

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202799Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: February 21, 2012

Reviewer: Yelena Maslov, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Irene Z. Chan, Pharm.D., BCPS., Team Leader
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, R.Ph., Director
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Omontys (Peginesatide) Injection,
Single-Use Vials: 2 mg/0.5 mL, 3 mg/0.5 mL,
4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL.

Pre-filled Syringe: 1 mg/0.5 mL, 2 mg/0.5 mL,
3 mg/0.5 mL, 4 mg/0.5 mL, 6 mg/0.5 mL

Multi-Use Vials: 10 mg/mL and 20 mg/2 mL (10 mg/mL)

Application Type/Number: NDA 202799

Applicant/sponsor: Affymax, Inc.

OSE RCM #: 2011-3902

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Omontys, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Omontys, acceptable in OSE Review #2011-1025 and 2011-2387, dated August 25, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2011-1025 and 2011-2387. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name (b) (4) thought to look or sound similar to Omontys and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with (b) (4) and lead to medication errors. This analysis determined that the name similarity between Omontys and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 31, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on December 29, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

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4 REFERENCES

1. *Maslov, Yelena, Proprietary Name Review for Omontys, OSE Review #2011-1025 and 2011-2387.*

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

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

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

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

<p>Proposed name: Omontys (Peginesatide) Injection</p>	<p>Strength(s): Single-use Vials and Prefilled Syringes: 1 mg/0.5 mg (pre-filled syringe only), 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL Multi-Dose Vials: 10 mg/mL and 20 mg/2 mL</p>	<p>Usual dose: Treatment naïve patients: 0.04 mg/kg to 0.08 mg/kg as a single intravenous or subcutaneous injection once monthly Conversion from Epoetin Alfa or Darbepoetin Alfa: 2 mg to 20 mg as a single intravenous or subcutaneous injection once monthly.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>(b) (4)</p>		

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/s/

YELENA L MASLOV
02/21/2012

CAROL A HOLQUIST on behalf of IRENE Z CHAN
02/22/2012

CAROL A HOLQUIST
02/22/2012

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Proprietary Name Review

Date: August 25, 2011

Application Type/Number: IND 063257
NDA 202799

Reviewer: Yelena Maslov, Pharm.D., Safety Evaluator
Division of Medication Error Prevention and Analysis

Team Leader Zachary Oleszczuk, Pharm.D., Team Leader
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, R.Ph, Director
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Omontys (Peginesatide) Injection,
Single-Dose Vial and Prefilled Syringe:
2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL,
and 6 mg/0.5 mL
Multi-Dose Vials: 10 mg/mL and 20 mg/2 mL

Applicant/sponsor: Affymax, Inc

OSE RCM #: #2011-1025 and #2011-2387

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Omontys, 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 proposed product characteristics are provided in Section 1.2.

1.1 REGULATORY HISTORY

This review responds to a request from Affymax, Inc., dated June 23, 2011, for an assessment of the proposed proprietary name, Omontys, regarding potential name confusion with other proprietary or established drug names in the usual practice setting. The Applicant submitted the Application to the FDA under NDA 202799 on May 27, 2011.

1.2 PRODUCT INFORMATION

Omontys (Peginesatide) Injection is an erythropoiesis-stimulating agent (ESA) that is indicated for the treatment of anemia associated with chronic renal failure in adult patients on dialysis. Omontys will be supplied in single-dose vials and prefilled syringes containing 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, and 6 mg/0.5 mL. Additionally, Omontys will be supplied as multi-dose vials containing 10 mg/mL and 20 mg/2 mL. Omontys should be dosed at 0.04 mg/kg to 0.08 mg/kg subcutaneously or intravenously once a month for treatment-naïve patients and between 2 mg and 20 mg subcutaneously or intravenously once a month for patients previously treated with Epoetin Alfa or Darbapoetin Alfa. Omontys vials or prefilled syringes should be stored between 2°C and 8°C (36°F to 46°F) and protected from light.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on June 15, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

There are no components of the proposed proprietary name that can contribute to medication error or render the name unacceptable.

2.2.3 FDA Name Simulation Studies

Thirty-seven practitioners participated in DMEPA's prescription studies. Twenty-four practitioners interpreted the proposed name 'Omontys' correctly with correct interpretation occurring with inpatient (n=9) and outpatient (n=14) prescription studies. The remaining fourteen practitioners misinterpreted the name. The most common misinterpretation occurred with ten voice study participants misinterpreting the letter 'O' as the letter 'A' and the letter 'y' as the letter 'i'. See Appendix D for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, March 29, 2011 email, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Table 1 (page 5) lists the names identified by the primary reviewer and the Expert Panel Discussion (EPD) to have orthographic, phonetic, or spelling similarity to the proposed proprietary name, Omontys (see Appendix C).

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		Sound Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Amitiza	EPD	Mentax	EPD	Onsolis	EPD
(b) (4)	EPD			Omnaris	EPD
Omnicef	EPD			Ionsys	EPD
Amaryl	EPD			Omnihist LA	EPD
Cromolyn	EPD				
(b) (4)	EPD				
Amosyt	EPD				
Amoclan	EPD				
Oncolym***	EPD				
Onrigin***	EPD				
Amerge	EPD				
Omapro	EPD				
Omcaspar	EPD				
Qutenza	EPD				
Ozurdex	EPD				
Ovidrel	EPD				
Ornidyl	EPD				
(b) (4)	EPD				
(b) (4)	EPD				
Omnitrope	EPD				
Oncovite	EPD				
Quartuss	EPD				
Questran	EPD				
Orvaten	Primary reviewer				
Oncolyn	Primary reviewer				
(b) (4)	Primary reviewer				

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Our analysis of the thirty-one names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics for the names. We determined that all thirty-one names will not pose a risk for confusion as described in Appendix E through F.

DMEPA communicated these findings to the Division of Hematology Products (DHP) via e-mail on July 6, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Hematology Products on July 6, 2011 and July 7, 2011 the Division agreed with DMEPA's proprietary name risk assessment and had no additional concerns.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name, Omontys, is acceptable from both a promotional and safety perspective. However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

The proposed proprietary name, Omontys, must be re-reviewed 90 days prior to approval of the NDA.

4 REFERENCES

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

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

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

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

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

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

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

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

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

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

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

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

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)
USPTO provides information regarding patent and trademarks.
9. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)
Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.
10. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (www.thomson-thomson.com)
The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.
11. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)
Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.
12. ***Stat!Ref*** (www.statref.com)
Stat!Ref contains full-text information from approximately 30 texts; it 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.
13. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)
USAN Stems List contains all the recognized USAN stems.
14. ***Red Book Pharmacy's Fundamental Reference***
Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.
15. ***Lexi-Comp*** (www.lexi.com)
Lexi-Comp is a web-based searchable version of the Drug Information Handbook.
16. ***Medical Abbreviations Book***
Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.² The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
	Similar spelling	Identical prefix Identical infix Identical suffix	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name

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

Look-alike		Length of the name Overlapping product characteristics	confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the

trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA

requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

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

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

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

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Product Characteristics Provided for Omontys

Omontys
(Peginesatide acetate)
IND# 063257

Indication: Erythropoiesis-Stimulating Agent indicated in treatment of anemia in patients with chronic renal failure who are on dialysis.

Route: Intravenous or subcutaneous injection

Dosage Form: Injection

Strength: Single dose vials and prefilled-syringes: 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL

Multi-dose vials: 10 mg/mL and 20 mg/2 mL

Dose: Tx naïve pts: 0.04 mg/kg to 0.08 mg/kg as a single injection once monthly
Tx for pts converting from Epoetin Alfa or Darbepoetin Alfa: 2 mg to 20 mg once monthly

How supplied: Single dose vials, multi-dose vials, and prefilled syringes

Applicant: Affymax, Inc.

Appendix C: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Omontys	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'O'	'a', 'C', 'Q', 'D', 'U'	Any vowel
lower case 'o'	'a', 'e', 'c',	Any vowel
lower case 'm'	'n', 'w', 'vi', 'eu', 'ni', 'm'	'n'
lower case 'n'	'a', 'u', 'o', 'r', 'v', 'n'	'm'
lower case 't'	'f', 'd', 'b', 'x'	'd'
lower case 'y'	'p', 'g', 'v'	'e', 'i', 'u'
Lower case 's'	'g', 'z', 'r', 'v'	'x', 'z'

Appendix D: Prescription Simulation Samples and Results

Figure 1. Omontys Study (Conducted on 3/25/2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Omoutys 4mg IV x 1 today</i></p>	<p>Omoutys #1 syringe 6 mg subcutaneously once monthly</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Omoutys #1 syringe 6 mg subcutaneous once monthly</i></p>	

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

	Product Name	Similarity to Omontys	Failure preventions
1	Amerge	Looks alike	Lacks sufficient orthographic similarity
2	Ovidrel	Looks alike	Lacks orthographic similarity
3	(b) (4)	Looks alike	(b) (4)
4	Oncolym***	Looks alike	No information regarding product characteristics is available from any of the databases in Reference Section 4.
5	Omcaspar	Looks alike	No information regarding the product or product characteristics is available from any of the databases in Reference Section 4.
6	(b) (4)	Looks alike	(b) (4)
7	Onrigin*** (Laromustine)	Looks alike	The Application (NDA 022489) (b) (4)
8	Omapro*** (Omacetaxine Mespesuccinate)	Looks alike	The Application (NDA 022374) (b) (4)
9	(b) (4)	Looks alike	(b) (4)
10	(b) (4)	Looks alike	(b) (4)
11	Amosyt (Dimenhydrinate)	Looks alike	Foreign proprietary name for Dimenhydrinate in Sweden
12	Ormidyl (Eflornithine Hydrochloride) Injection	Looks alike	The product is discontinued without a generic equivalent available
13	Ionsys (Fentanyl) Patch, 10.8 mg	Looks alike and sounds alike	The product is discontinued without a generic equivalent available

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

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

	Proposed name: Omontys (Peginesatide) Injection	Strength(s): Single-use Vials and Prefilled Syringes: 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL Multi-Dose Vials: 10 mg/mL and 20 mg/2 mL	Usual dose: Treatment naïve patients: 0.04 mg/kg to 0.08 mg/kg as a single intravenous or subcutaneous injection once monthly Conversion from Epoetin Alfa or Darbepoetin Alfa: 2 mg to 20 mg as a single intravenous or subcutaneous injection once monthly.
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
14	Amitiza (Lubiprostone) Capsules, 8 mcg and 24 mcg <u>Usual Dose</u> 8 mcg to 48 mcg twice daily with food and water.	<u>Orthographic</u> Both names contain an upstroke (letter ‘t’) and a down stroke (letter ‘y’ vs. letter ‘z’). Additionally, the letter string ‘Om-’ may appear similar to the corresponding letter string ‘Am-’ when scripted. <u>Numerical Overlap Strength and Dose</u> Omontys may be doses at the strength of 8 mg vs. Amitiza may be dosed at the strength 8 mcg.	<u>Orthographic</u> The upstroke letter ‘t’ appears in different positions of the names. Additionally, the letter string ‘ont’ in Omontys lacks orthographic similarity to the corresponding letter string ‘iti’ and in Amitiza when scripted. <u>Frequency of Administration</u> Once a month vs. twice daily
15	Omnicef (Cefdinir) Capsules, 300 mg Powder for Suspension, 125 mg/5 mL, 250 mg/5 mL <u>Usual Dose</u> Children < 43 kg: 7 mg/kg every 12 hours or 14 mg/kg every 24 hours. Children over 43 kg and adults: 300 mg orally every 12 hours or 600 mg every 24 hours	<u>Orthographic</u> Both names contain a down stroke (letter ‘y’ vs. letter ‘f’). Additionally, both names start with the letter string ‘Om-’.	<u>Orthographic</u> The ending of the names appear different when scripted ‘tys’ vs. ‘cef’ <u>Route of Administration</u> Intravenous or subcutaneous vs. oral <u>Frequency of Administration</u> Once a month vs. once daily

16	<p>Amaryl (Glimepiride) Tablet, 1 mg, 2 mg, 4 mg</p> <p><u>Usual Dose</u> 1 mg to 8 mg orally once daily</p>	<p><u>Orthographic</u> Both names contain two upstrokes and one down stroke (letter ‘y’). Additionally, the letter string ‘Omon-’ may appear similar to the corresponding letter string ‘Amar-’ when scripted.</p> <p><u>Overlap in Strength and Dose</u> Omontys and Amaryl may be dosed at the strength of 2 mg or 4 mg</p>	<p><u>Orthographic</u> The name Omontys contains an upstroke in the fifth position vs. the name Amaryl contains an upstroke in the last position.</p> <p><u>Route of Administration</u> Intravenous or subcutaneous vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. once daily</p>
17	<p>Cromolyn Inhalation Solution, 20 mg/2 mL</p> <p><u>Usual Dose</u> Inhale 20 mg orally via nebulizer four times per day at regular intervals.</p> <p>Cromolyn Nasal Spray, 5.2 mg per actuation</p> <p><u>Usual Dose</u> 1 spray in each nostril 3 to 4 times per day, may be increased to 6 times a day as needed</p> <p>Cromolyn Ophthalmic Solution, 4%</p> <p><u>Usual Dose</u> 1 drop to 2 drops in each eye 4 to 6 times per day</p>	<p><u>Orthographic</u> Both names share the letter string ‘mo’ and the letter ‘y’. Additionally, the letter ‘O’ and the letter string ‘ty’ in Omontys may appear similar to the corresponding letter ‘C’ and the letter string ‘ly’ in Cromolyn.</p> <p><u>Overlap in Strength</u> Both Omontys and Cromolyn Inhalation solution may be dosed at 20 mg. Additionally, Omontys and Cromolyn Ophthalmic Solution may be dosed at strengths of 4 mg vs. 4%.</p>	<p><u>Dosage Form</u> Injection vs. Inhalation Solution, Nasal Spray or Ophthalmic solution.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral inhalation, nasally, or ophthalmically.</p> <p><u>Frequency of Administration</u> Once a month vs. 3 to 6 times daily depending on the product used</p>

18	<p>Amoclan*</p> <p>*Proprietary name is no longer marketed, but several generic equivalents are available (Amoxicillin and Clavulanate Potassium) Powder for Suspension, 200 mg/28.5 mg per 5 mL 400 mg/57 mg per 5 mL 600 mg/42.9 mg per 5 mL</p> <p><u>Usual Dose</u> Less than 40 kg: 45 mg/kg per day in equally divided doses every 12 hours. Greater than 40 kg: 200 mg/28.5 mg per 5 mL to 600 mg/42.9 mg per 5 mL every 12 hours depending on the indication</p>	<p><u>Orthographic</u> The letter string ‘Omo’ and the letter ‘t’ in Omontys may appear similar to the letter string ‘Amo’ and the letter ‘l’ in Amoclan.</p> <p><u>Numerical similarity in strength</u> Omontys may be dosed at the strength of 5 mg and Amoclan dose may be 5 mL.</p>	<p><u>Orthographic</u> The name Omontys contains a down stroke vs. the name Amoclan does not.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. twice daily</p>
19	<p>Qutenza (Capsaicin) Topical Patch, 8%</p> <p><u>Usual Dose</u> Not for self-administration. Use up to 4 patches per application, patches should be applied for 60 minutes and procedure should not be repeated more frequently than 3 months.</p>	<p><u>Orthographic</u> Both names contain an upstroke (letter ‘t’) and a down stroke (letter ‘y’ vs. letter ‘z’). Additionally, the letter ‘O’ and the letter strings ‘on’ and ‘ys’ in Omontys may appear similar to the corresponding letter ‘Q’ and the letter strings ‘en’ and ‘za’ in Qutenza.</p> <p><u>Numerical overlap in strength</u> Omontys may be dosed at the strength of 8 mg and Qutenza may be dosed at 8%</p>	<p><u>Orthographic</u> The upstroke ‘t’ is located in different positions of the names; thus, the names do not have the same shape.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. topical</p>

20	<p>Ozurdex (Dexamethasone) Ophthalmic Implant, 0.7%</p> <p><u>Usual Dose</u> Inject 0.7 mg intravitreally.</p>	<p><u>Orthographic</u> The letter string ‘Om’ and the letter ‘t’ in Omontys may appear similar to the corresponding letter string ‘Ozu’ and the letter ‘d’ in Ozurdex.</p>	<p><u>Orthographic</u> The name Omontys contains a down stroke near the end of the name and Ozurdex contains a down stroke near the beginning of the name. Additionally, the letter string ‘ys’ in Omontys lacks orthographic similarity to the corresponding letter string ‘ex’ in Ozurdex when scripted.</p> <p><u>Strength</u> 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL, 10 mg/mL, or 20 mg/mL vs. 0.7 %</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. intravitreally</p>
21	<p>Omnihist LA*</p> <p>*Proprietary name is no longer marketed, but several generic equivalents are available (Chlorpheniramine Methscopolamine, Phenylephrine) Extended-release Tablets, 8 mg/2.5 mg/20 mg</p> <p><u>Usual Dose</u> ½ to 1 tablet orally every 12 hours.</p>	<p><u>Orthographic</u> Both names share the letter string ‘Om’ and the letter ‘s’ in similar positions. Additionally, the letter ‘t’ in Omontys may appear similar to the letter ‘h’ in Omnihist.</p> <p><u>Phonetic</u> Both names start with the letter string ‘Om’</p> <p><u>Partial Overlap in Strength and Dose</u> Omontys may be dosed at the strength of 8 mg or 20 mg and Omnihist LA may be dosed at the strength of Chlorpheniramine of 8 mg and strength of Phenylephrine of 20 mg</p>	<p><u>Orthographic</u> The name Omontys contains 1 upstroke and 1 down stroke vs. the name Omnihist contains 2 upstrokes and no down strokes. Additionally, the name Omnihist LA contains a modifier ‘LA’</p> <p><u>Phonetic</u> The letter string ‘ont’ lacks phonetic similarity to the letter string ‘nih’.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. Oral</p> <p><u>Frequency of Administration</u> Once a month vs. every 12 hours</p>

22	<p>Omnitrope (Somatropin) Powder for Injection, 5.8 mg Injection, 5 mg/1.5 mL and 10 mg/1.5 mL</p> <p><u>Usual Dose</u> 0.04 mg/kg to 0.08 mg/kg subcutaneously per week divided into 7 equal daily injections</p>	<p><u>Orthographic</u> Both names contain an upstroke (letter ‘t’) and a down stroke (letter ‘y’ vs. letter ‘p’). Additionally, both names share the letter string ‘Om’.</p> <p><u>Overlap in Strength and Dose</u> Omontys may be dosed at the strength of 5 mg or 10 mg and Omntrope may be dosed at the same strengths as well.</p> <p><u>Route of Administration</u> Subcutaneous</p>	<p><u>Orthographic</u> The name Omnitrope appears longer than the name Omontys (9 letters vs. 7 letters). Additionally, the letter string ‘ys’ in Omnotys lacks orthographic similarity to the corresponding letter string ‘ro’ in the name Omnitrope when scripted.</p> <p><u>Frequency of Administration</u> Once a month vs. once daily</p>
23	<p>Oncovite (Multivitamin) Tablets</p> <p><u>Usual Dose</u> Take 1 tablet orally once daily</p>	<p><u>Orthographic</u> Both names share the letter ‘t’. Additionally, the letter string ‘Omon’ may appear similar to the letter string ‘Onco’.</p>	<p><u>Orthographic</u> The letter string ‘tys’ lacks orthographic similarity to the corresponding letter string ‘vite’ in Oncovite.</p> <p><u>Strength</u> 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL, 10 mg/mL, or 20 mg/mL vs. single strength</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. once daily</p> <p><u>Usual Dose</u> 0.04 mg/kg to 0.08 mg/kg or 2 mg to 20 mg vs. 1 tablet</p>

24	<p>Quartuss (Chlorpheniramine, Dextromethorphan, Guaifenesin, Phenylephrine) Syrup, 2 mg/15 mg/100 mg/10 mg per 5 mL</p> <p><u>Usual Dose</u> 5 mL to 10 mL orally every 4 hours to 6 hours as needed</p> <p>Quartuss DM (Chlorpheniramine, Dextromethorphan, Phenylephrine) Solution, 2 mg/3 mg/1.5 mg per mL</p> <p><u>Usual Dose</u> 1 mL to 2 mL every 4 to 6 hours, do not exceed 4 doses in 24 hours</p>	<p><u>Orthographic</u> Both names share the letter ‘t’ and the letter ‘s’ in similar positions. The letter string ‘Om’ may appear similar to the corresponding letter string ‘Qua’ when scripted.</p> <p><u>Partial Overlap in Strength and Dose</u> Omontys may be dosed at the strength of 2 mg or 3 mg and Quartuss may be dosed at the strength of Chlorpheniramine of 2 mg and strength of Dextromethorphan of 3 mg. Additionally, Omontys may be dosed at 5 mg and Quartuss may be dosed at 5 mL.</p>	<p><u>Orthographic</u> The name Omontys contains a down stroke vs. the name Quartuss does not.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. every 4 to 6 hours as needed</p>
25	<p>Questran (Cholestyramine) Powder for Suspension, 4 g</p> <p><u>Usual Dose</u> 4 g orally once to twice daily before a meal</p>	<p><u>Orthographic</u> Both names share the letter ‘t’ in similar positions. The letter string ‘Om’ in Omontys may appear similar to the corresponding letter string ‘Que’ when scripted.</p> <p><u>Numerical Overlap in Strength and Dose</u> Omontys may be dosed at the strength of 4 mg and Questran may be dosed at the strength of 4 g</p>	<p><u>Orthographic</u> The name Omontys contains a down vs. the name Questran does not. Additionally, the letter strings ‘on’ and ‘ys’ in Omontys lack orthographic similarity to the corresponding letter ‘s’ and the letter string ran in Questran.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. once daily to twice daily</p>

26	<p>Orvaten*</p> <p>*Proprietary name is no longer marketed, but several generic equivalents are available (Midodrine) Tablets, 2.5 mg, 5 mg, 10 mg</p> <p><u>Usual Dose</u> 2.5 mg to 10 mg orally three times daily.</p>	<p><u>Orthographic</u> Both names share the letter 't'. Additionally, the letter string 'Omo' in Omontys may appear similar to the corresponding letter string 'Orva-' in Orvaten when scripted.</p> <p><u>Overlap in Strength and Dose</u> Omontys and Orvaten may be dosed at the strength of 5 mg or 10 mg</p>	<p><u>Orthographic</u> The name Omontys contains a down vs. the name Orvaten does not. Additionally, the letter string 'ys' in Omontys lacks orthographic similarity to the letter string 'en' in Orvaten.</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. three times daily</p>
27	<p>Oncolyn (Oncolyn 750 mg, Proanthocyanidins 100 mg, Plant Saponin 100 mg, Plant Polyphenols 100 mg) Tablet (Herbal Supplement)</p> <p><u>Usual Dose</u> Take 1 tablet daily.</p>	<p><u>Orthographic</u> The name Omontys may appear similar to the name Oncolyn when scripted.</p>	<p><u>Route of Administration</u> Subcutaneous or intravenous vs. oral</p> <p><u>Usual Dose</u> 0.04 mg/kg to 0.08 mg/kg or 2 mg to 20 mg vs. 1 tablet</p> <p><u>Strength</u> 2 mg/0.5 mL, 3 mg/0.5 mL, 4 mg/0.5 mL, 5 mg/0.5 mL, 6 mg/0.5 mL, 10 mg/mL, or 20 mg/mL vs. single strength</p> <p><u>Frequency of Administration</u> Once a month vs. once daily.</p>

28	<p>Onsolis (Fentanyl) Buccal Soluble Film, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg</p> <p><u>Usual Dose</u> 200 mcg to 1200 mcg separated by at least 2 hours, do not exceed 4 doses in 24 hours.</p>	<p><u>Orthographic</u> The letter string ‘Omo’ and the letter ‘t’ in Omontys may appear similar to the letter string ‘Onso’ and the letter ‘l’ in Onsolis.</p> <p><u>Phonetic</u> The letter strings ‘Om’ and the letter string ‘ys’ in Omontys are phonetically similar to the letter strings ‘On’ and ‘is’ in Onsolis</p> <p><u>Similarity in Strength and Dose</u> Omontys may be dosed at the strength of 2 mg, 4 mg, 6 mg, 8 mg, or 12 mg vs. Onsolis can be dosed at the similar strengths of 200 mg, 400 mg, 600 mg, 800 mg, and 1200 mg</p>	<p><u>Orthographic</u> The name Omontys contains a down stroke vs. the name Onsolis does not. Additionally, the name Omontys appears longer than the name Onsolis due to wider letters ‘m’ and ‘y’.</p> <p><u>Phonetic</u> The letter string ‘ont’ in Omontys lacks phonetic similarity to the corresponding letter string ‘sol’ in Onsolis</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. oral</p> <p><u>Frequency of Administration</u> Once a month vs. at least 2 hours apart, not to exceed 4 doses per 24 hours</p>
29	<p>Omnaris (Ciclesonide) Nasal Spray, 50 mcg per actuation</p> <p><u>Usual Dose</u> 2 sprays in each nostril once daily</p>	<p><u>Orthographic</u> Both names share the letter string ‘Om’.</p> <p><u>Phonetic</u> Both names share the letter string ‘Om’ and the letter string ‘ys’ in Omontys is phonetically similar to the letter string ‘is’ in Omnaris</p> <p><u>Similarity in Strength and Dose</u> Omontys may be dosed at the strength of 5 mg vs. Omnaris can be dosed at the similar strength of 50 mcg, especially if trailing zero is used.</p>	<p><u>Orthographic</u> The name Omontys contains 2 upstroke and 1 down stroke vs. the name Omnaris contains 1 upstroke and no down strokes.</p> <p><u>Phonetic</u> The letter string ‘ont’ in Omontys lacks phonetic similarity to the corresponding letter string ‘nar’ in Omnaris</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. nasally</p> <p><u>Frequency of Administration</u> Once a month vs. once daily</p>

30	<p>Mentax (Butenafine) Topical Cream, 1%</p> <p><u>Usual Dose</u> Apply to affected area and the immediately surrounding skin once daily</p>	<p><u>Phonetic</u> The letter string 'mont' in Omontys is phonetically similar to the letter string 'ment' in Mentax</p> <p><u>Similarity in Strength and Dose</u> Omontys may be dosed at the strength of 10 mg vs. Mentax can be dosed at the similar strengths of 1%.</p>	<p><u>Phonetic</u> The name Omontys contains 3 syllables vs. the name Mentax contains 2 syllables. Additionally, the letter string 'ys' in Omontys lacks phonetic similarity to the letter string 'ax' in Mentax.</p> <p><u>Usual Dose</u> 0.04 mg/kg to 0.08 mg/kg or 2 mg to 20 mg vs. apply to affected area</p> <p><u>Route of Administration</u> Subcutaneous or intravenous injection vs. topically</p> <p><u>Frequency of Administration</u> Once a month vs. once daily</p>
31	<div style="text-align: right;">(b) (4)</div>		<div style="text-align: right;">(b) (4)</div>

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

/s/

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