietary name Rectiv.
19.	(b) (4) ***	54	This is a proposed secondary name. The primary name (b) (4) *** was found unacceptable by DMEPA (OSE # 2011-387).
20.	Benzepril	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Bextra	54	Product withdrawn from the market due to safety concerns
22.	Bonjela	54	International Product marketed in the United Kingdom

No.	Name	POCA Score (%)	Failure preventions
23.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-1375). Product approved under new proprietary name Zelboraf.
24.	Nerventra ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-789). No new proprietary name requests were received for this product.
25.	(b) (4) ***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-415). Product approved under new proprietary name Besivance.
26.	(b) (4) ***	53	This is a proposed secondary name and the primary name Exalgo was granted.
27.	Orbexa	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Solzira ***	53	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-113). Product approved under new proprietary name Horizant.
29.	Antepar	52	Product withdrawn from the market due to safety concerns

No.	Name	POCA Score (%)	Failure preventions
30.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-863). Product approved under new proprietary name Staxyn
31.	(b) (4) ***	52	Proposed Proprietary Name withdrawn by sponsor (OSE #2012-1080). No new proprietary name requests were received for this product.
32.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-484). Product approved under new proprietary name Banzel.
33.	Movectro ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE # 2008-1986). No new proprietary name requests were received for this product.
34.	Natrova ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-1989). Product approved under new proprietary name Natroba
35.	Ozespa ***	52	Name and entire application withdrawn by Applicant.
36.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-2047). Product approved under established name.

No.	Name	POCA Score (%)	Failure preventions
37.	Encora	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	(b) (4) ***	51	This is a secondary proposed proprietary name and the primary name Aristada *** was granted.
39.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1966). Product approved under new proprietary name Jublia.
40.	(b) (4) ***	51	Proposed Proprietary Name withdrawn by sponsor (OSE # 2011-4083).
41.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1101). No new proprietary name requests were received for this product.
42.	(b) (4) ***	51	Name identified in Safety Evaluator database. Unable to find product characteristics in commonly used drug databases
43.	Sanfed A	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	Amitraz	50	Product is not a drug (bulk ingredient for animal compounding)

No.	Name	POCA Score (%)	Failure preventions
45.	Ignatia	50	Product is not a drug (herbal ingredient not available independently)
46.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-216). Product approved under new proprietary name Kazano.
47.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE # 2012-1126). No new proprietary name requests were received for this product.
48.	(b) (4) ***	50	Name identified in Safety Evaluator database. Unable to find product characteristics in commonly used drug databases.
49.	Omapro ***	50	Proposed Proprietary Name never evaluated due to CR (OSE# 2010-193). Product approved under new proprietary name Synribo.
50.	(b) (4) ***	50	Name and entire application withdrawn by the Applicant
51.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3238). No new proprietary name requests were received for this product.
52.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1047). Product approved under new proprietary name Osphena.

No.	Name	POCA Score (%)	Failure preventions
53.	(b) (4) ***	50	This is a proposed secondary name and the primary name Qoliana was granted.
54.	Oxymeta-12	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	(b) (4) ***	50	This is a proposed secondary name and the primary name Qysmia was granted.
56.	Rovera	50	Veterinary product
57.	Sonapram	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
58.	Spedra ***	50	This is a proposed secondary name and the primary name Stendra was granted.
59.	Uni-Cenna	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Vistra	50	International product marketed in Phillipines.

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/s/

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07/14/2014

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