

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204114Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: April 10, 2013

Reviewer: James Schlick, RPh, MBA
Division of Medication Error Prevention and Analysis

Team Leader: Todd Bridges, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strengths: Mekinist (Trametinib) Tablets
0.5 mg, 1 mg, 2 mg

Application Type/Number: NDA 204114

Applicant: GlaxoSmithKline

OSE RCM #: 2012-2273

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Mekinist, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Mekinist, acceptable in OSE Review 2012-1588 dated September 19, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-1588. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded two new names (Velivet and (b) (4)), thought to look similar to Mekinist and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if these two names could potentially be confused with Mekinist and lead to medication errors. This analysis determined that the name similarity between Mekinist and the identified names was unlikely to result in medication error for the reasons presented in Appendix A and B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 10, 2013. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on February 21, 2013, and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Oncology Products 2 should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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

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4 REFERENCES

1. **OSE Reviews # 2012-1588 Proposed Proprietary Name Review for Mekinist, September 19, 2012**
2. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. ***Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request***
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

Proprietary Name	Active Ingredient	Similarity to Mekinist	Failure Preventions
(b) (4)			

Appendix B: FMEA Table

Mekinist (Trametinib) Tablets 0.5 mg, 1 mg, 2 mg Usual Dose: 1.5 mg or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion: Causes (could be multiple)	Prevention of Failure Mode
<p>Velivet (Desogestrel/ Ethinyl Estradiol) Tablets</p> <p>Triphasic Birth Control Consisting of the Following Strengths:</p> <p>0.1 mg/0.025 mg 0.125 mg/0.025 mg 0.15 mg/0.025 mg</p> <p>Usual Dose: Take 1 tablet by mouth once daily</p>	<p><u>Orthographic</u> The letter string ‘Velive’ can look similar to the letter string ‘Mekini’. Both names end with the letter ‘t’.</p> <p>Dosage Form and Route of Administration: Both products are tablets taken by mouth</p> <p>Dose: Both products can be dosed as ‘take 1 tablet’</p> <p>Frequency of Administration: Both products are taken once daily</p>	<p><u>Orthographic</u> The name Mekinist has an additional letter ‘s’ in the second to last position where the name Velivet does not.</p> <p><u>Strength</u> Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between strengths.</p>

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/s/

JAMES H SCHLICK
04/10/2013

TODD D BRIDGES
04/10/2013

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

Proprietary Name Review

Date: September 19, 2012

Reviewer(s): James Schlick, RPh, MBA
Division of Medication Error Prevention and Analysis

Team Leader: Todd Bridges, RPh
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Deputy Director: Kellie Taylor, Pharm.D., MPH
Division of Medication Error Prevention and Analysis

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

Drug Name and Strengths: Mekinist (Trametinib) Tablets
0.5 mg, 1 mg, 2 mg

Application Type/Number: NDA 204114

Applicant/Sponsor: GlaxoSmithKline

OSE RCM #: 2012-1588

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Mekinist, 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 PRODUCT INFORMATION

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

- Active Ingredient: Trametinib
- Indication of Use: Metastatic melanoma therapy
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 0.5 mg, 1 mg, 2 mg
- Dose and Frequency: 1 mg to 2 mg once daily
- How Supplied: Bottle containing (b) (4) or 30 tablets (one month supply).
- Storage: (b) (4)
- Container and Closure Systems: (b) (4) high-density polyethylene bottle with (b) (4) caps

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) SEARCH*

The August 2, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Mekinist, has no intended meaning. This proprietary name is presented as a single word. The composition does not include components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Twenty-nine practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Only 5 of 29 participants correctly interpreted the name Mekinist. The letter string ‘Mek’ was misinterpreted as ‘Mak’ (n=5 in the voice study) and ‘Meh’ (n=3 in the outpatient study). The letter string ‘inist’ was misinterpreted as ‘enist’ (n=5 in the voice study and n=10 in the inpatient study). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Phase of Name Review

In response to the OSE August 10, 2102 email, the Division of Oncology Products 2 (DOP2) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

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

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and (b)(4) Name Study)

Look Similar		Sound Similar		Look and Sound Similar	
Name	Source	Name	Source	Name	Source
Helistat	FDA	Melafix	FDA	Beconase AQ	(b)(4)
Marinol	FDA	Kionex	(b)(4)	Macugen	(b)(4)
(b)(4)***	FDA	Malarone		Magnevist	Both
Maxifed	FDA	Mandol		Makena	FDA
Maxiphen	FDA	Megace		Maxalt	Both
Maxitrol	FDA	Metoprolol		Mefloquine	(b)(4)
Mebaral	FDA	Mirapex		Mekinist***	FDA

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Table 1 Continued

Look Similar		Sound Similar		Look and Sound Similar	
Meclizine	Both	Mucinex	(b) (4)	Melanex	(b) (4)
Med-Hist	FDA			Melatonin	
Meditest	FDA			Menest	Both
Melanocid	FDA			Metagest	(b) (4)
Melfiat	FDA			Metenix	(b) (4)
Mellaril	FDA			Metformin	(b) (4)
Mentax	Both			Methitest	
Metozolv ODT	FDA			Mexitil	Both
Metrogel	FDA			Miconazole	(b) (4)
Mintezol	FDA			Mucomyst	Both
Mitosol	FDA			Mycelelex	(b) (4)
Monoket	FDA			(b) (4) ***	FDA
Nebupent	FDA			Medimist	FDA
Nebusal	FDA				
(b) (4) ***	FDA				
Nitromist	FDA				
Vistaril	FDA				
Vitrasert	FDA				
Votrient	FDA				
Maxinate	FDA				
Maxivate	FDA				
Maxovite	FDA				
Nulecit	FDA				
NoHist	FDA				
Nuhist	FDA				

Our analysis of the 60 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 60 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines Following the Promotional and Safety Review

DMEPA communicated our findings to the Division of Oncology Products 2 via e-mail on August 23, 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 September 12, 2012, they stated no additional concerns with the proposed proprietary name, Mekinist.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796 4216.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Mekinist, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your July 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.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and 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 possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

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

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

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

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

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

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

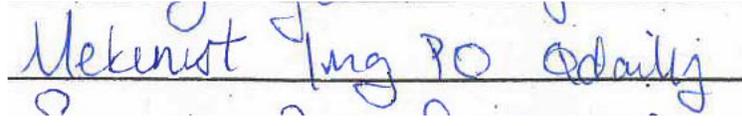
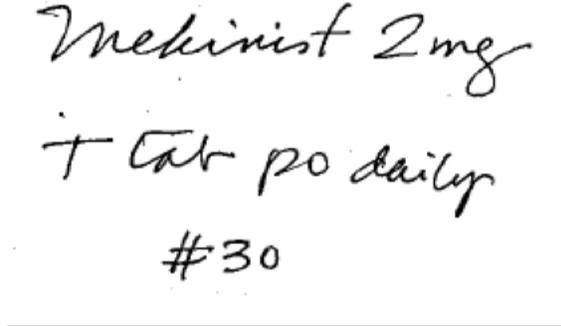
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Mekinist	Scripted May Appear as	Spoken May Be Interpreted as
Upper case ‘M’	‘M’, ‘N’, ‘V’, ‘H’	‘N’
Lower case ‘m’	‘m’, ‘mm’, ‘n’, ‘v’, ‘w’, ‘wi’, ‘vi’, ‘onc’, ‘z’	‘n’
Lower case ‘e’	‘a’, ‘i’, ‘l’, ‘o’, ‘u’, ‘p’	Any vowel
Lower case ‘k’	‘x’, ‘h’, ‘la’, ‘d’, ‘b’ ‘l’	‘c’, ‘g’
Lower case ‘i’	‘e’	Any vowel
Lower case ‘n’	‘m’, ‘u’, ‘x’, ‘r’, ‘h’, ‘s’	‘dn’, ‘gn’, ‘kn’, ‘mn’ ‘pn’
Lower case ‘s’	‘G’, ‘5’, ‘g’, ‘n’	‘x’
Lower case ‘t’	‘r’, ‘f’, ‘x’, ‘A’	‘d’

Appendix C: Prescription Simulation Samples and Results

Figure 1. Mekinist Study (Conducted on 07/26/2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p>  <p>Mekinist 2mg po daily</p>	<p>Mekinist 2 mg Sig: 1 tab once daily Qty: #30</p>
<p><u>Outpatient Prescription:</u></p>  <p>Mekinist 2mg 1 tab po daily #30</p>	

Appendix C Continued:
FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Mekinist

As of Date 8/13/2012

88 People Received Study 29 People Responded				
Study Name: Mekinist				
Total	11	9	9	29
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
MACENTIST	0	1	0	1
MAKENIST	0	3	0	3
MAKENTIST	0	1	0	1
MAKINEST	0	1	0	1
MCKENIST	0	1	0	1
MCKINNIS	0	1	0	1
MEBIMIST	0	0	1	1
MEDHIMIST	0	0	1	1
MEHINIST	0	0	3	3
MEKENIST	10	0	0	10
MEKINIST	1	0	4	5
MIKENIST	0	1	0	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Mekinist	Failure preventions
1.	Helistat	Gelatin Sponge	Looks alike	The pair has sufficient orthographic differences
2.	Marinol	Dronabinol	Looks alike	The pair has sufficient orthographic differences
3.	Mintezol	Thibendazole	Looks alike	The pair has sufficient orthographic differences
4.	Maxifed	Guaifenesin/ Pseudoephedrine	Looks alike	The pair has sufficient orthographic differences
5.	Maxiphen	Guaifenesin/ Phenylephrine	Looks alike	The pair has sufficient orthographic differences
6.	Maxitrol	Dexamethasone/ Neomycin/ Polymixin	Looks alike	The pair has sufficient orthographic differences
7.		Meclizine	Looks alike	The pair has sufficient orthographic differences
8.	Melfiat	Phendimetrazine	Looks alike	The pair has sufficient orthographic differences
9.	Mentax	Butenafine	Looks alike	The pair has sufficient orthographic differences
10.	Metozolv ODT	Metoclopramide	Looks alike	The pair has sufficient orthographic differences
11.	Metrogel	Metronidazole	Looks alike	The pair has sufficient orthographic differences
12.	(b) (4)			
13.	Nebupent	Pentamidine	Looks alike	The pair has sufficient orthographic differences
14.	Vistaril	Hydroxyzine	Looks alike	The pair has sufficient orthographic differences
15.	Vitrasert	Ganciclovir	Looks alike	The pair has sufficient orthographic differences
16.	Beconase AQ	Beclomethasone	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
17.	Mekinist***	Trametinib	Looks and sounds alike	Name that is the subject of this review
18.		Melatonin	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
19.		Miconazole	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences

No.	Proprietary Name	Active Ingredient	Similarity to Mekinist	Failure preventions
20.	Metenix	Metolazone	Looks and sounds alike	International product marketed in United Kingdom, Greece and Singapore
21.		Metformin	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
22.	Mycelex	Clotrimazole	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
23.	Macugen	Pegaptanib	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
24.	Malarone	Atovaquone/ Proguanil	Sounds alike	The pair has sufficient phonetic differences
25.	Mandol	Cefamandole	Sounds alike	The pair has sufficient phonetic differences
26.	Mirapex	Pramipexole	Sounds alike	The pair has sufficient phonetic differences
27.	Megace	Megestrol	Sounds alike	The pair has sufficient phonetic differences
28.		Metoprolol	Sounds alike	The pair has sufficient phonetic differences
29.		Mefloquine	Looks and sounds alike	The pair has sufficient orthographic and phonetic differences
30.	(b) (4)			
31.	Melanocid	Pegylated Arginine Deiminase	Looks alike	Name identified in Facts and Comparisons database. Unable to find product characteristics in commonly used drug databases.

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.

No.	<p>Proposed name: Mekinist</p> <p>Dosage Form: Tablets</p> <p>Strengths: 0.5 mg, 1 mg, and 2 mg</p> <p>Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	(b) (4)		
2.	<p>Mitosol (Mitomycin) Powder for Topical Solution</p> <p>0.2 mg</p> <p>Usual Dose: Apply fully saturated sponges equally to the treatment area for 2 minutes once only</p>	<p>Orthographic: The letter string ‘Mi’ can look similar to the letter string ‘Me’ when scripted. The letter string ‘ini’ can look similar to the letter string ‘oso’ when scripted.</p> <p>Strength: There is numerical similarity in strength with 2 mg and 0.2 mg, especially if a leading zero is not used and the decimal is not well pronounced.</p>	<p>Orthographic: Mekinist contains an upstroke letter ‘k’ in the third position where Mitosol contains a cross stroke letter ‘t’ in the third position. Mekinist contains a cross stroke letter ‘t’ at the end of the name where Mitosol contains an upstroke letter ‘l’ at the end of the name.</p> <p>Frequency of Administration: Once only vs. daily</p> <p>Dose: Apply to affected area vs. 1 or 2 tablets</p>

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

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	Votrient (Pazopanib) Tablets 200 mg Usual Dose: 400 mg to 800 mg orally daily	Orthographic: The letter string ‘inist’ can look similar to the letter string ‘rient’ when scripted. Dosage Form: Both products are tablets Route of Administration: Both are given orally Setting of Use: Both products are proposed for use in an oncology setting Frequency of Administration: Both products are taken daily	Orthographic: The letter ‘M’ in Mekinist does not look similar to the letter ‘V’ in Votrient. Mekinist contains an upstroke letter ‘k’ in the third position where Votrient contains a cross stroke letter ‘t’ in the third position. Dose and Strength: There is no overlap or numerical similarity
4.	Mellaril (Thioridazine) Tablets and Oral Solution Tablet: 10 mg, 15 mg, 25 mg, 50 mg, 100 mg, 150 mg, 200 mg Oral Solution: 30 mg/mL and 100 mg/mL Usual Dose: 10 mg to 100 mg orally three times daily	Orthographic: Both names begin with the letter string ‘Me’. The letter string ‘inis’ can look similar to the letter string ‘ari’ when scripted. Strength There is numerical similarity between the 10 mg and 1 mg strength. Dose: There is numerical similarity with the 10 mg, 15 mg and 20 mg dose. Each product can be taken as 1 tablet.	Orthographic: Mellaril has an additional upstroke letter in the fourth position where Mekinist does not. Mekinist has a cross stroke letter ‘t’ at the end of the name where Mellaril has an upstroke letter at the end of the name. Frequency: once daily versus three times daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
5.	Mebaral (Mephobarbital) Tablets 32 mg, 50 mg, 100 mg Usual Dose: 16 mg to 200 mg orally three times daily or 200 mg orally at bedtime	Orthographic: The letter string ‘Mek’ can look similar to the letter string ‘Meb’ when scripted. The letter string ‘ari’ can look similar to the letter string ‘ini’ when scripted. Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both products can be taken daily	Orthographic: Mebaral has an upstroke letter ‘l’ at the end of the name where the name Mekinist has a cross stroke letter ‘t’ at the end of the name. Dose and Strength: There is no overlap or numerical similarity
6.	Med-Hist (Chlorpheniramine/ Pseudoephedrine) Capsule 8 mg/120 mg Usual Dose: 1 capsule orally every 12 hours	Orthographic: Both names begin with the letter string ‘Me’. Both names end with the letter string ‘ist’. Dose: Both products can be taken as 1 tablet Route of Administration: Both are given orally	Orthographic: Med-Hist has an additional upstroke letter in the fourth position where Mekinist does not. The hyphen provides orthographic differences when scripted. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
7.	Meditest (Testosterone Cypionate) Oil for Injection 100 mg/mL Usual Dose: 50 mg to 400 mg intramuscularly once every 2 to 4 weeks	Orthographic: The letter string ‘Medi’ can look similar to the letter string ‘Meki’ when scripted. The letter string ‘est’ can look similar to the letter string ‘ist’ when scripted.	Orthographic: Meditest has a cross stroke letter ‘t’ in the middle of the name where Mekinist does not. Dose and Strength: There is no overlap or numerical similarity Frequency of Administration: Every 2 to 4 weeks vs. daily
8.	Monoket (Isosorbide Mononitrate) Tablets 10 mg and 20 mg Usual Dose: 10 mg to 20 mg orally twice daily, 7 hours apart.	Orthographic: The letter string ‘Mo’ can look similar to the letter string ‘Me’ when scripted. Both names have a cross stroke letter ‘t’ at the end of the name. Strength: There is numerical similarity with the 10 mg and 20 mg strength. Dose: Both products can be taken as 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Monoket does not. Monoket has an upstroke letter ‘k’ in the fifth position where Monoket does not.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
9.	Nebusal (Sodium Chloride) Solution for Inhalation 6% Usual Dose: Once only or as directed	Orthographic: The letter string ‘Neb’ can look similar to the letter string ‘Mek’ when scripted.	Orthographic: Mekinist has a cross stroke letter ‘t’ at the end of the name where Nebusal has an upstroke letter ‘l’ in the name. Dose: There is no overlap or numerical similarity Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency of Administration: Once only vs. daily
10.	Nitromist (Nitroglycerin) Lingual Spray 400 mcg/spray Usual Dose: 1 to 2 sprays every 5 minutes for 3 doses or as directed	Orthographic: The letter string ‘Ni’ can look similar to the letter string ‘Me’ when scripted. The letter string ‘mist’ can look similar to the letter string ‘nist’ when scripted. Dose: Both products can be given as 1 (spray versus tablet)	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Nitromist has a cross stroke letter ‘t’ in the third position. The letter string ‘ro’ does not look similar to the letter string ‘in’ when scripted. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency of Administration: Every 5 minutes for 3 doses OR as directed vs. daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
11.	Melanex (Hydroquinone) Topical Solution 30 mg/mL Usual Dose: Apply to affected area twice daily	Orthographic: The letter string 'Mel' can look similar to the letter string 'Mek' when scripted. Phonetic: Both names begin with the letter string 'Me'. The letter string 'ane' in Melanex is phonetically similar to the letter string 'ini' in Mekinist.	Orthographic: The letter string 'anex' does not look similar to the letter string 'inist' when scripted. Phonetic: The letter 'l' in Melanex is not phonetically similar to the letter 'k' in Mekinist. The letter 'x' in Melanex is not phonetically similar to the letter 't' in Mekinist. Dose: Apply to affected area vs. 1 or 2 tablets Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	Makena (Hydroxyprogesterone) Solution for Injection 250 mg/mL Usual Dose: 250 mg (1 mL) intramuscularly once every 7 days	Orthographic: The letter string ‘Mak’ can look similar to the letter string ‘Mek’ when scripted. Phonetic: The letter string ‘Maken’ is phonetically similar to the letter string ‘Mekin’.	Orthographic: The letter string ‘ena’ does not look similar to the letter string ‘inist’ when scripted. Phonetic: The letter string ‘ist’ is not phonetically similar to the letter ‘a’ in Makena. Dose: There is no overlap or numerical similarity Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency of Administration: Every 7 days vs. daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13.	Methitest (Methyltestosterone) Tablets 10 mg and 25 mg Usual Dose: 10 mg to 200 mg orally daily	Orthographic: Both names begin with the letter string 'Me'. The letter string 'est' can look similar to the letter string 'ist' when scripted. Phonetic: Both names begin with the letter string 'Me'. The letter string 'est' is phonetically similar to the letter string 'ist'. Strength: There is numerical similarity with the 10 mg and 1 mg strength Dose: There is numerical similarity with the 10 mg and 20 mg dose. Both products can be taken as 1 tablet. Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both products are taken once daily	Orthographic: Methitest has a cross stroke and an upstroke letter 'th' near the beginning of the name where Mekinist only has an upstroke letter 'k'. Methitest has a cross stroke letter 't' at the sixth position where Mekinist does not. Phonetic: Methitest has only 2 syllables where Mekinist has 3 syllables. The letter string 'th' is not phonetically similar to the letter string 'k'.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
14.	Mexitil (Mexiletine) Capsules 150 mg, 200 mg, 250 mg Usual Dose: 150 mg to 400 mg orally three times daily	Orthographic: The letter string ‘Mex’ can look similar to the letter string ‘Mek’ when scripted. Phonetic: The letter string ‘Mex’ is phonetically similar to the letter string ‘Mek’. Dose: Both products can be taken as 1 tablet or 1 capsule Route of Administration: Both are given orally	Orthographic: The letter string ‘itil’ does not look similar to the letter string ‘inist’ when scripted. Phonetic: The letter string ‘itil’ is not phonetically similar to the letter string ‘inist’. Strength: There is no overlap or numerical similarity between products. Frequency: once daily versus three times daily
15.	Menest (Esterified Estrogens) Tablets 0.3 mg, 0.625 mg, 1.25 mg, 2.5 mg Usual Dose: 0.3 mg to 2.5 mg orally daily	Orthographic: Both names begin with the letter string ‘Me’. The letter string ‘ist’ can look similar to the letter string ‘est’ when scripted. Phonetic: Both names begin with the letter string ‘Me’. The letter string ‘ist’ is phonetically similar to the letter string ‘est’. Dose: Both products can be taken as 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both products are taken once daily	Orthographic: The letter ‘n’ in Menest does not look similar to the letter string ‘kin’ when scripted. Menest has 6 letters in the name where Mekinist has 8 letters. Thus, Mekinist looks longer when scripted. Phonetic: The letter ‘n’ in Menest is not phonetically similar to the letter string ‘kin’. Menest has 2 syllables in the name where Mekinist has 3 syllables. Strength There is no overlap or numerical similarity between products.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	Metagest (Betaine/Pepsin) Tablets 1300 mg/90 mg Usual Dose: 2 tablets three times daily	Orthographic: Both names begin with the letter string 'Me'. The letter string 'ist' can look similar to the letter string 'est' when scripted. Phonetic: Both names begin with the letter string 'Me'. The letter string 'ist' is phonetically similar to the letter string 'est'. Dose: Both products can be taken as 2 tablets Dosage Form: Both products are tablets Route of Administration: Both are given orally	Orthographic: Metagest has a cross stroke letter 't' at the third position where Mekinist has an upstroke letter 'k'. Metagest has a downstroke letter 'g' in the middle of the name where Mekinist does not. Phonetic: The letter string 'kin' is not phonetically similar to the letter string 'tag'. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency: once daily versus three times daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
17.	Maxalt (Rizatriptan) Tablets 5 mg and 10 mg Usual Dose: 5 mg or 10 mg orally. May repeat in 2 hours if needed. Max 30 mg per day	Orthographic: The letter string ‘Ma’ can look similar to the letter string ‘Me’ when scripted. Both names end with the letter ‘t’. Phonetic: The letter string ‘Max’ is phonetically similar to the letter string ‘Mek’ Dose: Both products can be taken as 1 tablet Strength: The 10 mg strength is numerically similar to the 1 mg strength Dosage Form: Both products are tablets Route of Administration: Both are given orally	Orthographic: The letter string ‘xal’ in Maxalt does not look similar to the letter string ‘kinis’ when scripted. Maxalt contains only 6 letters where Mekinist contains 8 letters. Thus Mekinist look longer when scripted. Phonetic: The letter string ‘alt’ is not phonetically similar to the letter string ‘inist’. Maxalt has only 2 syllables where Mekinist has 3 syllables. Frequency of Administration: 5 mg or 10 mg orally. May repeat in 2 hours if needed OR as directed vs. once daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
18.	Magnevist (Gadopentetate) Solution for Injection 469 mg/mL Usual Dose: 0.2 mL/kg/dose (2 mL to 40 mL) intravenously once only	Orthographic: The letter string ‘Ma’ looks similar to the letter string ‘Me’ when scripted. The letter string ‘vist’ looks similar to the letter string ‘nist’ when scripted. Phonetic: The letter string ‘Ma’ is phonetically similar to the letter string ‘Me’. The letter string ‘vist’ is phonetically similar to the letter string ‘nist’. Dose: Both products could be dosed at 3 (3 x 0.5 mg = 1.5 mg dose or 3 mL).	Orthographic: The letter string ‘gne’ in Magnevist does not look similar to the letter string ‘kin’ in Mekinist. Phonetic: The letter ‘g’ in Magnevist is not phonetically similar to the letter ‘k’. The letter string ‘in’ in Mekinist is not phonetically similar to the letter string ‘ne’ in Magnevist. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency of Administration: Once only vs. once daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
19.	Kionex (Sodium Polystyrene Sulfonate) Powder and Suspension for Oral or Rectal Use Powder: 454 gram/ bottle Suspension: 15 gm/60 mL Usual Dose: 15 gm orally or rectally once to four times daily	Phonetic: The letter string ‘Kion’ is phonetically similar to the letter string ‘kin’. Dose: The 15 gm dose is numerically similar to the 1.5 mg dose especially if the decimal point is not well pronounced. Route of Administration: Both products can be given orally Frequency of Administration: Both products can be given once daily	Phonetic: Mekinist has three syllables where Kionex only has two syllables. Mekinist begins with the letter string ‘Me’ where Kionex does not. The letter string ‘ex’ in Kionex is not phonetically similar to the letter string ‘ist’. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.
20.	Mucinex (Guaifenesin) Tablets 600 mg and 1200 mg Usual Dose: 1 to 2 tablets orally twice daily	Phonetic: The letter string ‘Mucin’ is phonetically similar to the letter string ‘Mekin’. Dose: Both products can be dosed at 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally	Phonetic: The letter string ‘ex’ in Mucinex is not phonetically similar to the letter string ‘ist’. Strength: There is no overlap or numerical similarity between the two products.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
21.	Melafix (Melaleuca Oil) Topical Solution 1% Usual Dose: Apply to affected area once or twice daily	Phonetic: The letter string ‘Mel’ is phonetically similar to the letter string ‘Mek’. Frequency of Administration: Both products can be given once daily	Phonetic: The letter string ‘afix’ is not phonetically similar to the letter string ‘inist’. Dose: Apply as directed vs. 1 tablet Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.
22.	Mucomyst (Acetylcysteine) Solution for Nebulization, Oral Solution 10% and 20% Usual Dose: 3 mL to 10 mL 3 to 4 times daily OR 10 mL to 75 mL every 4 hours for 17 doses.	Orthographic: The letter string ‘Mu’ looks similar to the letter string ‘Me’ when scripted. Both names end in the letter string ‘st’. Phonetic: The letter string ‘Muc’ is phonetically similar to the letter string ‘Mek’ The letter string ‘myst’ is phonetically similar to the letter string ‘nist’. Dose: Both products could be dosed at 3 (3 x 0.5 mg = 1.5 mg dose or 3 mL). Route of Administration: Both products can be given orally	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Mucomyst does not. Mucomyst has a downstroke letter ‘y’ near the end of the name where Mekinist does not. Phonetic: The ‘o’ in Mucomyst is not phonetically similar to the first letter ‘i’ in Mekinist. Strength: There is no overlap or numerical similarity Frequency of Administration: 3 to 4 times daily OR every 4 hours for 17 doses vs. once daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
23.	Maxinate Prenatal Vitamin Tablets Usual Dose: 1 to 2 tablets orally daily	Orthographic: The letter string ‘Ma’ can look similar to the letter string ‘Me’ when scripted. The letter string ‘ina’ can look similar to the letter string ‘ini’ when scripted. Dose: Both products can be dosed at 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both are given once daily	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Maxinate does not. Maxinate has the letter ‘e’ after the letter ‘t’ at the end of the name where Mekinist does not. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.
24.	Maxivate (Betamethasone) Cream, Lotion, Ointment Usual Dose: Apply to affected area 2 to 4 times daily	Orthographic: The letter string ‘Ma’ can look similar to the letter string ‘Me’ when scripted. The letter string ‘iva’ can look similar to the letter string ‘ini’ when scripted. Dose: Both products can be dosed at 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both are given once daily	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Maxivate does not. Maxivate has the letter ‘e’ after the letter ‘t’ at the end of the name where Mekinist does not. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
25.	Maxovite Multivitamin Tablets Usual Dose: 1 to 2 tablets orally daily	Orthographic: The letter string ‘Ma’ can look similar to the letter string ‘Me’ when scripted. The letter string ‘ovi’ can look similar to the letter string ‘ini’ when scripted. Dose: Both products can be dosed at 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally Frequency of Administration: Both are given once daily	Orthographic: Mekinist has an upstroke letter ‘k’ in the third position where Maxovite does not. Maxovite has the letter ‘e’ after the letter ‘t’ at the end of the name where Mekinist does not. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.
26.	Nulecit (Sodium Ferric Gluconate Complex) Solution for Injection 12.5 mg/mL Usual Dose: 62.5 mg to 125 mg intravenously after each dialysis session	Orthographic: The letter string ‘Nul’ can look similar to the letter string ‘Mek’ when scripted. Both names end in the letter ‘t’.	Orthographic: The letter string ‘eci’ in Nulecit does not look similar to the letter string ‘inis’ when scripted. Dose: There is no overlap or numerical similarity Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Frequency of Administration: after each dialysis session vs. once daily

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
27.	NoHist (Chlorpheniramine/ Phenylephrine) Tablets 3 mg/10mg 8 mg/20 mg Usual Dose: 1 tablet orally every 12 hours	Orthographic: If the 'H' in NoHist is scripted in lower case then the letter string 'Noh' looks similar to the letter string 'Mek' when scripted. Both names end in the letter string 'ist'. Dose: Both products can be given as 1 tablet Dosage Form: Both products are tablets Route of Administration: Both are given orally	Orthographic: Mekinist is 8 letters long where NoHist is only 6 letters long. Thus, Mekinist looks longer when scripted. Strength: There is no overlap or numerical similarity
28.	Nuhist (Chlorpheniramine/ Phenylephrine) Oral Solution 4.5 mg/5 mg per 5mL Usual Dose: 2.5 mL to 10 mL orally every 12 hours	Orthographic: The letter string 'Nuh' looks similar to the letter string 'Mek' when scripted. Both names end in the letter string 'ist'. Route of Administration: Both are given orally	Orthographic: Mekinist is 8 letters long where Nuhist is only 6 letters long. Thus, Mekinist looks longer when scripted. Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products. Dose: There is no overlap or numerical similarity

No.	Proposed name: Mekinist Dosage Form: Tablets Strengths: 0.5 mg, 1 mg, and 2 mg Usual Dose: 1 mg, 1.5 mg, or 2 mg orally once daily	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
29.	Medimist Herbal/Homeopathic Sublingual Oral Spray Multiple Products 60 mL bottle Usual Dose: 1 to 2 sprays sublingually once daily or as directed	Orthographic: The letter string 'Medi' can look similar to the letter string 'Meki'. The letter string 'mist' can look similar to the letter string 'nist'. Phonetic: The letter string 'Medi' is phonetically similar to the letter string 'Meki'. The letter string 'mist' is phonetically similar to the letter string 'nist'. Dose: Both products can be given as 1 Frequency of Administration: Both products can be given as once daily	Strength: Mekinist has multiple strengths that would need to be indicated on a prescription. There is no overlap or numerical similarity between the two products.

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/s/

JAMES H SCHLICK
09/19/2012

ZACHARY A OLESZCZUK on behalf of TODD D BRIDGES
09/19/2012

ZACHARY A OLESZCZUK on behalf of KELLIE A TAYLOR
09/19/2012

CAROL A HOLQUIST
09/19/2012