CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205931Orig1s000

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 Memorandum

Date:	March 7, 2014
Reviewer:	Aleksander Winiarski, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	Julie Neshiewat, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	Acticlate (Doxycycline Hyclate) Tablets, 75 mg and 150 mg
Application Type/Number:	NDA 205931
Applicant/Sponsor:	Aqua Pharmaceuticals
OSE RCM #:	2014-16913

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Acticlate, is written in response to the Applicant's re-submission of the proposed proprietary name, Acticlate, under NDA 205931, that reflects a change in the product's achievable doses, specifically because the 150 mg tablet will be scored to allow for dividing the tablet into three equal parts. DMEPA previously found the name acceptable in OSE Review# 2013-1254 dated October 24, 2013.

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# 2013-1254. We note that there is a change in the product characteristics for Acticlate, and that additional achievable doses using the proposed tablets include: 50 mg, 100 mg, 125 mg, 175 mg, and 200 mg. Therefore, 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 did not yield any new names to look or sound similar to Acticlate or represent a potential source of drug name confusion.

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 March 3, 2014.

3 CONCLUSION

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

If any of the proposed product characteristics as stated in your February 13, 2014 submission are altered, the name must be resubmitted for review.

If you have further questions or need clarifications, please contact Karen Townsend, OSE Project Manager, at 301-796-5413.

4 REFERENCES

1. Winiarski, Aleksander; OSE Review 2013-1254, Proprietary Name Review; October 24, 2013.

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.

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

/s/

ALEKSANDER P WINIARSKI
03/07/2014

JULIE V NESHIEWAT
03/07/2014

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:	October 24, 2013
Reviewer:	Aleksander Winiarski, PharmD
	Division of Medication Error Prevention and Analysis
Acting Team Leader:	Morgan Walker, PharmD, MBA
	Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH
	Division of Medication Error Prevention and Analysis
Drug Names and Strengths:	Acticlate (Doxycycline Hyclate) Tablets,
	75 mg and 150 mg
Application Type/Number:	IND 113575
Applicant/Sponsor:	Aqua Pharmaceuticals
OSE RCM #:	2013-1254

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Acticlate, 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 May 9, 2013 proprietary name submission.

- Active Ingredient: Doxycycline Hyclate
- Indication of Use: Treatment of infections caused by susceptible organisms, including respiratory, genital/STD, urinary, intestinal, acne, (prophylaxis) malaria, tick infections and other infectious diseases.
- Dosage Form: Tablet
- Strength: 75 mg and 150 mg
- Dose and Frequency:
  - Adult: (b) (4)
  - Children less than 45 kg: (b) (4)
- How Supplied: 60 tablet count bottles of each strength
- Storage: Room temperature, protect from light and moisture

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 Anti-Infective Products (DAIP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation for the proposed name, Acticlate, in their submission. This proprietary name is comprised of a single word that does not contain any components (such as a modifier, route of administration, dosage form, etc.).

2.2.3 FDA Name Simulation Studies

Seventy-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products.

In the outpatient study, 12 out of 23 participants interpreted the name correctly. All 11 misinterpretations included confusion of the infix -icl- for -ul-, -ril-, or -id- due to the sample.

In the voice study, 23 out of 28 participants identified the name correctly. Common misinterpretations included confusion between the vowels such as 'i' or 'a' with 'a', 'e' or 'o' and one omission of the last letter 'e'.

In the inpatient study only 6 out of 22 participants identified the name correctly. The errors included misinterpretations of the infix -icl- for -ul-, -ril-, or -id- , and the suffix -ate for -uti, -ote, -nta, -ati, -ute, -irti, -evti, -entis or -enti due to the sample.

All of the identified misinterpretations were considered in the search and evaluation of phonetically and orthographically similar names.

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 Review

In response to the OSE, June 7, 2013 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

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[1] The October 21, 2013 search of the United States Adopted Name (USAN) stems.

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. These variations were used in the search for names similar to Acticlate. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Acticlate identified by the primary reviewer, and the Expert Panel Discussion (EPD). Our analysis of the 25 names determined all 25 names will not pose a risk for confusion as described in Appendices D through E.

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Acetadote	FDA	Activella	FDA	Adalat cc	FDA
Actahist	FDA	Actidil	FDA	Amidate	FDA
Actedril	FDA	Actidose	FDA	Clofibrate	FDA
Actical	FDA	Actidose Aqua	FDA	Cutivate	FDA
Acticort / Acticort 100	FDA	(b) (4)	FDA	Etomidate	FDA
Metadate CD	FDA	Metadate ER	FDA	Octreotide	FDA
Actisite	FDA	Adalat	FDA		
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Accolate	FDA	Activate	FDA	Aclovate	FDA
(b) (4) ***	FDA	Activase	FDA		

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anti-Infective Products via e-mail on October 22, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Division of Anti-Infective Products on October 23, 2013, they stated no additional concerns with the proposed proprietary name, Acticlate.

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 Karen Townsend, OSE project manager, at 301-796-5413

3.1 COMMENTS TO THE APPLICANT

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

Additionally, the proposed proprietary name must be submitted at the time of NDA submission. If any of the proposed product characteristics as stated in your May 9, 2013 submission are altered, the name must be resubmitted for review.

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. [2]

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

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

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.

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.[3]

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).

[3] 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**		
	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 gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the 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.[4] 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

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

use of the product in the usual practice settings by considering the clinical and product 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name,	Scripted May Appear as	Spoken May Be Interpreted as
Upper case A	ce, FL, H, s	Any vowel
Lower case a	el, o, u,	Any vowel
Lower case c	a, e, i, l	z, k
Lower case t	b, l, h, r, f, x	D
Lower case i	i ,c, e	Any vowel
Lower case c	a, e, i, l	Z, k
Lower case l	b, e, s, i	w
Lower case a	el, o, u,	Any vowel
Lower case t	b, l, h, r, f, x	D
Lower case e	a, c ,i, l, p	Any vowel
Letter Strings		Scripted Sound as
cl	d	
ct	d	
la	k	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Acticlate Study (Conducted on June 7, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: [redacted] (b) (4)	Acticlate [redacted] (b) (4) Dispense # 2
Outpatient Prescription: [redacted] (b) (4)	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

191 People Received Study

73 People Responded

Study Name: Acticlate

Total	23	28	22	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ACTACLATE	0	1	0	1
ACTECLATE	0	2	0	2
ACTIC?	0	0	1	1
ACTICLAT	0	1	0	1
ACTICLATE	12	23	6	41
ACTICLENTI	0	0	1	1
ACTICLENTS	0	0	1	1
ACTICLET	0	1	0	1
ACTICLEVTI	0	0	1	1
ACTICLIRTI	0	0	1	1
ACTICLUTE	0	0	4	4
ACTIDATE	6	0	2	8
ACTIDATI	0	0	1	1
ACTIDENTA	0	0	1	1
ACTIDOTE	0	0	1	1
ACTIDUTI	0	0	1	1
ACTRILATE	3	0	0	3

ACTRILATI	0	0	1	1
ACTULATE	2	0	0	2

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 Acticlate	Failure preventions
1.	Actical	calcium/ magnesium/ phytonadione/ vitamin d/zinc	Looks similar	The pair has sufficient orthographic differences.
2.	Activella	Estradiaol / norethindrone acetate	Looks similar	The pair has sufficient orthographic differences.
3.	---	Clofibrate	Looks similar	The pair has sufficient orthographic differences.
4.	Activase	Alteplase recombinant	Looks and sound similar	The pair has sufficient orthographic and phonetic differences.
5.	(b) (4)			
6.				
7.	Activate	Unknown	Look and sound similar	Name identified in Red Book, unable to duplicate the results. Did not find the name or product characteristics in commonly used drug information 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.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
1.	Acetadote (Acetylcysteine) injection Strength: 6 g /30 mL vial (200 mg/mL) Dose, Route and Frequency: Dose range based on 5 kg to 100 kg 150 mg/kg once (750 mg to 15,000 mg) 50 mg/kg once (250 mg to 5,000 mg) 100 mg/kg once (500 mg to 2,000 mg) Infused intravenously over 1 hour, over 4 hours, and over 16 hours	**Orthographic similarity** Both names start with the same letter 'A', have the same number of letters (n=9) and have 3 upstrokes in the similar positions. **Overlapping product characteristics** Potential dose overlap (300 mg vs. 50 mg/kg x 6 kg = 300 mg).	**Orthographic differences** The prefix Acet- in Acetadote appears elongated compared to the prefix Act- in Acticlate. **Key differences in product characteristics** Frequency: Acetadote is administered in 3 consecutive infusions over a specific duration of time. If an order is written individually it will likely include the administration time since there are 3 different infusion schedules, for example 300 mg intravenously over 4 hours. Acticlate is administered on a set daily or twice daily schedule (b) (4)

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
2.	Actahist (pseudoephedrine / tripolidine) syrup Strength: 30 mg-1.25 mg per 5 mL Dose, Route and Frequency: 5 mL to 10 mL orally every 4 hours to 6 hours as needed.	**Orthographic similarity** Both names start with the same 3 letters 'Act', and have 3 upstrokes in similar positions. **Overlapping product characteristics** Oral route.	**Orthographic differences** The suffix -late in Acticlate has a different shape and appearance (smaller space between upstrokes) from the suffix -hist in Actahist. **Key differences in product characteristics** Strength Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Actahist is a single strength product and the strength may be omitted from the prescription/order without preventing the product from being dispensed. There is no overlap in strength (75 mg and 150 mg vs. 30 mg-1.25 / 5 mL) Dose: There is no overlap in dose (5 mL or 10 mL vs. 75 mg or 300 mg). Frequency: Acticlate is administered (b) (4) on a set daily or twice daily schedule compared to Actahist which is administered every 4 to 6 hours as needed.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Actedril (pseudoephedrine / tripolidine) tablet Strength: 60 mg-2.5 mg Dose, Route and Frequency: 1 tablet orally every 4 hours to 6 hours as needed	**Orthographic similarity** Both names start with the same 3 letters 'Act', and have 3 upstrokes in similar positions. **Overlapping product characteristics** Oral route.	**Orthographic differences** Acticlate has an additional cross-stroke 't' in the 8th position which Actedril does not, giving the names slightly different appearance. **Key differences in product characteristics** Strength Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Actedril is a single strength product and the strength may be omitted from the prescription/order without preventing the product from being dispensed. There is no overlap in strength (75 mg and 150 mg vs. 60 mg-2.5 / 5 mL) Frequency: Acticlate is administered (b) (4) on a set daily or twice daily schedule compared to Actahist which is administered every 4 to 6 hours as needed.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
4.	Acticort/ Acticort 100 (Hydrocortisone) topical lotion Also indentified as Acticort Strength: 1 % Dose, Route and Frequency: Apply sufficient amount to the affected area topically up to 3 to 4 times daily as needed.	**Orthographic similarity** Both names start with the same 5 letters 'Actic' and have 2 upstrokes in the similar positions.	**Orthographic differences** The suffix -late in Acticlate has a different shape (additional upstroke) and appearance from the suffix -cort in Acticort. **Key differences in product characteristics** Strength Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Acticort is a single strength product and the strength may be omitted from the prescription/order without preventing the product from being dispensed. There is no overlap in strength (1 % vs. 75 mg and 150 mg) Dose: There is no overlap in dose (75 mg or 300 mg vs. sufficient amount). Frequency: Acticlate is administered (b) (4) on a set daily or twice daily schedule compared to Acticort 100 which is administered three to 4 times daily as needed or may be written with directions to use as directed.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Metadate CD (methylphenidate) extended release capsules Strength: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg Dose, Route and Frequency: 1 capsule daily orally in the morning before breakfast	**Orthographic similarity** Both names have 3 upstrokes in similar positions and both names end with the suffix -ate. When scripted the infix -icl- may look like the infix -ad-. **Overlapping product characteristics** Route (oral) and frequency (daily). Dose similarity (30 mg vs. 300 mg)	**Orthographic differences** The prefix Met- in Metadate appears elongated compared to the prefix Act- in Acticlate. **Key differences in product characteristics** Strength: Both products are available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed There is no overlap in strength (10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg vs. 75 mg and 150 mg).

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
6.	Metadate ER (methylphenidate) extended release tablet Strength: 10 mg (strength currently discontinued) and 20 mg (unscored) Dose, Route and Frequency: 20 mg to 30 mg (if 10 mg tablet becomes available) twice daily orally (duration 8 hours)	**Orthographic similarity** Both names have 3 upstrokes in similar positions and both names end with the suffix -ate. When scripted the infix -icl- may look like the infix -ad-. **Overlapping product characteristics** Route (oral) and frequency (twice daily). If 10 mg tablet becomes available then dose similarity (30 mg vs. 300 mg)	**Orthographic differences** The prefix Met- in Metadate appears elongated compared to the prefix Act- in Acticlate. **Key differences in product characteristics** Strength Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Metadate ER was available in two strengths and currently may be available as a single strength. There is no overlap in strength There is no overlap in strength (10 mg and 20 mg, vs. 75 mg and 150 mg).

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Actisite (Tetracycline) fiber, extended release, periodontal Strength: 12.7 mg Dose, Route and Frequency: 1 via oromucosal route once Additional: Product no longer on the market there is no generics on the market.	**Orthographic similarity** Both names start with the same 4 letters 'Acti', end with the same suffix -te, and have 2 upstrokes in similar positions. **Overlapping product characteristics** Frequency (once)	**Orthographic differences** The infix -cla- in Acticlate is elongated and has an up stroke compared to the infix -si- in Actisite, which appears shorter and does not have an upstroke, giving the names slightly different shape and appearance. **Key differences in product characteristics** Strength and Dose: Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Actisite is a single strength product. There is no overlap in strength or dose.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
8.	Actidil (Triprolidine) oral solution and extended release suspension Strength: 1.25 mg/5 mL and 2.5 mg /5 mL Dose, Route and Frequency: 1.25 mL, 2.5 mL, 3.75 mL, 5 mL or 10 mL orally every 4 hours to 6 hours as needed or 10 mL, 5 mL or 2.5 mL every 12 hours as needed (extended release suspension)	**Orthographic similarity** Both names start with the same 4 letters 'Acti' and have 2 upstrokes in the similar positions. When scripted the infix -icl- may look like the infix -id- **Overlapping product characteristics** Oral route	**Orthographic differences** The suffix -ate in Acticlate elongates the name compared to the suffix -il in Actidil. **Key differences in product characteristics** Strength Both products are available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. There is no overlap in strength 1.25 mg/5 mL and 2.5 mg/5 mL vs. 75 mg and 150 mg Dose: There is no overlap in dose (1.25 mL, 2.5 mL, 3.75 mL, 5 mL or 10 mL vs. 75 mg, 300 mg) Frequency: Acticlate is administered (b) (4) on a set daily or twice daily schedule compared to Actidil which is administered every 4 to 6 hours or every 12 hours as needed.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Actidose Aqua (Activated charcoal/) suspension Strength: 15 g/72 mL 25 g/120 mL 50 g/240 mL Dose, Route and Frequency: Single oral dose: Under 1 year: 1 gm/kg (5 g to 15 g) Older children and adults: 25 g to 100 g Multi-dose oral: Under 1 year: 1 gm/kg (5 g to 15 g) every 4 hours to 6 hours as needed Older children and adults: 25 g to 100 g every 4 hours to 6 hours As needed	**Orthographic similarity** Both names start with the same 4 letters 'Acti', and have 2 upstrokes in the similar positions. When scripted the infix -icl- may look like the infix -id- **Overlapping product characteristics** Route (oral), dose similarity (75 mg vs. 75 g), potential frequency (once).	**Orthographic differences** The suffix -ate in Acticlate has a 't' and the suffix -ose in Actidose does not, giving the names different appearance. **Key differences in product characteristics** Strength: Both products are available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. There is no overlap in strength (75 mg or 150 mg vs. 15 g/72 mL, 25 g/120 mL, 50 g/240 mL)

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
10.	Actidose w/sorbitol (Activated charcoal/sorbitol) suspension Strength: 25 g/120 mL 50 g/240 mL Dose, Route and Frequency: Indicated as single oral dose only: Older children and adults: 25 g to 50 g	**Orthographic similarity** Both names start with the same 4 letters 'Acti', and have 2 upstrokes in the similar positions. When scripted the infix -icl- may look like the infix -id- **Overlapping product characteristics** Route (oral), frequency (once).	**Orthographic differences** The suffix -ate in Acticlate has a cross-stroke 't' and the suffix -ose in Actidose does not, giving the names different appearance. **Key differences in product characteristics** Strength and Dose: Both products are available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. There is no overlap in strength or dose.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Adalat (Nifedipine) capsule Strength: 10 mg and 20 mg Dose, Route and Frequency: 10 mg to 30 mg orally three to four times daily. 10 mg to 30 mg single doses titrated to control pain and arrhythmia due to ischemia	**Orthographic similarity** Both names start with the same letter 'A' and have upstrokes in the similar positions. When scripted the prefix Act- may look like Ad-, the and the infix -iclat- may look like -alat. **Overlapping product characteristics** Route (oral), frequency (once), dose similarity (300 mg vs. 30 mg)	**Orthographic differences** When scripted Acticlate appears slightly elongated compared to Adalat.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Adalat cc (Nifedipine) extended release tablets Strength: 30 mg, 60 mg and 90 mg Dose, Route and Frequency: 30 mg to 90 mg orally once daily	**Orthographic similarity** Both names start with the same letter 'A' and have upstrokes in the similar positions. When scripted the prefix Act- may look like Ad-, the infix -icla- may look like -ala- and the suffix -te may look like the suffix -tcc (when the modifier cc is written together with the name). **Overlapping product characteristics** Route (oral), strength and dose similarity (300 mg vs. 30 mg)	**Key differences in product characteristics** Strength: Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Adalat cc is available in 3 strengths. There is no overlap in strength (30 mg, 60 mg and 90 mg vs. 75 mg and 150 mg)

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Cutivate (Fluticasone propionate) cream, lotion, and ointment Strength: 0.05% (cream and lotion), 0.005% (ointment) Dose, Route and Frequency: Apply a thin film to affected skin areas once or twice daily	**Orthographic similarity** Both names have 2 upstrokes in the similar positions and end with the same suffix –ate. When scripted the prefix Act- may look like the prefix Cut-. **Overlapping product characteristics** Frequency (once or twice daily)	**Orthographic differences** Acticlate has and additional upstroke 'l' in the middle of the name and Cutivate does not, giving the names slightly different shapes. **Key differences in product characteristics** Strength and Dose: Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Each dosage form of Cutivate is a single strength and the strength may be omitted from the prescription/order without preventing the product from being dispensed. There is no overlap in strength or dose (thin film or directions to use as directed vs. 300 mg or 75 mg).

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Amidate (Etomidate), injection Strength: 2 mg/mL available in 10 mL vial / ampule and 20 mL syringe Dose, Route and Frequency: Adults and children over 10 years of age, 0.2 mg/kg to 0.6 mg /kg (0.6 mg/ kg intravenously over 30 to 60 seconds to induce anesthesia	**Orthographic similarity** Both names have 2 upstrokes in similar positions. **Overlapping product characteristics** Potential dose similarity (0.6 mg/kg x 50 kg = 30 mg vs. 300 mg), and frequency (once).	**Orthographic differences** The prefix Act- in Acticlate appears shorter than the prefix Ami- in Amidate. Also Acticlate has an additional upstroke giving the names different shapes.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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
15.	Etomidate established name for Amidate, injection Strength: 2 mg/mL available in 10 mL vial / ampule and 20 mL syringe Dose, Route and Frequency: Adults and children over 10 years of age, 0.2 mg/kg to 0.6 mg /kg (0.6 mg/ kg intravenously over 30 to 60 seconds to induce anesthesia	**Orthographic similarity** Both names have the same number of letters (n=9) and have 3 upstrokes in the similar positions. **Overlapping product characteristics** Potential dose similarity (0.6 mg/kg x 50 kg = 30 mg vs. 300 mg), and frequency (once).	**Orthographic differences** The prefix Act- in Acticlate appears longer than the prefix Et- in Etomidate. Also the infix -omi- in Etomidate appears longer than the infix -icl- in Acticlate, giving the names different appearance.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	established name for Sandostatin, injection Strength: Ampules: 50 mcg/mL, 100 mcg/mL and 500 mcg/mL Multi-dose vials: 200 mcg/mL 1000 mcg/mL Dose, Route and Frequency: 50 mg to 500 mcg intravenously or subcutaneously twice or three or four times daily up to 1500 mcg/day.	**Orthographic similarity** Both names have the have 3 upstrokes in the similar positions. When scripted the prefix Act- may look like the prefix Oct- **Overlapping product characteristics** Frequency (twice daily) and dose similarity (300 mcg vs. 300 mg or 75 mcg vs. 75 mg)	**Orthographic differences** The infix -reo- in Octreotide appears longer than the infix -ic- in Acticlate, giving the names different appearance. **Key differences in product characteristics** Route of administration: Acticlate is administered orally and the route may or may not be included on an order. Octreotide may be administered subcutaneously or intravenously, therefore a route must be specified on a prescription/order for the product to be dispensed. There is no overlap in the route.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Accolate (Zafirlukast), tablet Strength: 10 mg and 20 mg Dose, Route and Frequency: 10 mg or 20 mg orally twice daily.	**Orthographic and Phonetic similarity** Both names start with the same two letters 'Ac', have 2 upstrokes in the similar positions and end with the same suffix -late. **Overlapping product characteristics** Route (oral) and frequency (twice daily)	**Orthographic differences** Acticlate has an additional upstroke 't' in the 3rd position and Accolate does not, giving the names slightly different shapes. **Phonetic differences** When spoken, the letter string -tic- in Acticlate sounds different from the letter string -co- in Accolate. **Key differences in product characteristics** Strength and Dose: Both products are available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. There is no overlap in strength or dose.

No.	Proposed name: Acticlate Dosage Form(s): Tablet Strengths:75 mg and 150 mg Usual Dose: (b) (4)	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.	Aclovate (Alclometasone dipropionate) cream and ointment Strength: 0.05% Dose, Route and Frequency: Apply a thin film to affected skin two or three times daily	**Orthographic similarity** Both names start with the same tow letters 'Ac', end with the same suffix -ate and have 2 upstrokes in the similar positions. When scripted the prefix Act- may look like the prefix Acl- **Overlapping product characteristics** Frequency (twice daily)	**Orthographic differences** Acticlate has an additional upstroke 'l' in the infix and Aclovate does not, giving the names slightly different shapes. **Key differences in product characteristics** Strength: Acticlate is available in multiple strengths; therefore either the strength or an achievable milligram dose must be specified on a prescription/order for the product to be dispensed. Each dosage form of Aclovate is a single strength and the strength may be omitted from the prescription/order without preventing the product from being dispensed. There is no overlap in strength (0.05 % vs. 75 mg and 150 mg) Dose: There is no overlap in dose (thin film or directions to use as directed vs. 300 mg or 75 mg).

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/s/

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10/24/2013

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