CENTER FOR DRUG EVALUATION AND RESEARCH

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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

Date:	May 31, 2012
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Drug Name and Strength:	Afinitor Disperz (Everolimus) Tablets for Oral Suspension; 2 mg, 3 mg, and 5 mg
Application Type/Number:	NDA 203985
Applicant/Sponsor:	Novartis
OSE RCM #:	2012-560

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Afinitor Disperz, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Afinitor (Everolimus) immediate release tablets submitted under NDA 022334 were originally approved on March 30, 2009 for the treatment of patients with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. On October 20, 2010, Afinitor received approval for the treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis in patients three years old or older that required therapeutic intervention but were not candidates for curative surgical resection. On May 5, 2011, Afinitor was approved for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable locally advanced or metastatic disease. Everolimus was also approved under the brand name, Zortress, on April 20, 2010 as a dual trade name for prophylaxis of organ rejection in adult patients at low to moderate immunologic risk receiving a kidney transplant.

The sponsor is currently seeking approval for the treatment of SEGA to patients less than three years old. Because of this new pediatric population subset, a dispersible suspension formulation is proposed to provide an appropriate dosage form for this patient population, Afinitor Disperz. This new dosage from is a dispersible tablet in water for suspension submitted under a separate NDA (203985).

The proprietary name review for Afinitor (OSE 2008-257) was consulted to provide guidance for the current review for Afinitor Disperz.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 2, 2012 proprietary name submission.

- Active Ingredient: Everolimus
- Indication of Use: Treatment of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis in patients that require therapeutic intervention but are not candidates for curative surgical resection.
- Route of Administration: Orally
- Dosage Form: Tablets for Oral Suspension
- Strength: 2 mg, 3 mg, 5 mg
- Dose and Frequency: 4.5 mg/m^2 rounded to the nearest dose that can be achieved with a whole tablet or tablets. The dose of Afinitor is reduced by 50% if moderate CYP3A4 inhibitors are taken concurrently. If strong CYP3A4 inducers are used concurrently, the Afinitor dose should be doubled. Dose adjustments

should be made based on achieving steady state trough levels between (b) (4) ng/mL to 15 ng/mL.

- How Supplied: White to slightly yellowish, round, flat tablets with a beveled edge and no score. The 2 mg tablet is engraved with "D2" on one side, the 3 mg tablet with "D3", and the 5 mg tablet with "D5". All tablet strengths have "NVR" engraved on the other side.
- Storage: Store Afinitor Disperz (b) (4). Excursions are allowed between 59°F to 86°F (15°C to 30°C).
    - Keep Afinitor Disperz in the package it comes in.
    - Open the blister package just before taking.
    - Keep the blister package and tablets dry prior to taking.
    - Keep Afinitor Disperz out of light.
- Container and Closure Systems: Each carton contains 4 blister cards of 7 tablets each for a total of 28 tablets per carton.

2 RESULTS

The following sections provide the information obtained and considered in the 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 Oncology Products 2 concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On April 11, 2012 the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed name, Afinitor Disperz, contains two components: 1) the proposed root name, Afinitor, and 2) a modifier, Disperz. In the proprietary name submission, the Applicant stated the root of the proposed name "Afinitor" is derived from the established brand name for the immediate release tablet formulation of everolimus. The modifier "Disperz" is intended to differentiate the new dispersible tablet formulation of everolimus from the immediate release tablet. Therefore, we have evaluated whether the proposed modifier "Disperz" is appropriate to signal that the formulation is to be dispersed in water prior to consumption (see Discussion – Section 3).

2.2.3 Medication Error Data Selection of Cases

DMEPA searched AERS database for medication errors involving Afinitor which would be relevant for this review.

The April 27, 2012 search of the Adverse Event Reporting System (AERS) database used the following search terms: active ingredient "Everolimus", trade name "Afinitor", and verbatim terms "Afin%" and "Ever%". The reaction terms used were the MedDRA High Level Group terms (HLGT) "Medication Errors" and "Product Quality Issues". The last AERS search conducted for Afinitor was June 17, 2011 in OSE review 2011-2264.

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, 8 reports were not included in the final analysis for the following reasons: medication error not related to Afinitor and adverse events not related to medication errors.

Following exclusions, the search yielded 12 relevant cases.

- Incorrect Administration Technique
    - Seven cases involved the splitting of tablets and administration of the drug. The outcomes in each case were not reported.
    - Two cases involved the crushing or chewing of the tablet with applesauce. The outcomes were reported as unchanged or unknown.

  No additional information explaining the cause of the error was provided. DMEPA found the currently marketed Afinitor labeling to have adequate statements to take the tablets whole, to not crush the tablet, and to not take broken tablets.

- Wrong Dose Omission - Two cases involved the patient missing a dose. No further information explaining the cause of the error or information on the outcome was provided.
- Wrong Frequency - One case involved the patient taking Afinitor once daily for four weeks, then taking two weeks off, before taking Afinitor again daily for four weeks. No further information explaining the cause of the error or information on the outcome was provided.

See Appendix F for the ISR numbers of included cases.

2.2.4 FDA Name Simulation Studies

Thirty-four practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. The word 'Disperz' was interpreted as either "Dispenz", "Disperse", or "Disperg" a total of 22 times in each of the three simulation categories. The letter 'f' in Afinitor was interpreted as 'rc', 's', or 'g' in the voice and outpatient simulations. The letter 'A' in Afinitor was interpreted as 'O' in three outpatient responses. Lastly, the modifier was not included in 5 of the responses. See Appendix C 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 22, 2012 email, the Division of Oncology Products 2 (DOP2) did forward comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

The only possible issue I have relates to potential confusion among patients or patients' family members regarding whether the tablets are orally disintegrating tablets rather than tablets that require dissolution in water prior to administration. Although I am not sure if it is a big concern given that the package will come with explicit instructions regarding how doses should be prepared, my first (incorrect) assumption was that they would be orally disintegrating.

DMEPA acknowledges this concern and assesses the potential impact in Section 3 – Discussion.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Afinitor Disperz. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Afinitor Disperz identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names not previously identified by DMEPA, but identified by (b) (4), a third party vendor, who completed an external name assessment for the proposed proprietary name for the Sponsor.

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

Look Similar to Afinitor		Look Similar to Afinitor		Look and Sound Similar to Afinitor	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Afluria	FDA	Aliclen	FDA	Afeditab CR	FDA
Akineton	FDA	Alimta	FDA	Afinitol	FDA
Alcortin	FDA	Alinia	FDA	Afinitor	FDA
Allertan	FDA	Atenolol	FDA	Carnitor	FDA
Alodox	FDA	Cefaclor	FDA	Affinitak***	FDA
Alomide	FDA	Oforta	FDA	Signifor***	FDA

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

Look Similar to Afinitor		**Look Similar to Afinitor**		**Look and Sound Similar to Afinitor**	
Zaditor	FDA	Afrinol	FDA	Effexor	External Study
Claritin	FDA	Rafinlar***	FDA	Lipitor	External Study
				Advicor	External Study
Look Similar to Disperz		**Look Similar to Disperz**		**Look and Sound Similar to Disperz**	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Buspar	FDA	Desyrel	FDA	Dispermox	FDA
Dacogen	FDA	Diazepam	External Study	Dispert	FDA
Cefoxitin	FDA	Doxepin	FDA	Disperz***	FDA
Desferal	FDA	Despec	FDA	Dysport	FDA
				Dispas	FDA
				(b) (4)	FDA
				Look and Sound Similar to Afinitor Disperz	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
				Advair Diskus	External Study

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

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Oncology Products 2 via e-mail on May 15, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 2 on May 26, 2012, they stated no additional concerns with the proposed proprietary name, Afinitor Disperz. However, DOP2 requested OPDP re-review the

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proposed proprietary name taking into consideration the fact that the dosage form designation [redacted] proposed by the Applicant has been revised by ONDQA to "Tablets for Oral Suspension". OPDP responded on May 31, 2012, via email, indicating they maintain their non-objection to the name based on the information provided by DOP2 and ONDQA.

3 DISCUSSION

The proposed proprietary name, Afinitor Disperz, includes the modifier "Disperz" to convey that it must be dispersed in water prior to consumption. The name and modifier does not look or sound similar to any currently marketed products or products in the pipeline and the modifier "Disperz" is not a standard medical abbreviation. Based on this information, we evaluated four distinct scenarios from a medication error perspective: (1) the consequence if the modifier, "Disperz", is dropped when prescribed, (2) the consequence if only the modifier is written when prescribed, (3) whether the modifier is ambiguous regarding the correct dosage form for the product and (4) whether a completely different brand name without the root name or modifier would be more appropriate to minimize medication errors.

To provide context for discussion, the product characteristics are reviewed in the following table:

	Afinitor	**Afinitor Disperz**
Established Name	Everolimus	Everolimus
Indication	TSC with SEGA, renal cell carcinoma, nueroendocrine tumors of pancreatic origin.	TSC with SEGA
Route of Administration	Oral	Oral
Dosage Form	Immediate Release Tablet The tablet should not be crushed, chewed or broken.	Tablets for Oral Suspension The tablet should not be crushed, chewed or broken.
Strength	2.5 mg, 5 mg, 7.5 mg, 10 mg tablets	2 mg, 3 mg, 5 mg dispersible tablets
Dose	SEGA- 2.5 mg, 5 mg, 7.5 mg orally once daily based on BSA range. RCC and PNET- 10 mg orally once daily.	4.5 mg/m^2 orally daily; round dose to the nearest whole tablet or tablets. Initial doses adjusted based on presence of CYP3A4 medications. Doses adjusted based on steady state trough concentrations between (b) (4) ng/mL to 15 ng/mL.
How Supplied	blister cards of 7 tablets each	blister cards of 7 tablets each
Storage	59°F to 86°F	59°F to 86°F
Container and Closure System	Cartons with 4 blister cards of 7 tablets each	Cartons with 4 blister cards of 7 tablets each

With regard to scenario one, post marketing medication error data shows the modifier of a proprietary name can be dropped when the medication is prescribed, thereby creating the potential for the wrong drug to be administered. We evaluated this scenario based on

the fact that Afinitor has overlapping characteristics in dose, strength, and frequency of administration. If a prescriber accidentally forgets to write the modifier "Disperz", Afinitor immediate release tablets may be dispensed. However, the patient would still be receiving the same drug and would be monitored for trough concentrations that could help detect the wrong dosage form dispensed. Additionally, a patient that received instructions to disperse the tablet, yet received the immediate release tablet could still dissolve the tablet since the immediate release formulation can be dispersed in water to form a suspension based on the current package insert. Therefore, we believe this scenario presents minimal risk to patients.

DMEPA also evaluated the second scenario where only the modifier "Disperz" is written on the prescription and the root name is omitted. Since the modifier is unique, there is a possibility that the root name is omitted since the prescriber thinks the unique modifier will adequately distinguish the product. Post marketing experience with Zyprexa Zydis has shown that only the modifier Zydis has been written on a prescription. An FMEA analysis was conducted to assess the likelihood of orthographic and phonetic similarities with "Disperz" and other similar names (see Appendix – E). The completed FMEA analysis in Appendix E did not reveal any names that could be confused if prescriptions were issued as "Disperz" when orthographic, phonetic and product characteristics were analyzed. Therefore, we conclude this scenario poses minimal risk for error.

In scenario three, DMEPA evaluated if the modifier "Disperz" clearly communicated the correct dosage form. A search of commonly used databases along with FDA databases was conducted to identify modifiers that attempted to convey dispersible tablets for oral suspension (see Appendix G for the databases used). The search revealed only 3 modifiers. Two of the three modifiers were considered ambiguous or could be confused with other commonly used medical abbreviations and were not found acceptable. Only Panixine Disperdose (OSE review 03-0073) was relevant to this review. Since there are few modifiers used to communicate oral tablets for suspension, it is difficult for a modifier to clearly communicate the dosage form to a high percentage of healthcare practioners. Based on the fact that healthcare practioners are not familiar with oral tablet for suspension modifiers, DMEPA reviewed the external study submitted by (b) (4) to assess what the modifier communicated to healthcare professionals. In the external study respondents were asked what "Disperz" communicated in the context of the root name, Afinitor. Thirty-five of forty-nine healthcare professionals (71%) correctly identified the intended modifier meaning as dispersible tablet, disperses in liquid, or suspension. Ten percent of respondents felt that "Disperz" communicated either melting, dissolves in mouth, or no water needed. This is concerning, since this type of interpretation could lead to the wrong route of administration (e.g. patients administering Afinitor Disperz sublingually). However, since there are no other modifiers that more appropriately communicate the dosage form, dispersible tablet for suspension, DEMPA believes the introduction of the dosage form modifier "Disperz" is acceptable if adequately defined labeling is in place to reinforce the method and route of administration for this product.

Lastly, we considered the medication error risks posed by scenario four: the use of a completely different brand name without the root name or modifier. DMEPA envisions a possible scenario occurring where even with a completely different name, dispersible

tablet information may be misconstrued as an orally disintegrating tablet and given to a pediatric patient less than 2 years old who may choke. Therefore, a completely different brand name may not prevent the incorrect administration of the drug. Moreover, since tuberous sclerosis complex with subependymal giant cell astrocytoma (TSC with SEGA) patients can see multiple pediatric specialists, and everolimus may have multiple pediatric indications in the future, it is possible that duplication of therapy could result which may increase the severity or number of adverse events. Lastly, Zortress, a brand name for everolimus indicated for the use in prophylaxis of organ rejection is also currently marketed. A third brand name for everolimus may further increase the chances of therapeutic duplication.

Given the totality of the factors considered above, we conclude that the proposed modifier, "Disperz", poses the least risk of errors with this product and, therefore, is appropriate.

4 CONCLUSION

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

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

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Afinitor Disperz, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your March 2, 2012 submission are altered, the name must be resubmitted for review.

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

5 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

17. ***Walgreens (www.walgreens.com)***

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

18. ***Rx List (www.rxlist.com)***

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

19. ***Dogpile (www.dogpile.com)***

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

20. ***OSE Review: 2008-257, Afinitor (Everolimus) Proprietary Name Review, August 11, 2008.***

21. ***OSE Review: 2003-0073, Panixine DisperDose Proprietary Name Review, May 7, 2003.***

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

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

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

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

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

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[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]

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 2 below for details).

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

Table 2. 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 Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• 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 discusses the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

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

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

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

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

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

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

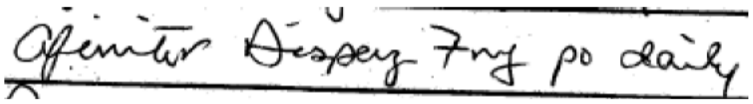
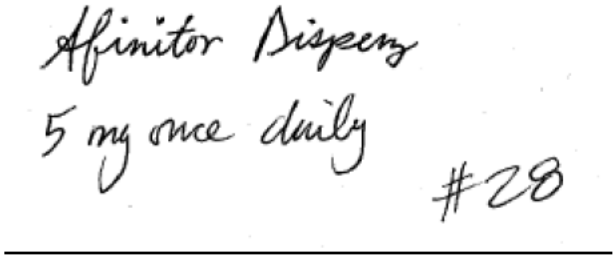
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Afinitor Disperz	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'A'	'C', 'O', 'ce', 'FL', 'H', 's'	Any Vowel
Lower case 'a'	'el, 'ci', 'cl', 'd', 'o', 'u'	Any Vowel
Lower case 'f'	'k', 'l', 'd', 'p', 't'	'ph'
Lower case 'i'	Any vowel	Any vowel
Lower case 'n'	'm', 'u', 'r', 'x', 'h', 's'	'dn' 'gn', 'kn' 'mn', 'pn'
Lower case 't'	'r', 'f', 'x', 'A'	'd'
Lower case 'o'	Any vowel, 'c'	'oh', Any vowel
Lower case 'r'	's', 'n', 'e', 'v'	
Capital 'D'	'O', 'T', 'B'	'B', 'T'
Lower Case 'd'	'cl', 'ci'	'b', 't'
Lower case 's'	'G', '5', 'g', 'n', 'c', 'r'	'x'
Lower case 'p'	'y', 'z', 'yn', 'ys', 'g', 'j', 'l', 'q'	'b'
Lower case 'e'	Any vowel, 'l', 'p'	Any vowel
Lower case 'z'	'c', 'e', 'g', 'n', 'm', 'q', 'r', 's', 'v'	'c', 's', 'x'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Afinitor Disperz Study (Conducted on 03/16/2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Afinitor Disperz 5 mg Sig: Take 5 mg orally once daily Disp: # 28

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study
34 People Responded

Study Name: **Afinitor Disperz**

Total: 34

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
???	1	0	0	1
AFENITOR DISPERG	1	0	0	1
AFENITOR DISPERZ	1	0	0	1
AFFINATOR DISPERSE	0	1	0	1
AFFINITOR DISPERSE	0	2	0	2
AFFINITOR-DISPERSE	0	1	0	1

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
AFINITOR	2	0	1	3
AFINITOR DISPENZ	0	0	10	10
AFINITOR DISPERG	0	0	1	1
AFINITOR DISPERSE	0	1	0	1
AFINITOR DISPERZ	3	0	1	4
AFINTIOR DISPERZ	1	0	0	1
AGINITOR DISPENZ	0	0	1	1
ALFINITOR DISPERZ	0	0	1	1
ARCINITOR	0	1	0	1
ASINATOR DISPERSE	0	1	0	1
OCINIFORCE	0	1	0	1
OFENITOR DISPERSE	0	1	0	1
OPHENATOR	0	1	0	1

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

Proprietary Name	Active Ingredient	Similarity to Afinitor	Failure preventions
Alodox	Doxycycline	Look alike	The pair has sufficient orthographic differences
Afinitol		Look and sound alike	Name identified in Saegis database. Unable to find product characteristics in commonly used drug databases.
Proprietary Name	**Active Ingredient**	**Similarity to Disperz**	**Failure preventions**
	Cefoxitin	Look alike	The pair has sufficient orthographic differences
(b) (4)	(b) (4)	Look alike	Name only identified in Micromedex database. Unable to find product characteristics in other commonly used drug databases.
Dispert		Look and sound alike	Name only identified in Saegis database. Unable to find product characteristics in other commonly used drug databases.
Disperz***		Look and sound alike	Modifier that is the subject of this review

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

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

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: (b) (4) orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Afluria (Influenza Virus Vaccine) Suspension for Injection 45 mcg/0.5 mL 5mL vial and 0.5 mL pre-filled syringe Usual Dose 0.5 mL intramuscularly once only each year	Orthographic Similarity with Afinitor Both names begin with the letter string 'Af'. The letter string 'ia' looks similar to the letter string 'or' when scripted. Numerical Similarity in Dose The 0.5 mL dose of Afluria looks similar to the 5 mg dose of Afinitor Disperz when scripted especially if a leading zero is not scripted (.5 mL).	Orthographic Difference with Afinitor The name Afluria has an upstroke letter 'l' in the third position where Afinitor does not. The name Afinitor has an upstroke letter 't' near the end of the name where the Afluria does not. The modifier adds orthographic difference when included. Strength Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. Also, there is no overlap or numerical similarity between strengths. Frequency of Administration The frequency of administration for each drug has no overlap or numerical similarity between them.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Akineton (Biperiden) Tablets 2 mg <u>Usual Dose</u> One tablet orally one to three times daily	<u>Orthographic Similarity with Afinitor</u> The letter string 'Akin' looks similar to the letter string 'Afin' when scripted. The letter string 'eton' looks similar to the letter string 'itor' when scripted. <u>Route of Administration</u> Both drugs are given orally. <u>Frequency of Administration</u> Both drugs can have an overlap in the frequency of administration. <u>Overlap in Dose and Strength</u> Both drugs have an overlap in dose and strength (2 mg). <u>Dosage Form</u> Both drugs are oral tablets.	<u>Orthographic Difference with Afinitor</u> The name Afinitor has the letter 'f', an upstroke and downstroke letter, in the second position where Akineton has the letter 'k', an upstroke letter only, in the second position. This can help to differentiate the names. The modifier adds orthographic difference when included.
Alcortin (b) (4)	<u>Orthographic Similarity with Afinitor</u> The letter string 'Alc' looks similar to the letter string 'Afi' when scripted. The letter string 'tin' looks similar to the letter string 'tor' when scripted.	<u>Dose</u> 4.5 mg/m^2 based on body surface area vs. (b) (4) <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. (b) (4) .

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Allertan (b) (4) (b) (4)	<u>Orthographic Similarity with Afinitor</u> The letter string 'Al' looks similar to the letter string 'Af' when scripted. The letter string 'tan' looks similar to the letter string 'tor' when scripted. (b) (4)	<u>Orthographic Difference with Afinitor</u> The name Allertan has an upstroke letter 'l' in the third position where Afinitor does not. The modifier adds orthographic difference when included. <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. (b) (4)
Alomide (Lodoxamide) Ophthalmic Solution 0.1% <u>Usual Dose</u> One to two drops in the affected eye four times daily	<u>Orthographic Similarity with Afinitor</u> The letter string 'Alo' looks similar to the letter string 'Afi' when scripted. <u>Overlap in Dose</u> Both drugs have an overlap in dose(one drop vs. one tab). <u>Frequency of Administration</u> The abbreviation q.d. (daily) can be confused with q.i.d. (four times daily) when scripted.	<u>Orthographic Difference with Afinitor</u> The name Afinitor has the letter 'f', an upstroke and downstroke letter, in the second position where Alomide has the letter 'k', an upstroke letter only, in the second position. Afinitor has the cross stroke letter 't' near the end of the name where Alomide does not. This can help to differentiate the names. The modifier adds orthographic difference when included. <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. Alomide has only one strength that will likely be omitted. There is no overlap or numerical similarity between strengths.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Zaditor (Ketotifen) Ophthalmic Solution 0.025% Usual Dose One drop in the affected eye twice to three times daily	Orthographic Similarity with Afinitor Both names have the letter string 'itor' at the end of the name. Each name is similar in length. Overlap in Dose Both drugs have an overlap in dose (one drop vs. one tab).	Orthographic Difference with Afinitor The letter string 'Za' does not look similar to the letter string 'Af' when scripted. The modifier adds orthographic difference when included. Strength Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. Zaditor has one strength that will likely be omitted. There is no overlap or numerical similarity between strengths.
Claritin (Loratadine) Tablets, Oral Syrup, Capsule Capsule and Tablet: 10 mg Oral Syrup: 1 mg/mL Usual Dose 10 mg orally once daily	Orthographic Similarity with Afinitor The letter string 'Cla' looks similar to the letter string 'Afi' when scripted. The letter string 'tin' looks similar to the letter string 'tor' when scripted. Overlap in Dose Both drugs have an overlap in dose (10 mg). Route of Administration Both drugs are given orally. Frequency of Administration Both drugs have an overlap in the frequency of administration.	Orthographic Difference with Afinitor The name Afinitor has the letter 'f', an upstroke and downstroke letter, in the second position where Claritin has the letter 'l', an upstroke letter only, in the second position. If the letter 'C' and the letter 'l' are merged together to script the letter 'A', The name Claritin will appear to have no upstroke or downstroke letter in the second position. This can help to differentiate the names. The modifier adds orthographic difference when included. Strength There is no overlap or numerical similarity between strengths.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Aiclen (b) (4)	<u>Orthographic Similarity with Afinitor</u> The letter string 'Ali' looks similar to the letter string 'Afi' when scripted. (b) (4)	<u>Orthographic Difference with Afinitor</u> Afinitor has the cross stroke letter 't' near the end of the name where Alomide does not. This can help to differentiate the names. The modifier adds orthographic difference when included. <u>Dose</u> 4.5 mg/m^2 based on body surface area vs. (b) (4). <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. (b) (4)
Alimta (Pemetrexed) Powder for Injection 100 mg and 500 mg <u>Usual Dose</u> 500 mg/m^2 intravenously every 21 days	<u>Orthographic Similarity with Afinitor</u> The letter string 'Alim' looks similar to the letter string 'Afin' when scripted. The letter string 'ta' looks similar to the letter string 'tor' when scripted. <u>Setting of Use</u> Both drugs are used or proposed for the oncology setting.	<u>Orthographic Difference with Afinitor</u> Afinitor has eight letters in the name where Alimta has six letters. Afinitor appears longer when scripted. The modifier adds orthographic difference when included. <u>Dose and Strength</u> There is no overlap or numerical similarity between strengths and dose. <u>Frequency of Administration</u> The frequency of administration for each drug has no overlap or numerical similarity between them.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Alinia (Nitazoxanide) Tablet and Powder for Suspension Powder for Suspension: 100 mg/5 mL Tablet: 500 mg <u>Usual Dose</u> 100 mg to 500 mg (5 mL to 25 mL) orally twice daily for 3 days or 14 days	<u>Orthographic Similarity with Afinitor</u> The letter string 'Alin' looks similar to the letter string 'Afin' when scripted. <u>Route of Administration</u> Both drugs can be given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form. <u>Numerical Similarity in Dose</u> The 100 mg dose of Alinia looks similar to the 10 mg dose of Afinitor Disperz when scripted.	<u>Orthographic Difference with Afinitor</u> The name Afinitor has the letter 'f', an upstroke and downstroke letter, in the second position where Alinia has the letter 'l', an upstroke letter only, in the second position. The name Afinitor has an upstroke letter 't' near the end of the name where Alinia does not. The modifier adds orthographic difference when included. <u>Strength</u> There is no overlap or numerical similarity between strengths.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Atenolol	Tablets: 25 mg, 50 mg, 100 mg <u>Usual Dose</u> 25 mg to 200 mg orally once daily	<u>Orthographic Similarity with Afinitor</u> The letter string 'Aten' looks similar to the letter string 'Afin' when scripted. <u>Route of Administration</u> Both drugs can be given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form. <u>Numerical Similarity in Strength</u> The 50 mg strength of Atenolol looks similar to the 5 mg strength of Afinitor Disperz when scripted. <u>Numerical Similarity in Dose</u> The 50 mg and 100 mg dose of Atenolol looks similar to the 5 mg and 10 mg dose of Afinitor Disperz when scripted. <u>Frequency of Administration</u> Both drugs can have an overlap in the frequency of administration.	<u>Orthographic Difference with Afinitor</u> Afinitor has the cross stroke letter 't' near the end of the name where Atenolol does not. Atenolol has an upstroke letter 'l' in the last position of the name where Afinitor does not. Atenolol has three upstroke letters where Afinitor has only two upstroke letters. The modifier adds orthographic difference when included.
	Solution for Injection: 5 mg/10 mL <u>Usual Dose</u> 5 mg intravenously over 5 minutes, may be followed with another 5 mg based on response.	<u>Orthographic Similarity with Afinitor</u> The letter string 'Aten' looks similar to the letter string 'Afin' when scripted. <u>Overlap in Dose and Strength</u> Both drugs have an overlap in dose and strength (5 mg).	<u>Orthographic Difference with Afinitor</u> Afinitor has the cross stroke letter 't' near the end of the name where Atenolol does not. Atenolol has an upstroke letter 'l' in the last position of the name where Afinitor does not. Atenolol has three upstroke letters where Afinitor has only two upstroke letters. The modifier adds orthographic difference when included. <u>Frequency of Administration</u> The frequency of administration for each drug has no overlap or numerical similarity between them.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Cefaclor Tablets, Capsules and Powder for Suspension Tablets: 500 mg ER tablet Capsules: 250 mg and 500 mg Powder: 125 mg/5 mL, 187 mg/5 mL, 250 mg/5 mL and 375 mg/5 mL <u>Usual Dose</u> 125 mg to 750 mg orally twice daily or three times daily	<u>Orthographic Similarity with Afinitor</u> The letter string 'Cefa' looks similar to the letter string 'Afi' when scripted. Both names end in the letter string 'or'. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form.	<u>Orthographic Difference with Afinitor</u> Afinitor has the cross stroke letter 't' near the end of the name where Cefaclor does not. This can help to differentiate the names. The modifier adds orthographic difference when included. <u>Dose and Strength</u> There is no overlap or numerical similarity between strengths and dose.
Oforta (Fludarabine) Tablet 10 mg Usual Dose (b) (4) orally daily on days 1 to 5 of a 28 day cycle.	<u>Orthographic Similarity with Afinitor</u> The letter string 'Ofo' looks similar to the letter string 'Afi' when scripted. The letter string 'ta' looks similar to the letter string 'tor' when scripted. <u>Numerical Similarity in Dose</u> The doses of Oforta (30 mg to 80 mg) look similar to the doses of Afinitor Disperz (3 mg to 8 mg) when scripted. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs are oral tablets. <u>Setting of Use</u> Both drugs are used or proposed for the oncology setting.	<u>Orthographic Difference with Afinitor</u> Afinitor has eight letters in the name where Oforta has 6 letters. Afinitor appears longer when scripted. The modifier adds orthographic difference when included. <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. There is no overlap or numerical similarity between strengths.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Afrinol (Pseudoephedrine) Extended Release Tablet 120 mg Usual Dose 1 tablet orally every 12 hours	Orthographic Similarity with Afinitor The letter string 'Afrin' looks similar to the letter string 'Afin' when scripted. Route of Administration Both drugs are given orally. Numerical Similarity in Dose The 120 mg dose of Afrinol looks similar to the 12 mg dose of Afinitor Disperz when scripted.	Orthographic Difference with Afinitor The name Afinitor has the cross stroke letter 't' near the end of the name where Afrinol does not. Afrinol has an upstroke letter 'l' at the end of the name where Afinitor does not. The modifier adds orthographic difference when included. Strength Afinitor Disperz has multiple strengths that would need to be indicated on the prescription.
Rafinlar*** (b) (4)	Orthographic Similarity with Afinitor Both names have the letter string 'afin' in the name. The letter string 'ar' looks similar to the letter string 'or' when scripted. (b) (4)	Orthographic Difference with Afinitor The first two letters 'Af' in Afinitor do not look similar to the first two letters 'Ra' in Rafinlar when scripted. The modifier adds orthographic difference when included.

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Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Afeditab CR (Nifedipine) Extended Release Tablet 30 mg and 60 mg Usual Dose 30 mg to 120 mg orally daily	Orthographic Similarity with Afinitor The letter string 'Afe' looks similar to the letter string 'Afi' when scripted. The letter string 'ita' looks similar to the letter string 'ito' when scripted. Phonetic Similarity with Afinitor The letter string 'Afedit' is phonetically similar to the letter string 'Afinit'. Route of Administration Both drugs are given orally. Frequency of Administration Both drugs have an overlap in the frequency of administration. Numerical Similarity in Dose and Strengths The doses and strengths (30 mg, 60 mg, 90 mg, 120 mg) of Afeditab CR look similar to the doses and strengths of Afintor Disperz (3 mg, 6, mg, 9 mg, 12 mg) when scripted.	Orthographic Difference with Afinitor The name Afeditab has upstroke letters in the fourth and last position of the name where Afinitor does not. The modifier adds orthographic difference when included. Phonetic Difference with Afinitor The letter string 'ab' in Afeditab is not phonetically similar to the letter string 'or'. The modifier adds phonetic difference when included.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Carnitor (Levocarnitine) Tablet, Solution for Injection, Oral Solution Tablet: 330 mg Injectable: 200 mg/mL Oral Solution: 1 gm/10 mL <u>Usual Dose</u> Adult: 1 to 3 grams per day in divided doses Pediatric: 50 mg to 100 mg/kg/ day in divided doses	<u>Orthographic and Phonetic Similarity with Afinitor</u> Both Carnitor and Afinitor have the letter string 'nitor' in the name. Each name is similar in length. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form. <u>Dose</u> Both drugs can be dosed with the same numeric strength (2 gm vs. 2 mg). The abbreviations gm and mg look similar when scripted.	<u>Orthographic Difference with Afinitor</u> The letter string 'Afi' is not similar to the letter string 'Car' when scripted. The modifier adds orthographic difference when included. <u>Phonetic Difference with Afinitor</u> The letter string 'Afi' is not phonetically similar to the letter string 'Car'. The modifier Disperz adds phonetic difference when included. <u>Strength</u> There is no overlap or numerical similarity between strengths.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Affinitak*** (ISIS 3521) (b) (4) Usual Dose (b) (4)	<u>Orthographic Similarity with Afinitor</u> Both names begin with the letter string 'Af'. Both names have the letter string 'init' in the name. <u>Phonetic Similarity with Afinitor</u> The letter string 'Affinit' sounds phonetically similar to the letter string 'Afinit'. Setting of Use (b) (4) .	<u>Orthographic Difference with Afinitor</u> The name Affinitak has an additional upstroke letter 'f' in the third position where Afinitor does not. The name Affinitak has an upstroke letter 'k' at the end of the name where Afinitor does not. The modifier adds orthographic difference when included. <u>Phonetic Difference with Afinitor</u> The letter string 'ak' is not phonetically similar to the letter string 'or'. The modifier Disperz adds phonetic difference when included. Dose and Strength (b) (4) . <u>Frequency of Administration</u> Afinitor is administered once daily where Affinitak is (b) (4)

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Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Signifor*** (Pasireotide) Injection 0.3 mg/mL, 0.6 mg/mL, 0.9 mg/mL Usual Dose 0.3 mg to 0.9 mg subcutaneously twice daily	Orthographic Similarity with Afinitor The letter string 'ifor' looks similar to the letter string 'itor' when scripted. Each name is similar in length. Phonetic Similarity with Afinitor The letter string 'ifor' is phonetically similar to the letter string 'itor'. Numerical Similarity in Dose and Strength The strength 0.3 mg/mL is numerically similar to the 3 mg strength of Afinitor. The 0.3 mg, 0.6 mg, and 0.9 mg dose is numerically similar to the 3 mg, 6 mg and 9 mg dose of Afinitor Disperz.	Orthographic Difference with Afinitor The letter string 'Sig' does not look similar to the letter string 'Afi' when scripted. The modifier adds orthographic difference when included. Phonetic Difference with Afinitor The letter string 'Sig' is not phonetically similar to the letter string 'Afi'. The modifier Disperz adds phonetic difference when included.

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Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Effexor (Venlafaxine) Tablets 25 mg, 37.5 mg, 50 mg, and 100 mg Usual Dose 25 mg to 100 mg orally twice daily to three times daily	Orthographic Similarity with Afinitor Both names end with the letter string 'or'. Both names have the letter 'f' in the same position. Phonetic Similarity with Afinitor The letter string 'exor' is phonetically similar to the letter string 'itor' when scripted. The letter string 'Eff' is phonetically similar to the letter string 'Af'. Route of Administration Both drugs are given orally. Dosage Form Both drugs are oral tablets. Numerical Similarity in Strength The 50 mg strength of Effexor looks similar to the 5 mg strength of Afinitor Disperz when scripted. Numerical Similarity in Dose The 50 mg and 100 mg dose of Effexor is numerically similar to the 5 mg and 10 mg dose of Afinitor Disperz.	Orthographic Difference with Afinitor The name Effexor has an additional upstroke letter 'f' in the third position where Afinitor does not. Afinitor has a cross stroke letter 't' near the end of the name where Effexor does not. The modifier adds orthographic difference when included. Phonetic Difference with Afinitor The name Afinitor has four syllables where Effexor has only three syllables. The modifier Disperz adds phonetic difference when included.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Lipitor (Atorvastatin) Tablets 10 mg, 20 mg, 40 mg, 80 mg Usual Dose 10 mg to 80 mg orally once daily	Orthographic Similarity with Afinitor Both names end with the letter string 'itor'. Each name is similar in length. Phonetic Similarity with Afinitor Both names end with the letter string 'itor'. Numerical Similarity in Strength The 20 mg strength of Lipitor looks similar to the 2 mg strength of Afinitor Disperz when scripted. Overlap in Dose Both drugs have an overlap in dose (10 mg). Route of Administration Both drugs are given orally. Frequency of Administration Both drugs have an overlap in the frequency of administration. Dosage Form Both drugs are oral tablets.	Orthographic Difference with Afinitor The letter string 'Lip' does not look similar to 'Afin' when scripted. The modifier adds orthographic difference when included. Phonetic Difference with Afinitor The letter string 'Lip' is not phonetically similar to the letter string 'Afin'. The name Lipitor has only three syllables while Afinitor has four syllables. The modifier Disperz adds phonetic difference when included.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Advicor (Niacin/Lovastatin) Tablet 1 gm/20 mg 1 gm/40 mg 500 mg/20 mg 750 mg/20 mg Usual Dose 500 mg/20 mg to 1 gm/40 mg orally daily	Orthographic Similarity with Afinitor The letter string 'Ad' looks similar to the letter string 'Af' when scripted. Both names have the letter string 'or' at the end of the name. Phonetic Similarity with Afinitor The letter string 'icor' is phonetically similar to the letter string 'itor'. Route of Administration Both drugs are given orally. Dosage Form Both drugs are oral tablets. Frequency of Administration Both drugs have an overlap in the frequency of administration.	Orthographic Difference with Afinitor The name Afinitor has the letter 'f', an upstroke and downstroke letter, in the second position where Advicor has the letter 'd', an upstroke letter only, in the second position. Afinitor has the cross stroke letter 't' near the end of the name where Advicor does not. This can help to differentiate the names. The modifier Disperz adds orthographic difference when included. Phonetic Difference with Afinitor The letter string 'Adv' is not phonetically similar to the letter string 'Afin'. The modifier Disperz adds phonetic difference when included. Strength Xuriden has multiple strengths that would need to be indicated on the prescription. Advicor is a combination product with multiple strengths and a strength would need to be indicated on the prescription as well. There is no overlap or numerical similarity between the strengths.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Buspar (Buspirone) Tablet 5 mg and 10 mg Usual Dose 2.5 mg to 15 mg orally twice to three times daily	Orthographic Similarity with Disperz The letter string 'Busp' can look similar to the letter string 'Disp' when scripted. The letter string 'ar' looks similar to the letter string 'erz' especially if the letter 'z' is not scripted with a downstroke. Overlap in Dose and Strength Both drugs have an overlap in dose (5 mg and 10 mg) and strength (5 mg). Route of Administration Both drugs are given orally. Dosage Form Both drugs are oral tablets.	Orthographic Difference with Disperz The name Afinitor adds orthographic difference when written with the modifier Disperz.
Dacogen (Decitabine) Powder for Injection 50 mg per vial Usual Dose 11 mg/m^2 to 15 mg/m^2 based on BSA intravenously every 8 hours for 3 days.	Orthographic Similarity with Disperz The letter string 'Dac' looks similar to the letter string 'Dis' when scripted. Both names have a downstroke letter in a similar position. Numerical Similarity in Strength The 50 mg strength of Dacogen looks similar to the 5 mg strength of Afinitor Disperz when scripted. Numerical Similarity in Dose The 20 mg and 30 mg doses of Dacogen can look similar to the 2 mg and 3 mg doses of Afinitor Disperz when scripted. Setting of Use Both drugs are used or proposed for the oncology setting.	Orthographic Difference with Disperz The name Afinitor adds orthographic difference when written with the modifier Disperz. Frequency of Administration The frequency of administration for each drug has no overlap or numerical similarity between them.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Desferal (Deferoxamine) Powder for Injection 500 mg and 2 gram per vial <u>Usual Dose</u> **Iron Toxicity** <u>Adult:</u> 1 gram initially followed by 500 mg every 4 hours until symptom resolution intramuscularly or intravenously. <u>Pediatric:</u> 40 mg/kg to 90 mg/kg every 4 hrs intramuscularly or intravenously **Iron Overload due to Chronic Transfusion** <u>Intravenous:</u> Children and Adults: 20 mg/kg to 80 mg/kg per day via continuous infusion daily <u>Intramuscular:</u> Children and Adults: 500 mg to 1 gram daily <u>Subcutaneous:</u> Adult: 1 gm to 2 grams per day via continuous infusion. Pediatric: 20 mg/kg per day based on body weight via continuous infusion	<u>Orthographic Similarity with Disperz</u> The letter string 'Desf' looks similar to the letter string 'Disp' when scripted. <u>Numerical Similarity in Strength</u> The 2 gram strength of Desferal looks similar to the 2 mg strength of Afinitor Disperz when scripted. <u>Numerical Similarity in Dose</u> The 2 gram subcutaneous dose of Desferal looks similar to the 2 mg dose of Afinitor Disperz when scripted. The 1 gram dose of Desferal can look similar to the 10 mg dose of Afinitor Disperz. <u>Frequency of Administration</u> Both drugs can have an overlap in the frequency of administration.	<u>Orthographic Difference with Disperz</u> The name Desferal has the upstroke letter 'l' at the end of the name where the name Disperz does not. The name Afinitor adds orthographic difference when written with the modifier Disperz.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Despec (b) (4)	<u>Orthographic Similarity with Disperz</u> The letter string 'Despe' looks similar to the letter string 'Dispe' when scripted. (b) (4)	<u>Orthographic Difference with Disperz</u> The name Afinitor adds orthographic difference when written with the modifier Disperz. (b) (4) <u>Strength</u> Afinitor Disperz has multiple strengths that would need to be indicated on the prescription. (b) (4)

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Desyrel (Trazodone) Tablet 50 mg, 100 mg, 300 mg <u>Usual Dose</u> 50 mg orally once daily to 300 mg orally twice daily	<u>Orthographic Similarity with Disperz</u> The letter string 'Desy' looks similar to the letter string 'Disp' when scripted. <u>Numerical Similarity in Strength</u> The 50 mg strength of Desyrel looks similar to the 5 mg strength of Afinitor Disperz when scripted. <u>Numerical Similarity in Dose</u> The 50 mg and 100 mg dose of Desyrel looks similar to the 5 mg and 10 mg dose of Afinitor Disperz when scripted. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs are oral tablets. <u>Frequency of Administration</u> Both drugs can have an overlap in the frequency of administration.	<u>Orthographic Difference with Disperz</u> The name Desyrel has the upstroke letter 'l' at the end of the name where the name Disperz does not. The name Afinitor adds orthographic difference when written with the modifier Disperz.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Dispas (Hyoscamine) Orally Disintegrating Tablet 0.25 mg Tablet Usual Dose 0.25 mg orally every 4 hours as needed	Orthographic Similarity with Disperz The letter string 'Dispa' looks similar to the letter string 'Dispe' when scripted. Phonetic Similarity with Disperz The name Dispas is phonetically similar to Disperz. Route of Administration Both drugs are given orally. Dosage Form Both drugs are oral tablets.	Orthographic Difference with Disperz The name Afinitor adds orthographic difference when written with the modifier Disperz. Frequency of Administration The frequency of administration for each drug has no overlap or numerical similarity between them. Dose and Strength There is no overlap or numerical similarity between strengths and dose. Afinitor Disperz has multiple strengths that would need to be indicated on the prescription.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Doxepin: Capsules, Oral Solution Silenor (Doxepin) Oral Tablets Capsules: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg Oral Tablet: (Silenor) 3 mg and 6 mg Oral Solution: 10 mg/mL <u>Usual Dose</u> Major Depression: 25 mg orally twice daily to 100 mg orally three times daily Insomnia (Silenor) **Adult Indication Only:** 3 mg to 6 mg orally once daily at bedtime. Doxepin, although not FDA approved for the indication can be prescribed for insomnia: 10 mg to 50 mg orally daily at bedtime.	<u>Orthographic Similarity with Disperz</u> The letter string 'perz' can look similar to the letter string 'pen' when scripted especially if the letter 'z' is scripted without a downstroke. Both names begin with the letter 'D'. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form. <u>Frequency of Administration</u> Silenor and Doxepin can have an overlap in the frequency of administration. <u>Dose and Strength</u> Silenor (Doxepin) has an overlap in dose (3 mg and 6 mg) and strength (3 mg) with Afinitor Disperz. Doxepin has numerical similarity in dose and strength (50 mg and 100 mg vs. 5 mg and 10 mg) with Afinitor Disperz.	<u>Orthographic Difference with Disperz</u> The letter string 'oxe' does not look similar to 'is' when scripted. The name Afinitor adds orthographic difference when written with the modifier Disperz.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Diazepam Tablet, Rectal Gel, Oral Solution, Solution for Injection Tablet: 2 mg, 5 mg, 10 mg Rectal Gel: 2.5 mg, 10mg, 20 mg Oral Solution: 5 mg/5 mL solution Injection: 5 mg/mL <u>Usual Dose</u> Oral: 2 mg to 10 mg daily to four times daily Intramuscular/Intravenous: 2 mg to 10 mg initially; may repeat in 15 min to 4 hours if necessary depending on indication. Rectally: 0.2 mg/kg based on weight rectally once.	<u>Orthographic Similarity with Disperz</u> The letter string 'Diaz' can look similar to the letter string 'Disp' when scripted especially if the letter 'z' is scripted with a downstroke. <u>Route of Administration</u> Both drugs can be given orally. <u>Dosage Form</u> Both drugs have oral tablets as a dosage form. <u>Frequency of Administration</u> Both drugs can have an overlap in the frequency of administration. The abbreviation q.d. can look similar to the abbreviation q.i.d. when scripted. <u>Dose and Strength</u> Diazepam has an overlap in dose and strength (2 mg and 5 mg) with Afinitor Disperz.	<u>Orthographic Difference with Disperz</u> If the letter z is scripted with a downstroke, Diazepam has two downstroke letters in the middle of the name where Disperz has one. If the letter 'z' in Diazepam is not scripted with a downstroke, there are 5 letters before the letter 'p' in Diazepam compared to three letters in the modifier Disperz. The name Afinitor adds orthographic difference when written with the modifier Disperz.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
DisperMox (Amoxicillin) Tablet for Suspension 200 mg, 400mg, 600 mg <u>Usual Dose</u> 200 mg to 600 mg orally twice daily to three times daily	<u>Orthographic Similarity with Disperz</u> Both names begin with the letter string 'Disper'. <u>Phonetic Similarity with Disperz</u> Both names begin with the letter string 'Disper'. <u>Route of Administration</u> Both drugs are given orally. <u>Dosage Form</u> Both drugs are oral tablets for suspension.	<u>Orthographic Difference with Disperz</u> The letter string 'mox' is not similar to the letter 'z' in Disperz when scripted. DisperMox has 9 letters in the name while Disperz has 7 letters. The name Afinitor adds orthographic difference when written with the modifier Disperz. <u>Phonetic Difference with Disperz</u> The letter string 'mox' is not phonetically similar to the letter 'z' in Disperz. DisperMox has three syllables where Disperz has only two syllables. The name Afinitor adds phonetic difference when included . <u>Dose and Strength</u> There is no overlap or numerical similarity between strengths and dose.

Proposed Name: **Afinitor Disperz (Everolimus)** **Dosage Form:** **Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Dysport (Abobotulinumtoxin A) Powder for Injection 300 units and 500 units <u>Usual Dose</u> 50 units intramuscularly to each affected muscle once per 12 week cycle	<u>Orthographic Similarity with Disperz</u> Both names begin with the letter 'D'. The letter string 'spor' in Dysport looks similar to the letter string 'sper' in Disperz. <u>Phonetic Similarity with Disperz</u> The letter string 'Dysp' is phonetically similar to the letter string 'Disp'. <u>Numerical Similarity in Dose</u> Dysport has a similar dose (50 units vs. 5 mg) with Afinitor Disperz.	<u>Orthographic Difference with Disperz</u> The name Dysport has a downstroke letter 'y' in the second position and a cross stroke letter 't' at the end of the name where Disperz does not. The name Afinitor adds orthographic difference when written with the modifier. <u>Phonetic Difference with Disperz</u> The letter string 'ort' is not phonetically similar to the letter string 'erz'. The name Afinitor adds phonetic difference when included. <u>Strength</u> There is no overlap or numerical similarity between strengths <u>Frequency of Administration</u> The frequency of administration for each drug has no overlap or numerical similarity between them.

Proposed Name: Afinitor Disperz (Everolimus) **Dosage Form: Tablet for Oral Suspension** **Strengths: 2 mg, 3 mg, 5 mg** **Usual Dose: 2 mg to 12 mg orally daily**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes**	**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**
Advair Diskus (Fluticasone/Salmeterol) Inhalation Powder and Suspension for Inhalation Inhalation Powder: 100 mcg/50 mcg 250 mcg/50 mcg 500 mcg/50 mcg Inhalation Suspension: 45 mcg/21 mcg 115 mcg/21 mcg 230 mcg/21 mcg Usual Dose 1 to 2 inhalations twice daily	Orthographic Similarity with Afinitor Disperz Both names begin with the letter 'A'. Both names have the letter string 'Dis' in the second word of the drug name. Advair has an upstroke letter 'd' in the same position as the letter 'f' in Afinitor. Phonetic Similarity with Afinitor Disperz Both names begin with the letter 'A'. Both names have the letter string 'Dis' in the second word of the drug name. Route of Administration Both drugs are given orally. Overlap in Dose Both drugs have an overlap in dose (one inhalation vs. one tab).	Orthographic Difference with Afinitor Disperz Afinitor has a cross stroke letter 't' near the end of the name where Advair does not. Diskus has an upstroke letter 'k' in the name where Disperz does not. Afinitor is eight letters long where Advair is only six letter long. Phonetic Difference with Afinitor Disperz Afinitor does not sound phonetically similar to Advair. Afinitor has four syllables where Advair has only two syllables. The letter string 'kus' is not phonetically similar to the letter string 'perz'. Strength Both drugs have multiple strengths which need to be indicated on the prescription. There is no overlap or numerical similarity between strengths.

Appendix F: ISR Cases Included from AERS Database Search

7603345	7978579	8178136
8270447	8178031	8226241
7722546	8178043	8225061
8177328	8226195	8178328

Appendix G: Databases Used for Modifier Search

- **Agency Information Management System (AIMS)** – A CDER government searchable workload tracking database.
- **Med Consults Completed** – Searchable internal DMEPA file system of completed reviews.
- **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.
- **Drugs @FDA** – See References
- **Orange Book** – See References
- **Clinical Pharmacology** – See References
- **Micromedex** – See References
- I**SMP List of Products With Drug Name Suffixes** - www.**ismp**.org/tools/**drug**name**suffixes**.pdf
- **United States Patent and Trademark Office** – See References

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/s/

JAMES H SCHLICK
05/31/2012

TODD D BRIDGES
05/31/2012

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
05/31/2012
Signing on behalf of Kellie Taylor

CAROL A HOLQUIST
05/31/2012