However, if **any** of the proposed product characteristics as stated in this review are altered prior to approval of the product; DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. If the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. Additionally, if the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

## 6 RECOMMENDATIONS

6.1 DMETS does not object to the use of the proprietary name Onsolis for this product.

6.2 If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review.

6.3 If the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

## 7 REFERENCES


### *1. Adverse Events Reporting System (AERS)*

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

### *2. Micromedex Integrated Index (http://weblern/)*

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

### *3. Phonetic and Orthographic Computer Analysis (POCA)*

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

### *4. Drug Facts and Comparisons, online version, St. Louis, MO (http://weblern/)*

Drug Facts and Comparisons is a compendium organized by therapeutic Course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

### *5. AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in review divisions.

***6. Division of Medication Errors and Technical Support proprietary name consultation requests***

This is a list of proposed and pending names that is generated by DMETS from the Access database/tracking system.

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

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologicals, discontinued drugs and "Chemical Type 6" approvals.

***8. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)***

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

***9. WWW location http://www.uspto.gov.***

Provides information regarding patent and trademarks.

***10. Clinical Pharmacology Online (http://weblern/)***

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

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

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

***12. Natural Medicines Comprehensive Databases (http://weblern/)***

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

***13. Stat!Ref (http://weblern/)***

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

***14. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)***

List contains all the recognized USAN stems.

***15. Red Book Pharmacy's Fundamental Reference***

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

### *16. Lexi-Comp (www.pharmacist.com)*

A web-based searchable version of the Drug Information Handbook.

### *17. Medical Abbreviations Book*

Contains commonly used medical abbreviations and their definitions.

Use standard format for citations for previous OSE reviews; literature.

## APPENDICES

## Appendix A:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMETS also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The Medication Error Staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g. "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMETS will consider the Sponsor's intended pronunciation of the proprietary name. However, because the Sponsor has little control over how the name will be spoken in practice, DMETS also considers a variety of pronunciations that could occur in the English language.

**Table 1.** Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name

| Type of similarity | Considerations when searching the databases | | |
|---|---|---|---|
| | Potential causes of drug name similarity | Attributes examined to identify similar drug names | Potential Effects |
| Look-alike | Similar spelling | Identical prefix<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |

| | | | |
|---|---|---|---|
| | Orthographic similarity | Similar spelling<br>Length of the name<br>Upstrokes<br>Downstrokes<br>Cross-stokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

**Appendix B:**

Prescription Study Responses

| **Outpatient Prescription** | **Voice Prescription** | **Inpatient Medication Order** |
|---|---|---|
| Grisalis | Omsolace | Onsalis |
| Gusolis | onsolun | Onsolis |
| Onsalis | Opsolin | Onsolis |
| Onsalis | | Onsolis |
| Onsalis | | Onsolis |
| Onsalis | | Onsolis |

| | | |
|---|---|---|
| Onsalis | | Onsolis |
| Onsalis | | Onsolis |
| Onsalis | | |
| Onsalis | | |
| Onsolis | | |
| Onzalis | | |
| Onzalis | | |
| Orisales | | |
| Orsalis | | |
| Orsalis | | |
| Orsalis | | |

**Appendix D:** Products with no numerical overlap in strength and dose.

| **Onsolis (Fentanyl)** | | **200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg** | **Usual dose: Titrated to an effective, tolerable dose, not to exceed 4 doses daily. Dose range from 200 mcg to 1200 mcg.** |
|---|---|---|---|
| **Product name with potential for confusion** | **Similarity to Onsolis** | **Strength** | **Usual Dose (if applicable)** |
| Anusol HC | Look | 2.5%, 25 mg | Cream - thin film applied topically 2 to 4 times daily, Suppository - 25 mg rectally twice daily |
| Oncovin | Look | 1 mg/mL | 1.4 $mg/m^2$ to 2 $mg/m^2$ on days 1 and 8, every 28 days |
| Orudis | Look | 12.5 mg, 25 mg, 50 mg, 75 mg | 50 mg four times daily or 75 mg three times daily |
| Mycelex | Sound | 1%, 10 mg | Cream – apply vaginally once daily for 3 to 14 days, Oral Troche – 10 mg five times daily for 14 days |
| Ambien | Look | 5 mg, 6.25 mg, 10 mg, 12.5 mg | 5 mg, 6.25 mg, 10 mg, or 12.5 mg once daily at bedtime |
| Solia | Sound | 30 mcg/0.15 mg | One tablet daily |
| Atacand | Sound | 4 mg, 8 mg, 16 mg, 32 mg | 8 mg to 32 mg in one or two divided daily doses |

Appendix E: Potential confusing name with numerical overlap in strength or dose

| **Onsolis (Fentanyl)** | **200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg** | **Usual dose: Titrated to an effective, tolerable dose, not to exceed 4 doses daily. Dose range from 200 mcg to 1200 mcg.** |
|---|---|---|
| **Failure Mode: Name confusion** | **Causes (could be multiple)** | **Effects** |
| Onxol | Orthographic similarity (On-, -ol-)<br>Potential numerical overlap in dose<br>(200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg vs. 120 mg/m$^2$ to 175 mg/m$^2$) | Medication error unlikely to occur due to orthographic differences in the names in addition to differing dosing frequencies and duration of administration.<br>*Rationale*:<br>The risk for medication error is minimized by orthographic differences in the names. Onxol has a cross-stroke introduced by the letter 'x' unlike Onsolis. Additionally, appears longer when scripted (seven letters vs. five letters). Moreover, the letters 'is' presented at the end of Onsolis help to differentiate the proposed name from Onxol.<br>Although there is a potential for numerical overlap in the doses of Onsolis and Onxol, Onxol is administered through intravenous infusion for a minimum of three hours ranging up to 96 hours. However, Onsolis is a buccal system that is administered as needed up to four times daily. |
| Cialis | Orthographic similarity ('O' vs. 'Ci', -lis)<br>Numerical overlap in strengths (200 mcg versus 20 mg). Overlap could be exacerbated if a trailing zero (e.g. 20.0) is included with Cialis 20 mg | Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.<br>*Rationale:*<br>The risk for medication error is minimized by the orthographic differences in the names. Although the letter 'O' in Onsolis my look similar to 'Ci" in Cialis, the middle portion of each name differs (-so- vs. –a-). Additionally, Onsolis appears longer when scripted (seven letters vs. five letters).<br>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error.<br>Onsolis is administered as needed up to four times daily unlike Cialis which is administered at a maximum of once daily. |

| | | |
|---|---|---|
| Ionsys | Orthographic similarity (-ns-, -s)<br><br>Numerical overlap in dosage (40 mcg vs. 400 mcg). Overlap could be exacerbated if a terminal zero (e.g. 40.0) is included with Ionsys 40 mcg<br><br>CII<br><br>Same active ingredient (Fentanyl) | Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.<br><br>*Rationale:*<br><br>The risk for medication error is minimized by the orthographic differences in the names. The beginning of each name differs orthographically (Ons- vs. Ion-). Additionally, Ionsys has a downstroke introduced by the letter 'y', unlike Onsolis, which has an upstroke introduced by the letter 'l'.<br><br>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error. |
| Insulin | Orthographic similarity (-nsolis vs -nsulin)<br><br>Numerical overlap in dosage (e.g. 200 mcg vs. 20 Units) Overlap could be exacerbated if a terminal zero (e.g. 20.0) is included with Insulin 20 Units | The necessity for specification of what type of insulin is desired minimizes the likelihood of medication error in the usual practice setting.<br><br>*Rationale:*<br><br>Insulin is available in many formulations, (i.e. regular, NPH, aspart, lispro, lente, glargine, detemir, glulisine). The availability of multiple formulations of insulin requires that the desired formulation be included in prescription orders. Thus, the presence of the name of one of the aforementioned insulin formulations should preclude the dispensing of Onsolis in error for insulin.<br><br>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error. |
| Oxycontin | Phonetic similarity (O-)<br><br>Numerical overlap in dosage (e.g. 200 mcg vs. 20 mg).<br><br>CII | Phonetic differences in the names minimize the likelihood of medication error in the usual practice setting.<br><br>*Rationale:*<br><br>The risk for medication error is minimized by the phonetic differences in the names. The middle and end portions of each name differ phonetically (-nsolis vs. –xycontin). Additionally, Onsolis has three syllables unlike Oxycontin which has four.<br><br>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when |

| | | |
|---|---|---|
| | | communicating drug information should help to further reduce risk of medication error. |
| Orasone | Orthographic similarity (O-, long 'o' sound at the beginning and middle of each name)<br><br>Numerical overlap in dosage (e.g. 200 mcg vs. 20 mg). Overlap could be exacerbated if a terminal zero (e.g. 20.0) is included with Orasone 20 mg | Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.<br><br>*Rationale:*<br><br>Although the beginnings of each name may appear similar when scripted (On- vs. Or-) the middle and end portion of each name differ orthographically (-solis vs. –asone). The upstroke of the letter 'l' in Onsolis helps to further differentiate the names from one another.<br><br>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (JCAHO, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error. |

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