CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203188Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	December 30, 2011
Reviewer(s):	Reasol S. Agustin, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Carlos Mena-Grillasca, RPh Division of Medication Error Prevention and Analysis
Acting Division Director:	Irene Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Drug Name(s) and Strength(s):	Kalydeco (Ivacaftor) Tablets, 150 mg
Application Type/Number:	NDA 203188
Applicant/Sponsor:	Vertex Pharmaceuticals, Inc
OSE RCM #:	2011-4006

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

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

DMEPA previously reviewed the proprietary name Kalydeco and found the name acceptable from a safety and promotional perspective in OSE review #2010-2600, dated May 25, 2011. On October 18, 2011 the Applicant submitted a New Drug Application, including a request for review of the proposed proprietary name, Kalydeco. The Application (NDA 203188) was granted a Priority Review due to orphan drug designation.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 18, 2011 proprietary name submission.

- Established Name: Ivacaftor
- Indication of Use: Treatment of Cystic Fibrosis in patients 6 years of age and older who have a G55ID mutation in the CFTR gene.
- Route of administration: Oral
- Dosage form: Tablets
- Strength: 150 mg
- Dose: One tablet every 12 hours with food
- How Supplied: 56-count carton containing 4 weekly blister cards of 14 tablets each
  60-count bottles
- Storage: Store between 15°C to 30°C
- Container and Closure systems:
  14-count blister card - (b) (4) blister film with heat seal foil lidding
  60-count bottles – 75cc HDPE bottle/33 mm induction sealed (b) (4) closure
- Intended pronunciation: kuh-LYE-deh-koh

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The October 27, 2011 United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

The Applicant stated that the proposed name, Kalydeco, (b) (4)

2.2.3 FDA Name Simulation Studies

Forty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Ten of the 12 inpatient participants responded correctly to Kalydeco and no common misinterpretation occurred. One out of the 17 voice participants responded correctly and a common misinterpretation was the consonant 'C' for 'K' and 'i' for 'y.' All 14 outpatient participants responded correctly to Kalydeco. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, October 27, 2011 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) 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, Kalydeco. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Kalydeco identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by Addison Whitney, not identified by DMEPA, that require further evaluation.

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

Look Similar		Sound Similar		Look and Sound Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Krystexxa	FDA	Caldecort	FDA	Kerledex	FDA
Rapamycin	FDA	Helidac	FDA	Carbodec	FDA
Razadyne	FDA	Alavert	External	Kaletra	Both
Reyataz	FDA				
(b) (4)	FDA				
Calcimar	FDA				
Kalexate	FDA				
Kinlytic	FDA				

Kalbitor	FDA				
Calcibind	FDA				
Calderol	FDA				
Caldolor	FDA				
Caladryl Caladryl Clear	FDA				
Kelnor	FDA				
Colestid	FDA				
Haloperidol	FDA				
Sotradecol	FDA				
Ketalar	FDA				
Ketoprofen	FDA				
Xeloda	FDA				
Xalkori	FDA				
Kolephrin Kolephrin GG/DM	FDA				
Xalatan	FDA				
Kadiflam	FDA				
Kaldyum	FDA				
Ralydan	FDA				
Kapidex	FDA				
K-lyte	FDA				
Refludan	FDA				
Elavil	External				
Kayexalate	Both				

Our analysis of the 39 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the 39 names will pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products during the team meeting on December 21, 2011. At that time we also requested additional information or concerns to consider for our review. The Review Team did not have additional concerns with the proposed proprietary name, Kalydeco.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Kalydeco, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 18, 2011 submission are altered, DMEPA rescinds this finding and 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 Pharmacy's Fundamental Reference***

    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 Book***

    Medical Abbreviations Book 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.

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.

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.

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

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).

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-	Phonetic	Identical prefix	• Names may sound similar

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

alike	similarity	Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	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 Division of Drug Marketing, Advertising, and Communications (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 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances

FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Kalydeco	Scripted may appear as	Spoken may be interpreted as
'K' or 'k'	R, X, C, h, c	X, G
lowercase 'a'	el, ei, c, u	any vowel
lowercase 'l'	b, e, s, A, P, i	r
lowercase 'y'	f, p, u, v, x, Z	e, i
lowercase 'd'	cl	t
lowercase 'e'	a, i, l, p	any vowel
lowercase 'c'	a, e, i, l	x, g
lowercase 'o'	a, c, e, u	Oh, any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Kalydeco Study (Conducted on 10/28/2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Kalydeco 150 mg 1 tab PO Q12h with food #60	Kalydeco 150 mg 1 tab by mouth every 12 hours with food.
Outpatient Prescription: Kalydeco 150 mg 1 tab PO q12° w/meals	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study

43 People Responded

Study Name: Kalydeco

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CALIDECO	0	5	0	5
CALIDEECO	0	1	0	1
CALIDICO	0	1	0	1
CALYDECO	1	1	0	2
KALEDEECO	0	1	0	1
KALIDECO	0	1	0	1
KALIDICO	0	1	0	1
KALYDECO	10	1	14	25
KALZDECO	1	0	0	1
KELEDECO	0	1	0	1
KELI-DECOTE	0	1	0	1
KELLEY DECO	0	1	0	1
KELLY DECO	0	1	0	1
TALIBICO	0	1	0	1
TOTAL	**12**	**17**	**14**	**43**

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

Proprietary Name	Active Ingredient	Similarity to Kalydeco	Failure preventions
Caldecort	Hydrocortisone Topical cream	Look or Sound	Lacks sufficient orthographic or phonetic similarity to result in name confusion
Sotradecol	Sodium Tetradecyl Injection solution	Look	Lacks sufficient orthographic similarity to result in name confusion
Krystexxa	Pegloticase Injection solution	Look	Lacks sufficient orthographic similarity to result in name confusion
Refludan	Lepirudin Injection powder for reconstitution	Look	Lacks sufficient orthographic similarity to result in name confusion
Calcibind	Cellulose Sodium Phosphate	Look	Lacks sufficient orthographic similarity to result in name confusion. This product has been discontinued and preliminary drug use data indicates that the name Calcibind is not used in prescribing.
Xalatan	Latanoprost Ophthalmic solution	Look	Lacks sufficient orthographic similarity to result in name confusion
Xeloda	Capecitabine Tablets	Look	Lacks sufficient orthographic similarity to result in name confusion
K-lyte	Bicarbonate and Citrate Effervescent tablets	Look	Lacks sufficient orthographic similarity to result in name confusion
Carbodec	Carbonoxamine and Pseudoephedrine	Look and Sound	Lacks sufficient orthographic and phonetic similarity to result in name confusion
Alavert	Loratadine	Sound	Lacks sufficient phonetic similarity to result in name confusion
Elavil	Amitriptyline	Look	Lacks sufficient orthographic similarity to result in name confusion
Calcimar	Calcitonin	Look	Lacks sufficient orthographic similarity to result in name confusion. International name for Calcitonin per Lexicomp. December 6, 2011 (Canada)
Kelnor	Ethinyl Estradiol and Ethynodiol Diacetate	Look	Lacks sufficient orthographic similarity to result in name confusion
Haloperdiol	Haloperidol	Look	Lacks sufficient orthographic similarity to result in name confusion

Kadiflam	Diclofenac Tablets	Look	International name for Diclofenac per Lexicomp. November 14, 2011 (Indonesia)
Kaldyum	Potassium Bicarbonate Tablet	Look	International name for Potassium Bicarbonate per Lexicomp. November 14, 2011 (Poland)
Kapidex	Dexlanzoprazole	Look	Original name for Dexlansoprazole which is now marketed as Dexilant per Micromedex/Martindales April 22, 2011
Kolephrin	Acetaminophen, Chlorpheniramine, and Pseudoephedrine	Look	Preliminary drug usage data indicates the name Kolephrin is not used in prescribing.
Kolephrin GG/DM	Guaifenesin and Dextromethorphan	Look	Preliminary drug usage data indicates the name Kolephrin is not used in prescribing.
Ralydan	Lidocaine and Tetracaine Transdermal patch	Look	International name for Lidocaine and Tetracaine per Lexicomp. Marketed in the U.S. as Synera. November 14, 2011 (Denmark)
(b) (4)	(b) (4)	(b) (4)	(b) (4)

Appendix E: Potentially confusing names with orthographic and/or phonetic differences and differentiating product characteristics that decrease the risk of medication errors.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Reyataz (Atanazavir) Capsules Strength: 150 mg, 200 mg, 300 mg Usual dose: Take one capsule by mouth once daily	**Orthographic similarity:** 'K' and 'R' appear orthographically similar when scripted. Both names contain a downstroke in similar positions and an upstroke in the fifth position. **Dosage form and Route of administration:** Both are available as solid oral dosage forms **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Reyataz will require strength as it is available in multiple strengths. However, there is overlap between the strengths during prescription writing *(150 mg)*.	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'd' and 'l' in the third, fourth, and fifth positions vs. Reyataz is missing the first upstroke and contains a downstoke and an upstroke separated by a letter 'a', giving the names different shapes when scripted. In addition, the letter 'z' in Reyataz may be scripted as a downstroke which may further differentiate the names.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Rapamycin (Sirolimus) Tablets: 0.5 mg, 1 mg, 2 mg Oral solution: 1 mg/mL Usual dose: For patient less than 40 kg: Loading dose: 3 mg/m^2 on day 1, followed by maintenance dosing of 1 mg/m^2 once daily. For patients greater than or equal to 40 kg: Loading dose: 6 mg on day 1; maintenance: 2 mg once daily	**Orthographic similarity:** 'K' and 'R' appear orthographically similar when scripted.	**Orthographic difference:** Kalydeco contains a downstroke in the fourth position and upstrokes in the third and fifth position vs. Rapamycin which is missing the upstrokes and contains downstrokes in the third and sixth position giving the names different shapes when scripted. **Strength:** Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Rapamycin will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Razadyne (Galantamine) Tablets: 4 mg, 8 mg, 12 mg Extended-release capsules: 8 mg, 16 mg, 24 mg Oral solution: 4 mg/mL Usual dose: Tablets: Take 16 mg to 24 mg by mouth twice daily; Extended-release capsules: Take 16 mg to 24 mg by mouth daily	**Orthographic similarity:** 'K' and 'R' appear orthographically similar when scripted. Both names contain an upstroke 'd' in the fifth position. **Dosage form and route of administration:** Both are available as solid oral dosage forms. **Frequency:** Both are taken twice daily	**Orthographic difference:** Kalydeco contains a downstroke in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Razadyne contains an upstroke followed a downstoke in the fifth and sixth position, giving the names different shapes when scripted. **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Razadyne will require strength as it is available in multiple strengths. There is no numerical overlap between the two strengths during prescription writing.

<u>Proposed name:</u> **Kalydeco** **(Ivacaftor) Tablets** **<u>Strength:</u> 150 mg** **<u>Usual dose:</u> One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Helidac (Bismuth Chewable, Metronidazole Tablets, Tetracycline Capsule) Strength: Bismuth Chewable 262.4 mg, Metronidazole 250 mg, and Tetracycline 500 mg Usual dose: Take 1 dose (all 4 pills) four times a day – at meal times and bedtime or Take as directed *Provided as a kit containing 14 multi-item blister cards of 8 each Bismuth Subsalicylate 262.4mg Chewable Tablet, 4 each Metronidazole 250 mg Tablet and 4 each Tetracycline 500 mg Capsule*	**Orthographic similarity:** Both names contain 2 upstrokes in the third and fifth position. **Phonetic similarity:** The second syllable 'ly' and 'li' and third syllable 'dec' and 'dac' sound similar when spoken. **Strength**: Kalydeco is available in single strength and may be omitted from a prescription and Helidac is a kit that does not require a strength for a complete prescription. **Dosage form and route of administration:** Both are available as solid oral dosage forms	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Helidac contains the letter 'i' in between the two upstrokes, giving the names different shapes when scripted. **Phonetic difference:** Kalydeco contains four syllables and Helidac contains three syllables. The first syllable 'Ka' vs 'He' sound distinctly different when spoken. Also, the last syllable 'co' is absent in Helidac.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Kalbitor (Ecallantide) Injection Strength: 10 mg/mL Usual dose: Subcutaneously: 30 mg (as three 10 mg [1 mL] injections); may repeat an additional 30 mg within 24 hours	**Orthographic similarity:** Both names begin with 'Kal' and contain upstrokes in similar positions. **Strength**: Both are available as single strengths and may be omitted from a prescription.	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Kalbitor which is missing the downstoke in between the two upstrokes and also contains an additional upstroke in the sixth position which is absent in Kalydeco, giving the names different shapes when scripted. **Dose:** One tablet or 150 mg vs. 30 mg
Calderol (Calcifediol) Capsules Strength: 20 mcg Usual dose: Initially, 300 mcg to 350 mcg by mouth weekly. Most patients require 50 mcg to 100 mcg given once daily or 100 to 200 mcg on alternate days	**Orthographic similarity:** Both names contain 'al' **Strength**: Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are available as solid oral dosage forms	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Calderol which is missing the downstoke in between the two upstrokes and also contains an additional upstroke in the last position which is absent in Kalydeco, giving the names different shapes when scripted.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Caldolor (Ibuprofen) Injection solution Strength: 100 mg/mL Usual dose: Intravenously: 400 mg to 800 mg every 6 hours as needed (maximum: 3.2 grams per day)	**Orthographic similarity:** Both names contain upstrokes in similar positions. **Strength**: Both are available as single strengths and may be omitted from a prescription.	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Caldolor which is missing the downstoke in between the two upstrokes and also contains an additional upstroke in the sixth position which is absent in Kalydeco, giving the names different shapes when scripted. **Frequency of use:** Twice daily vs. Every 6 hours as needed **Dose:** One tablet or 150 mg vs. 400 mg to 800 mg

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Kerledex (Betaxolol HCl/Chlorthalidone) Tablets Strength: 5 mg/12.5 mg; 10 mg/12.5 mg Usual dose: Take one tablet by mouth daily	**Orthographic similarity:** Both names begin with 'K' and have the same up strokes 'l' and 'd'. **Phonetic similarity:** Both names begin with similar sounding first, second and third syllables ('k', 'l', 'd'). **Dosage form and route of administration:** Both are available as solid oral dosage forms	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Kerledex which is missing the downstoke in between the two upstrokes and includes the letter 'x' which provides a cross stroke at the end of the name, giving the names different shapes when scripted. **Phonetic difference:** Kalydeco contains four syllables and Kerledex contains three syllables and although each syllable start with the same sound ('k', 'l', and 'd') they are followed by distinctly different sounds ('a' vs. 'er', 'y' vs. 'e'). **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Kerledex will require strength as it is available in multiple strengths. There is no numerical overlap between the strengths during prescription writing. Preliminary drug use data indicates that the name Kerledex is not used in prescribing.

<u>Proposed name:</u> **Kalydeco** **(Ivacaftor) Tablets** **<u>Strength:</u> 150 mg** **<u>Usual dose:</u> One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Colestid (Colestipol) granules for suspension and tablets Strength: Granules: 5 gm per scoop; Tablets: 1 gm Usual dose: Granules: 5 gm to 30 gm per day given once or in divided doses 2 to 4 times per day; Tablets: 2 gm to16 gm per day	**Orthographic similarity:** Both names contain an upstroke 'l' the third position. **Dosage form and route of administration:** Both are available as solid oral dosage forms **Dose and Frequency:** Both share numerically similar doses (150 mg twice daily vs. 15 g twice daily)	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Colestid is missing the downstroke. Colestid also contains an additional upstroke in the last position which is absent in Kalydeco, giving the names different shapes when scripted. **Dosage form:** Single vs. multiple. Kalydeco is available as a single dosage form and may be omitted from a prescription vs. an order for Colestid will require either a dosage form or a strength as it is available in multiple dosage forms. Each dosage form is available as a different strength.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Ketalar (Ketamine) Injection solution Strength: 10 mg/mL, 50 mg/mL, 100 mg/mL Usual dose: Continuous intravenous infusion: 2 to 7 mcg/kg/minute; Intramuscular: 2 to 4 mg/kg; Intravenous: 0.2 to 0.75 mg/kg	**Orthographic similarity:** Both names begin with 'K'. 'al' and 'et' appear orthographically similar when scripted. **Dose:** Both share numerically achievable doses (150 mg orally x 1 vs. 150 mg intramuscularly x 1)	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Ketalar is missing the downstroke in between the two upstrokes 't' and 'l', giving the names different shapes when scripted. In addition, Kalydeco (8 letters) appear longer than Ketalar (6 letters) when scripted. **Dosage form and route of administration:** Oral tablets vs. Injection solution given intravenously or intramuscularly

<u>Proposed name:</u> **Kalydeco** **(Ivacaftor) Tablets** **<u>Strength:</u> 150 mg** **<u>Usual dose:</u> One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Ketoprofen (Ketoprofen) Capsule and Extended release capsules Strength: Capsule, oral: 50 mg, 75 mg; Capsule, extended release, oral: 200 mg Usual dose: Extended release: Take one capsule by mouth once daily Immediate release: Take one capsule (50 mg) by mouth 4 times daily or 75 mg 3 times daily up to a maximum of 300 mg/day;	**Orthographic similarity:** Both names begin 'K' and 'al' and 'et' appears orthographically similar when scripted. Both names have a down stroke in similar position. **Dosage form and route of administration:** Both are available as solid oral dosage forms	**Orthographic difference:** Kalydeco (8 letters) appear shorter than Ketoprofen (10 letters) when scripted. In addition, Kalydeco has two up strokes in the letter string 'lyd' separated by the down stroke 'y' vs. the two up strokes 't' and 'f' are further separated by the letter string 'opro' in Ketoprofen, giving the names different shapes when scripted. **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Ketoprofen will require strength as it is available in multiple strengths. There is no numerical overlap between the strengths during prescription writing.

<u>Proposed name:</u> **Kalydeco** **(Ivacaftor) Tablets** **<u>Strength:</u> 150 mg** **<u>Usual dose:</u> One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Kaletra (Lopinavir and Ritonavir) Tablets and Oral solution Strength: Tablet: 100 mg/25 mg and 200 mg/50 mg Solution: Lopinavir 80 mg and Ritonavir 20 mg per mL (160 mL); Usual dose: Once Daily: 4 tablets (Total=800 mg/200 mg) Twice daily: 2 tablets (400 mg/100 mg);	**Orthographic similarity:** Both names begin with 'Kal' and contain an upstroke in the fifth position. **Phonetic similarity:** The first syllable 'ka' and second syllable 'ly' and 'le' sound similar when spoken. **Dosage form and route of administration:** Both are available as solid oral dosage forms **Frequency:** Both are taken twice daily	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Keletra is missing the downstroke in between the two upstrokes 'l' and 't', giving the names different shapes when scripted. In addition, Kalydeco (8 letters) appear longer than Kaletra (7 letters) when scripted. **Phonetic difference:** Kalydeco contains four syllables and Kaletra contains three syllables. The third syllable 'de' vs. 'tra' sound distinctly different when spoken. **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Kaletra will require strength as it is available in multiple strengths. There is no numerical overlap between the strengths during prescription writing.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Kalexate (Sodium Polystyrene Sulfonate) Powder for suspension Strength: 15 gm /60 mL Usual dose: Oral: Take 15 gm (60 mL) by mouth 1 to 4 times daily Rectal: 30 gm (120 ml) every 6 hours	**Orthographic similarity:** Both names contain the letter string 'Kal' **Strength**: Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are available as solid oral dosage forms **Dose and Frequency:** Both share numerically similar doses (150 mg twice daily vs. 15 g twice daily)	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Kalexate is missing the downstroke and upstroke following the first upstroke 'l' giving the names different shapes when scripted. In addition, Kalexate contains a cross stroke 't' towards the last position which is absent in Kalydeco.
Kinlytic (Urokinase) Injection solution Strength: 0.25 million units Usual dose: Coronary Artery: Infuse into the occluded artery at a rate of 4 mL per minute (6,000 units per minute) for periods up to 2 hours. Pulmonary Embolism: Continuous infusion of 2,000 units per pound per hour (4,400 units per kg per hour) at a rate of 15 mL per hour for 12 hours	**Orthographic similarity:** Both names begin with 'K' and contain the letter string 'ly' followed by an upstroke in similar positions. **Strength**: Both are available as single strengths and may be omitted from a prescription.	**Setting of use:** Kinlytic is used in emergency situations at onset of pulmonary embolism. **Frequency:** Kinlytic is primarily ordered as a stat or now order vs. twice daily for Kalydeco **Dose:** One tablet or 150 mg vs. 6000 units per minute or 4400 units/kg/hr

<u>Proposed name:</u> **Kalydeco** **(Ivacaftor) Tablets** **<u>Strength:</u> 150 mg** **<u>Usual dose:</u> One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Xalkori (Crizotinib) Capsules Strength: 200 mg, 250 mg Usual dose: Take one capsule by mouth (250 mg) twice daily	**Orthographic similarity:** 'K' and 'X' may appear orthographically similar when scripted. Both names contain the letter string 'al' and an up stroke in similar positions. **Dosage form and route of administration:** Both are available as solid oral dosage forms **Frequency of use:** Both are taken twice daily.	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Xalkori is missing the downstroke in between the two upstrokes 'l' and 'k', giving the names different shapes when scripted. **Strength**: Single vs. multiple. Kalydeco is available in single strength and may be omitted from a prescription vs. an order for Xalkori will require strength as it is available in multiple strengths. There is no numerical overlap between the strengths during prescription writing.

Proposed name: **Kalydeco** **(Ivacaftor) Tablets** **Strength: 150 mg** **Usual dose: One tablet by mouth every 12 hours with fat-containing food**		**Other failures to consider with this product:** • *This is a product available in one strength presentation. Thus, the strength may be omitted and the prescription may still be filled or ordered.*
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Caladryl (8% calamine, 1% pramoxine HCl) Topical lotion **Caladryl Clear** (1% pramoxine HCl, 0.1% zinc acetate) Topical lotion Usual dose: Apply to affected area 3 to 4 times daily as needed	**Orthographic similarity:** Both names contain the letter string 'al' and the up stroke 'd' in a similar position. **Strength**: Both are available as single strengths and may be omitted from a prescription.	**Orthographic difference:** Kalydeco contains a downstroke 'y' in between two upstrokes 'l' and 'd' in the third, fourth, and fifth position vs. Caladryl is missing the downstroke in between the two upstrokes 'l' and 'd', giving the names different shapes when scripted. In addition, Caladryl contains an upstroke in the last position which is absent in Kalydeco. **Dosage form and route of administration:** Oral tablets vs. Topical lotion
Kayexalate (Sodium polystyrene sulfonate) powder for suspension or suspension Strength: 15 gm/60 mL Usual dose: Powder for suspension: 15 gm (approximately 4 level teaspoons) one to four times daily. Suspension: 15 gm (60 mL) one to four times daily	**Orthographic similarity:** Both names begin with 'Ka' **Strength**: Both are available as single strengths and may be omitted from a prescription. **Dosage form and route of administration:** Both are available as solid oral dosage forms **Dose and Frequency:** Both share numerically similar doses (150 mg twice daily vs. 15 g twice daily)	**Orthographic difference:** Kalydeco contains two upstrokes in the middle of the name vs. Kayexalate contains the two upstrokes in the end of the name, giving the names different shapes. Kalydeco (8 letters) appear shorter than Kayexalate (10 letters) when scripted.

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/s/

CARLOS M MENA-GRILLASCA on behalf of REASOL AGUSTIN
12/30/2011

CARLOS M MENA-GRILLASCA
12/30/2011

IRENE Z CHAN
12/30/2011