

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204200Orig1s000

204200Orig2s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: November 15, 2012

Reviewer(s): Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Adrenalin (Epinephrine) Injection 1 mg/mL

Application Type/Number: NDA 204200

Applicant/sponsor: JHP Pharmaceuticals

OSE RCM #: 2012-2624

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Adrenalin is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Adrenalin, acceptable in OSE Review # 2012-968 dated July 16, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review RCM # 2012-968. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names, thought to look or sound similar to Adrenalin that would 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 November 5, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on November 14, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

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

4 REFERENCES

1. **OSE Reviews:** Owens, L., OSE RCM #2012-968, Proprietary Name Review for Adrenalin (NDA 204200), July 16, 2012
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

/s/

LISSA C OWENS
11/15/2012

LUBNA A MERCHANT
11/15/2012

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

Proprietary Name Review

Date: July 16, 2012

Reviewer(s): Lissa Owens, PharmD
Division of Medication Error Prevention and Analysis

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Deputy Director Kellie Taylor, PharmD, MPH
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Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Adrenalin (Epinephrine) Injection 1 mg/mL

Application Type/Number: NDA 204200

Applicant/Sponsor: JHP Pharmaceuticals

OSE RCM #: 2012-968

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Adrenalin, 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

This is an unapproved product currently marketed by JHP, the Applicant is now seeking an approval for this product and has submitted an NDA. The following product information is provided in the April 18, 2012 proprietary name submission.

- Active Ingredient: Epinephrine
- Indication of Use: Hypersensitivity reactions and induction of mydriasis during cataract surgery
- Route of Administration: Intramuscular, subcutaneous, (b) (4)
- Dosage Form: Injection Solution
- Strength: 1 mg/mL
- Dose and Frequency: : (b) (4) to 0.5 mg intramuscularly or subcutaneously once (may repeat every 5 to 10 minutes), (b) (4)
(b) (4) Pediatric: 0.1 mg/kg intramuscularly or subcutaneously once (may repeat every 5 to 10 minutes), (b) (4)
(b) (4)
- How Supplied: 1 mL (b) (4)
(b) (4)
- Storage: 20°C to 25°C (68°F to 77°F); Protect from light and freezing

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA, the Division of Pulmonary, Allergy, and Rheumatology Products and the Division of Transplant and Ophthalmology concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) SEARCH*

On May 29, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name. We note that Adrenaline is listed as an International Nonproprietary Name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proprietary name Adrenalin was derived based on the historical use of this name as it relates to the product. Based on historical labeling by Parke-Davis and their registration of the mark in 1906, Adrenalin was the name given by Dr. Takamine into the astringent, blood-pressure raising principle of the adrenals, or suprarenal glands, as first isolated by him in 1901.

We note that Adrenaline is listed as an International Nonproprietary Name (INN) in some references; however, it also appears that the name Adrenaline may have been a revised International Nonproprietary Name (rINN) since some references list Epinephrine and Adrenaline synonymously. Hence, we cannot conclude definitively if Adrenaline is an INN name.

2.2.3 Medication Error Data Selection of Cases

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

The April 23, 2012 search of the Adverse Event Reporting System (AERS) database used the following search terms: Adrenalin (trade name) and Adrenal% (verbatim). The search time frame was limited to the last date of our AERS search in OSE RCM # 2010-1559 dated October 13, 2011. The search retrieved 12 reports.

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

After individual review all 12 cases were not included in the final analysis of this review as they were label and labeling issues. There were no reports of name confusion with Adrenalin. There is an on-going label and labeling review, (OSE # 2012-1042) in which the 12 cases will be further analyzed.

2.2.4 FDA Name Simulation Studies

Thirty-one practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Twenty-one (10 in the inpatient study, 1 in the voice study, and 10 in the outpatient study) respondents interpreted the name correctly as 'Adrenalin'. Nine (1 in the inpatient study and 8 in the voice study) respondents interpreted the name as 'Adrenaline'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, April 30, 2012 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) and the Division of Transplant and Ophthalmology (DTOP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Adrenalin. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Adrenalin identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation.

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

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Ciclesonide	FDA	Refanalin	FDA	Adrenalone	FDA
Aclovate	FDA	Adcetris	FDA	Adacel	FDA
Aliskiren	FDA	Acitretin	FDA	Adenoscan	FDA
Anthralin	FDA	AdreView	FDA	AdvaCal	FDA
Adren-Aid	FDA	Androvite	FDA	Adenosine	FDA
Androderm	FDA	AdrenaClick	FDA	Adriamycin	FDA
Look and Sound Similar					
Adrenalium	FDA	Adrenal	FDA	Atralin	FDA

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

2.2.7 Failure Mode and Effect Analysis of the Use of Adrenalin

The Applicant proposed the name Adrenalin, due to their historical use of this name for Epinephrine. The name Adrenalin had been registered as a trademark since 1906, and marketed previously by Parke-Davis for Epinephrine. JHP acquired this product in 2007 and continued to label and market this unapproved product as Adrenalin.

The name Adrenalin is also used as a proprietary name outside of United States for Epinephrine. We have not identified any reports of name confusion with Adrenalin, given that it has been in use for a number of years in and out of the U.S. However, we acknowledge that the lack of reports does not mean that there may be no problems with this name in the U.S. market since under reporting of medication errors may occur and there may be dose differences in the various countries medication use system.

Adrenalin is also referred to in the literature as Epinephrine. FDA generally discourages proprietary names that comprise the established name. However, Epinephrine is the established name for this compound in the United States.

Additionally, DMEPA generally discourages the use of proprietary names that can be used interchangeably with the active ingredient and can be mistaken with other products containing that active ingredient. However, given the historical use of the name Adrenalin, the fact that Adrenalin = Epinephrine in drug references and the internet, the lack of any existing medication error reports with the name and the fact that the name does not appear to present a risk for look-alike and sound-alike confusion based on our analysis, we find the name Adrenalin, acceptable.

2.2.8 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) and the Division of Transplant and Ophthalmology (DTOP) via e-mail on May 29, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products and the Division of Transplant and Ophthalmology on May 29, 2012, they stated no additional concerns with the proposed proprietary name, Adrenalin.

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 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, Adrenalin, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your April 18, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

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

¹ 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.²

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and 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.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, NAME	Scripted May Appear as	Spoken May Be Interpreted as
A	Ce, FL, H,s	Any Vowel
d	cl,ci, ol	b,t
r	S,n,e,v,	none
e	a,i,l,o,u,p	Any Vowel
n	m,u,x,r,h,s	dn, gn,kn,mn,pn,m
a	a, el,ci,cl,d,o,u	Any Vowel
l	b,e,s,A,P,i	none
i	e	none

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Appendix C: Prescription Simulation Samples and Results

Figure 1. Adrenalin Study (Conducted on April 27, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Adrenalin 0.2mL IM x1</i></p> <hr/> <p><u>Outpatient Prescription:</u></p> <p><i>Adrenalin</i> <i>Bring to clinic</i> <i>#1 vial</i></p>	<p>Adrenalin</p> <p># 1 vial</p> <p>Bring to clinic</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

	Total	12	9	10
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
ADRENALIN	10	1	10	21
ADRENALIN 0.2ML	1	0	0	1
ADRENALINE	1	8	0	9

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 Adrenalin	Failure preventions
Ciclesonide	Ciclesonide	Look	The pair have sufficient orthographic differences
Adrenalium	Adrenalium	Look and Sound	Ingredient in the natural medicine product Synaptol. It is not available as a separate ingredient
Adrenal	N/A	Look and Sound	Product is not a drug. It is a gland
Refanalin	Refanalin	Look	Orphan drug. No pending NDA or commercial IND within the Agency
Adrenalone	Adrenalone	Look	Name identified in Micromedex database. Unable to find product characteristics in commonly used drug databases.

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

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Aclovate (Alclometasone Dipropionate) Cream and Ointment, 0.05%</p> <p><u>Usual Dose:</u> Apply a thin film to affected area(s) 2 to 3 times per day</p>	<p><u>Orthographic:</u> The pair have similar beginning letter strings, ‘Adr’ and ‘Acl’</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, ‘lin’ vs. ‘ate’ may appear different when scripted due to the upstroke letter ‘l’ in Adrenalin giving the pair different shapes.</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. 2 to 3 times daily</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Topical</p> <p><u>Dose:</u> xx mcg or mg vs. Apply a thin film or ‘UAD’</p>
<p>Adcetris (Brentuximab Vedotin) Injection, 50 mg</p> <p><u>Usual Dose:</u> 1.8 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks</p>	<p><u>Orthographic:</u> The pair have similar beginning letter strings, ‘Adr’ and ‘Adc’</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, ‘lin’ vs. ‘ris’ may appear different when scripted due to the position of the upstroke letter ‘l’ in Adrenalin giving the pair different shapes.</p>
<p>Adacel (TDAP) Injection Vaccine</p> <p><u>Usual Dose:</u> 0.5 mL intramuscularly once</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, ‘Ad’</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings ‘lin’ vs. ‘cel’ may look different when scripted due to the upstroke letter ‘l’ at the end of Adacel giving the pair different shapes. Adrenalin (9 letters) appears longer when scripted than Adacel (6 letters).</p>

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Aliskiren Hemifumarate Tablets, 150 mg and 300 mg</p> <p><u>Usual Dose:</u> 150 mg to 300 mg by mouth once daily</p>	<p><u>Orthographic:</u> The pair have similar beginning letter strings, 'Adr' and 'Ali'</p>	<p><u>Orthographic:</u> The position of the third upstroke is different in the name Aliskiren giving them different shapes.</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. once daily</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Oral</p> <p><u>Strength:</u> Single strength which may be omitted vs. multiple strengths which must be indicated on prescription or medication order.</p>
<p>Atralin (Tretinoin) Gel, 0.05%</p> <p><u>Usual Dose:</u> Apply a thin layer to skin lesions once daily before bedtime</p>	<p><u>Orthographic:</u> The pair have the same ending letter strings, 'lin' and both start with 'A'</p> <p><u>Phonetic:</u> The pair have the same ending sound, 'lin'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> Adrenalin (9 letters) appears longer when scripted than Atralin (7 letters).</p> <p><u>Phonetic:</u> Adrenalin has 4 syllables vs. Atralin which has 3 syllables. The second syllables, 'dren' vs. 'tra' sound different when pronounced.</p> <p><u>Dose:</u> xx mcg or mg vs. Apply a thin layer or 'UAD'</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Topical</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. daily</p>
<p>Acitretin Capsules, 10 mg, 17.5 mg, 22.5 mg, 25 mg</p> <p><u>Usual Dose:</u> 25 mg to 50 mg by mouth daily</p>	<p><u>Orthographic:</u> The pair have similar ending letter strings, 'lin' and 'tin' and both start with 'A'</p>	<p><u>Orthographic:</u> The beginning letter strings, 'Adr' vs. 'Aci' may look different when scripted due to the upstroke letter 'd' in Adrenalin giving the pair different shapes.</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. daily</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Oral</p> <p><u>Strength:</u> Single strength which may be omitted vs. multiple strengths which must be indicated on prescription or medication order.</p>

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Adenoscan (Adenosine) Solution, 60 mg/20 mL and 90 mg/30 mL</p> <p><u>Usual Dose:</u> 140 mcg/kg/min intravenous infusion over 6 minutes</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Ad'</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'can' may look different when scripted due to the upstroke letter 'l' in Adrenalin giving the pair different shapes.</p>
<p>Anthralin Shampoo, 1%</p> <p><u>Usual Dose:</u> Apply to wet scalp 3 to 4 times per week</p>	<p><u>Orthographic:</u> The pair have the same ending letter strings, 'lin'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The beginning letter strings, 'Adr' vs. 'Ant' may look different when scripted due to the upstroke letter 'd' in Adrenalin giving the pair different shapes. Also the infix 'rena' vs. 'thra' look different when scripted.</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Topical</p> <p><u>Dose:</u> xx mcg or mg vs. Apply to wet scalp</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. 3 to 4 times per week</p>
<p>AdreView (Iobenguane I 123) Injection, 2 mCi/mL</p> <p><u>Usual Dose:</u> 10 mCi/mL intravenously once</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Adre'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs 'iew' may look different when scripted due to the upstroke letter 'l' in Adrenalin giving the pair different shapes.</p> <p><u>Dose:</u> xx mcg or mg vs. xx mCi/mL</p>

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>AdvaCal (Ascorbic Acid, Calcium, Cholecalciferol Zinc, Copper Manganese) 100mg/500 mg/200IU/300 mg/6 mg/1mg/2 mg</p> <p><u>Usual Dose:</u> 3 Capsules in the morning and 3 capsules in the evening</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Ad'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'Cal' may differ when scripted due to the upstroke letter 'l' at the end of AdvaCal giving the pair different shapes. Adrenalin (9 letters) appears longer when scripted than AdvaCal (7 letters).</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Oral.</p> <p><u>Dose:</u> xx mcg or mg vs. 3 capsules</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. twice daily</p>
<p>Adren-Aid (Licorice Root, Eleuthero Root, Fresh Devils Club Root Bark, Fresh Dandelion Root, Sarsaparilla Root, Fresh Ginger Root) Tincture, Herb Strength ratio: 1:2.1</p> <p><u>Usual Dose:</u> 20 to 40 drops in water or juice 2 to 3 times daily or as needed</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Adren'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'Aid' may look different when scripted due to the upstroke letter 'd' at the end of Adren-Aid giving the pair different shapes.</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Oral.</p> <p><u>Dose:</u> xx mcg or mg vs. 20 to 40 drops</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. 2 to 3 times daily as needed.</p>
<p>Androvite for Men (Multivitamin) Tablets</p> <p><u>Usual Dose:</u> 6 tablets by mouth daily with meals</p>	<p><u>Orthographic:</u> The pair have similar beginning letter strings, 'Adr' and 'And'</p> <p><u>Strength:</u> Both are single strength products</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'ite' may appear different when scripted due to the upstroke letter 'l' in Adrenalin giving the pair different shapes.</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Oral</p> <p><u>Dose:</u> xx mcg or mg vs. 6 tablets</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. daily</p>

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Adenosine Solution, 60 mg/20 mL and 90 mg/30 mL</p> <p><u>Usual Dose:</u> 140 mcg/kg/min intravenous infusion over 6 minutes</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Ad'</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'ine' may look different when scripted due to the upstroke letter 'l' in Adrenalin giving the pair different shapes.</p>
<p>Androderm (Testosterone) Patch, 2.5 mg/day and 5 mg/day</p> <p><u>Usual Dose:</u> One 5 mg patch or two 2.5 mg patches applied nightly for 24 hours</p>	<p><u>Orthographic:</u> The pair have similar beginning letter strings, 'Adr' and 'And'</p> <p><u>Dose:</u> Both share a 5 (mg vs. mcg) dose</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'erm' may look different when scripted due to the upstroke letter 'l' in Adrenalin giving the pair different shapes.</p> <p><u>Frequency:</u> Once (may be repeated every 5 to 10 min) vs. daily</p> <p><u>Route:</u> Subcutaneous, Intramuscular, or Intravenous infusion which must be indicated vs. Topical</p> <p><u>Strength:</u> Single strength which may be omitted vs. multiple strengths which must be indicated on prescription or medication order.</p>
<p>Adrenaclick (Epinephrine) Injection, 0.15 mg and 0.3 mg</p> <p><u>Usual Dose:</u> 0.15 mg or 0.3 mg as a subcutaneous or intramuscular injection at the time of allergic reaction</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings 'Adrena'</p> <p><u>Phonetic:</u> The pair both have 4 syllables and share the 1st three syllables</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'ick' may look different when scripted due to the upstroke letter 'k' at the end of Adrenaclick giving the pair different shapes. Adrenalin (9 letters) may appear shorter when scripted than Adrenaclick (11 letters).</p> <p><u>Phonetic:</u> The 4th syllables, 'lin' vs. 'click' sound different and make the names sound different when pronounced.</p>

<p>Proposed name: Adrenalin</p> <p>Dosage Form(s): Injection Solution</p> <p>Strength(s): 1 mg/mL (b) (4)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Adriamycin (Doxorubicin Hydrochloride) Injection, 10 mg, 20 mg, 50 mg</p> <p>Usual Dose: As a single agent: 60 mg/m² to 75 mg/m² as a single intravenous injection administered at 21-day intervals. With other chemotherapeutic agents: 40 mg/m² to 60 mg/m² given as a single intravenous injection every 21 to 28 days</p>	<p><u>Orthographic:</u> The pair have the same beginning letter strings, 'Adr'</p>	<p><u>Orthographic:</u> The ending letter strings, 'lin' vs. 'cin' may look different when scripted due to the upstroke letter 'l' in Adrenalin. Adrenalin does not have any downstroke letters vs. Adriamycin which has a downstroke letter 'y' which give the pair different shapes.</p>

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/s/

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