

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**202667Orig1s000**

**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**

**Pre-Action Name Review**

Date: October 13, 2011

Reviewer(s): Morgan Walker, Pharm.D., M.B.A., Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

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Division of Medication Error Prevention and Analysis (DMEPA)

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Division of Medication Error Prevention and Analysis (DMEPA)

Drug Name(s): Cosopt PF (Dorzolamide Hydrochloride and Timolol Maleate)  
Ophthalmic Solution  
2% / 0.5%

Application Type/Number: NDA 202667

Applicant/sponsor: Merck Sharp & Dohme Corporation

OSE RCM #: 2011 - 2609

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## **1 INTRODUCTION**

This re-assessment of the proprietary name, Cosopt PF, is in anticipation of approval of NDA 202667 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Cosopt PF, acceptable in OSE Review 2010-510, dated May 13, 2011.

## **2 METHODS AND RESULTS**

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We used the same search criteria outlined in OSE Review #2011-510. Since none of the proposed characteristics were altered, we did not evaluate previous names of concern. Our searches of the databases did not yield any new names thought to look or sound similar to Cosopt PF and represent a potential source of drug name confusion.

Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Cosopt PF, as of October 5, 2011.

## **3 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment indicates that the proposed name, Cosopt PF, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proposed proprietary name, Cosopt PF, 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 Transplant and Ophthalmology (DTOP) 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 Karen Townsend, OSE Safety Regulatory Project Manager, at 301-796-5413.

#### 4 REFERENCES

1. Baksh C. OSE Review #2011-510: Proprietary Name Review for Cosopt PF. May 13, 2011.

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/category/4782.html>)

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis proprietary name 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.

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/s/  
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**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology**

Date:	May 13, 2011
Application Type/Number:	NDA 202667
Through:	Irene Z. Chan, Pharm.D., BCPS, Team Leader Kellie Taylor, Pharm.D., MPH, Associate Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Charlene A. Baksh, Pharm.D., Ph.D., Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Cosopt PF (Dorzolamide hydrochloride and Timolol maleate) Preservative-Free Ophthalmic Solution, 2%/0.5%
Applicant/sponsor:	Merck Sharp & Dohme Corporation
OSE RCM #:	2011-510

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## **EXECUTIVE SUMMARY**

This review summarizes DMEPA's evaluation of Merck Sharp & Dohme Corporation's proposed proprietary name, Cosopt PF, for Dorzolamide hydrochloride and Timolol maleate ophthalmic solution. Our evaluation of the proposed proprietary name, Cosopt PF, did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Cosopt PF acceptable for this product. The proprietary name must be re-reviewed 90 days prior to approval of the NDA. If we find the name unacceptable following the re-review, we will notify you..

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change. DMEPA will notify the applicant of these findings via letter.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This review evaluates the proposed proprietary name, Cosopt PF, regarding promotional concerns and potential name confusion with other proprietary or established drug names in the usual practice settings.

### **1.2 PRODUCT INFORMATION**

Cosopt PF is a combination of Dorzolamide hydrochloride/Timolol maleate ophthalmic solution. Cosopt PF differs from the currently marketed Cosopt because it lacks a preservative (benzalkonium chloride 0.0075%). Dorzolamide hydrochloride 2% is an ophthalmic carbonic anhydrase inhibiting drug. Timolol maleate 0.5% is a beta-blocking drug. Both drugs work to lower intraocular pressure in the eye in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers. The dose and frequency for Cosopt PF and Cosopt is 1 drop into the affected eye(s) twice daily. Cosopt PF will be supplied in a foil pouch containing 15 low-density polyethylene (LDPE) single dose containers, with 0.2 mL per container. Cosopt is packaged in bottle containing 10 mL of the drug.

## **2 METHODS AND MATERIALS**

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Cosopt PF.

### **2.1 SEARCH CRITERIA**

For this review, particular consideration was given to drug names beginning with the letter 'C' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>1,2</sup> Additionally, since omission of a modifier is cited in the literature as a common cause of medication

<sup>1</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>2</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

errors<sup>3</sup>, DMEPA considers ‘Cosopt PF’ as a complete name as well as ‘Cosopt,’ the root term, omitting the modifying term ‘PF.’

DMEPA staff evaluates the appropriateness of the modifier ‘PF’ for this product in addition to searching commonly used databases (see Section 6) for currently marketed product names that include ‘PF’ and defining the meaning of ‘PF’ for those products.

To identify drug names that may look similar to Cosopt PF, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the root name (6 letters), upstrokes (two, capital letter ‘C’ and lower case letter ‘t’), downstrokes (one, lower case ‘p’), cross strokes (one, lower case ‘t’ when written with a cross stroke), dotted (none), and modifiers (PF). Additionally, several letters in Cosopt PF may be vulnerable to ambiguity when scripted (see Appendix B). DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Cosopt PF.

When searching to identify potential names that may sound similar to Cosopt PF, the DMEPA staff search for names with similar number of syllables (four), stresses (CO-sopt ‘P F’ or co-SOPT ‘P F’), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Applicant’s intended pronunciation (CO-sopt PEA EHF) was also taken into consideration, as it was included in the Proprietary Name Review Request. Furthermore, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered. DMEPA staff also considers how the exclusion of ‘PF’ may change the sound of the name.

## 2.2 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE SELECTION OF CASES

Since the root name ‘Cosopt’ has been marketed since 1998, DMEPA conducted a search of the FDA Adverse Event Reporting System (AERS) database to determine if there is existing name confusion between Cosopt and the names of other marketed drugs. DMEPA conducted an AERS search on March 18, 2011, for medication errors involving Cosopt, dorzolamide or timolol.

The MedDRA High Level Group Terms (HLGT) “Medication Errors” and “Product Quality Issues” were used as search criteria for *Reactions*. The search criteria used for *Products* were active ingredients “dorzolamide” and “timolol”, trade name “Cosopt”, and verbatim substance search “dorz%”, “tim%”, and “cos%”. Date limitations were April 7, 1998 (Cosopt approval date) to present.

Additionally, since the PF modifier is marketed with other marketed drug products, DMEPA conducted a search of the FDA AERS database to determine if errors are present that may be attributable to the PF modifier. DMEPA conducted an AERS search on May 14, 2011, for medication errors involving HypoTears PF, Acular PF, and GenTeal PF.

The MedDRA High Level Group Terms (HLGT) “Medication Errors” and “Product Quality Issues” were used as search criteria for *Reactions*. The search criteria used for *Products* were trade names HypoTears PF, Acular PF, and GenTeal PF, and verbatim substance search “HypoT%”, “Acular%”, and “Gentea%”.

The reports were manually reviewed to determine if a medication error occurred. Duplicate reports were combined into cases. The cases that described a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors. If a root cause was associated with name confusion or look and/or sound alike to Cosopt, the case was considered pertinent to this review. Those reports that did not describe a medication error or did not

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<sup>3</sup> Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

describe an error applicable to this review (e.g. errors related to accidental exposures, intentional overdoses, etc.) were excluded from further analysis.

### **2.3 FDA PRESCRIPTION ANALYSIS STUDIES**

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient, and verbal prescriptions were communicated during the FDA prescription studies.

**Figure 1. Cosopt PF Prescription Study (conducted on January 28, 2011)**

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> <p><i>Cosopt PF 1 drop right eye bid</i></p>	<p>"Cosopt PF Use as directed Dispense #1"</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Cosopt PF</i></p> <p><i>Use as directed</i></p> <p><i>#1 Carton</i></p>	

### 3 RESULTS

The following sections represent the results from DMEPA's database searches, Expert Panel Discussion (EPD), Prescription studies, and the Safety Evaluator Risk Assessment. We also sought input from the Division of Anti-Infective and Ophthalmologic Products (DAIOP) regarding the proprietary name.

#### 3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of eight names as having some similarity to the name Cosopt PF.

Six of the names were thought to look like Cosopt PF. These include Azopt, Cipro HC, Cortef, Isoptin SR, Ocucoat PF, and Trusopt.

One name, Cosamin DS, was thought to sound similar to Cosopt PF.

One name, Cosopt, was thought to look and sound similar to Cosopt PF.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 18, 2011.

#### 3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Cosopt PF.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

#### 3.3 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE SELECTION OF CASES

The AERS search conducted on March 18, 2011 to identify errors with Cosopt, yielded 126 reports (see Appendix H). All reports were excluded from further evaluation in this review because they were not related to name confusion with Cosopt.

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The AERS search conducted on March 18, 2011 to identify errors with the PF modifier yielded 1 reports (ISR # 4156268-2). This report was excluded from further evaluation because the PF modifier did not contribute to error. The error involved confusion between Mycocide NS and Hypotears due to similar packaging appearance.

### **3.4 FDA PRESCRIPTION ANALYSIS STUDIES**

A total of 50 practitioners responded to the prescription analysis studies. All practitioner responses were evaluated, and it was found that no names were of currently marketed products.

Thirty (n=30) practitioners interpreted the name correctly as 'Cosopt PF'. Two practitioners omitted the modifier 'PF'. The majority of correct responses occurred in the written outpatient study. The remainder of the practitioners misinterpreted the drug name. The majority of misinterpretations occurred in the verbal study as misspelled phonetic variations of the proposed name with the ending letter string being misinterpreted as 'pt', 'art', or 'phe'. In the written inpatient studies, the misinterpretations involved either the second letter 'o' being interpreted as an 'a', or the fifth letter 'p' being interpreted as an 'f'. In the written outpatient studies, misinterpretations involved the first letter 'C' being interpreted as 'G', or rearranging the ending 'opt' to 'pot'. It is important to note that thirty-nine practitioners (n=39) presented the complete name with the modifier, however in 9 of the 39 responses the modifier were misinterpreted as 'PS', 'TS', or 'PI', none of which are modifiers currently used in the market. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### **3.5 COMMENTS FROM THE DIVISION OF ANTI-INFECTIVE AND OPHTHALMOLOGIC PRODUCTS (DAIOP)**

#### ***3.5.1 Initial Phase of Review***

In a response to the OSE December 29, 2010 e-mail, the Division of Anti-Infective and Ophthalmologic Products (DAIOP) did not have any concerns regarding the proposed proprietary name, Cosopt PF, provided that "PF" represents "Preservative-Free."

#### ***3.5.2 Midpoint of Review***

On April 6, 2011, DMEPA notified the Division of Anti-Infective and Ophthalmologic Products (DAIOP) via e-mail that we had no objections to the proposed proprietary name, Cosopt PF. Per e-mail correspondence from the Division of Anti-Infective and Ophthalmologic Products (DAIOP), they indicated that they have no additional comments to our assessment of the proposed proprietary name, Cosopt PF.

### **3.6 SAFETY EVALUATOR SEARCHES**

Independent searches by the primary Safety Evaluator resulted in six additional names that were thought to look similar to Cosopt PF and represent a potential source of drug name confusion. These names are Casopitant, Cellcept, Cesamet, Cosantix, Gengraf, and Lusalon.

Thus, a total of 14 names were identified for their similarity to Cosopt PF from the combined searches: eight names were identified from the database searches, and six names were identified by the primary safety evaluator.

## **4 DISCUSSION**

The proposed proprietary name, Cosopt PF, was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

## 4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Anti-Infective and Ophthalmologic Products concurred with the findings of this assessment.

## 4.2 SAFETY ASSESSMENT

The safety review considered all sources of potential confusion with the proposed name including orthographic or phonetic similarities with currently marketed products and use of the modifier PF.

### 4.2.1 Modifier “PF”

The Applicant proposes to use the root name Cosopt and the modifier ‘PF’ to differentiate the preservative-free formulation from the currently marketed Cosopt product. Cosopt PF will not contain the preservative, benzalkonium chloride 0.0075%, unlike the currently marketed Cosopt product. The modifier ‘PF’ distinguishes the only notable difference between Cosopt PF and the existing Cosopt product, which is the absence of the preservative. Other characteristics such as ingredients strength, directions for use, and indication that are used in prescribing, ordering, dispensing, and administration to distinguish formulations containing the same active are identical for Cosopt and Cosopt PF. Different proprietary names are needed to distinguish these formulations in practice.

Therefore, in our evaluation of the proposed name, Cosopt PF, we considered whether PF would be expected to convey the Applicant’s intended meaning (preservative-free) and would not inadvertently introduce error.

The Applicant did not provide data to support either the intended meaning of the modifier or that the modifier would not inadvertently introduce a source of error. Therefore, our evaluation focused on establishing the current usage of the PF modifier in other drug products, and whether errors are known to occur with this modifier.

In healthcare, ‘PF’ can mean Plasmodium falciparum, patellofemoral, peak flow, pemphigus foliaceus, peripheral fields, Pharmacopeia Forum, plantar flexion, Pontiac fever, power factor, preservative free, prostatic fluid, pulmonary fibrosis, or push fluids so there is some ambiguity as to whether the modifier would convey “preservative-free” to healthcare providers. However, when placed in conjunction with a drug name, PF has been consistently used to denote a preservative-free formulation of a drug product. Examples include HypoTears PF, Acular PF, and GenTeal PF. For each of these products, the PF modifier appears to represent a preservative-free formulation. Moreover, similar to Cosopt PF, each of these drug products are also eye drops. Given that PF is currently used consistently among eye drop products to denote a preservative-free formulation, we have no reason to expect that practitioners or patients would ascribe a different meaning if the modifier PF is used for the preservative-free formulation of Cosopt,

With respect to error potential, we did not identify any medication error reports in AERS involving the PF modifier. Additionally, review of ISMP’s Confused Drug Name List and ISMP’s Dangerous Abbreviations list did not identify the modifier PF or the names HypoTears PF, Acular PF, and GenTeal PF as source of error. Since there have been no identified reports of the modifier PF causing confusion or contributing to error, we have no reason to expect that the introduction of the modifier PF for the preservative-free formulation of Cosopt would inadvertently introduce error.

However, post-marketing experience has shown that the introduction of product line extensions result in medication errors if the modifier is overlooked or omitted and product characteristics are similar or overlap. We believe this risk may exist with Cosopt based on the results of our Prescription Studies.

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Two participants misinterpreted Cosopt PF as Cosopt. Since the dosing and administration of these products is identical, this misinterpretation would likely lead to Cosopt being dispensed instead of Cosopt PF. Therefore, medication errors may occur due to confusion between Cosopt PF and Cosopt. However, our postmarketing experience with Acular PF, GenTeal PF, and Hypotears PF has not identified any errors related to the oversight or omission of the modifier, which gives us some assurance that the modifier PF in conjunction with adequately distinguished labels may serve to adequately differentiate these drug products.

#### 4.2.2 Look-Alike and Sound-Alike Analysis of Cosopt

DMEPA identified 14 names for their potential similarity to the proposed name, Cosopt PF. Seven of the 14 names lacked convincing orthographic and/or phonetic similarity and were not evaluated further (see Appendix D).

One name identified was Ocucoat OF, however this product is not marketed in the US, only in Israel. Therefore it was not evaluated further. Thus, DMEPA evaluated the remaining six names.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the six remaining names and lead to medication errors. This analysis determined that the name similarity between Cosopt PF and five of the six remaining names identified were unlikely to result in medication errors for the reasons presented in Appendices E through G.

## 5 CONCLUSIONS AND RECOMMENDATIONS

We have completed our review of the proposed proprietary name, Cosopt PF, and it is not promotion or vulnerable to name confusion with other drug products that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis has no objections to the proprietary name, Cosopt PF, at this time. The Sponsor will be notified via letter.

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions are upon re-review are subject to change.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Brantley Dorch, OSE Project Manager at 301-796-0150.

### 5.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Cosopt PF, and have concluded that it is acceptable.

The proposed proprietary name, Cosopt PF, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics as stated in your February 16, 2011, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

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## 6 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.

### 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. *Electronic online version of the FDA Orange Book* (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

**9. Clinical Pharmacology Online ([www.clinicalpharmacology-ip.com](http://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.

**10. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://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.

**11. Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://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.

**12. Access Medicine ([www.accessmedicine.com](http://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.

**13. 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.

**14. Red Book Pharmacy's Fundamental Reference**

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

**15. Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

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

**16. Medical Abbreviations Book**

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

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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.<sup>4</sup>

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment 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 focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>5</sup> DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug 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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.<sup>6</sup> DMEPA provides the product characteristics considered for this review in section one.

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<sup>4</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>5</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

<sup>6</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. 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.

**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	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
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"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

Lastly, the DMEPA staff also 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 staff conducts searches of 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 using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

### **2. CDER Expert Panel Discussion**

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of 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 Analysis 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

#### **4. Comments from the OND review Division or Generic drugs**

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

#### **. 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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.<sup>7</sup> 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 one. 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?”***

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. 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.

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<sup>7</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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.

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 Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’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.

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 is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Sponsor. However, the safety concerns set forth in criteria a through e 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 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 a 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. (See Section 4 for limitations of the process).

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 is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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.

**Appendix B:** Letters with possible orthographic or phonetic misinterpretation

<b>Letters in name, Cosopt PF</b>	<b>Scripted may appear as</b>	<b>Spoken may be interpreted as</b>
Capital 'C'	A, L, O	K
lower case 'c'	a, e, i, l	k
lower case 'o'	a, e, u	Any vowel
lower case 's'	g, n, r	x
lower case 'o'	a, e, u	Any vowel
lower case 'p'	j, y	b
lower case 't'	b, r, f, x	d
<b>Modifier 'PF'</b>		
P		B
F	I, T	PF, Ph

**Appendix C:** FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Medication Order	Voice Prescription
Casopt PF	Cosopt PF	Cosopt
Cosoft PF	Cosopt PF	Cosopt PF
Cosoft PF	Cosopt PF	Cosopt PF
Cosoft PF	Cosopt PF	Cosopt PF
Cosopt PF	Cosopt PF	Cosopt PF
Cosopt PF	Cosopt PF	Cosopt PF
Cosopt PF	Cosopt PF	Cosopt PS
Cosopt PF	Cosopt PF	Cosopt PS
Cosopt PF	Cosopt PI	Cosopt PS
Cosopt PF	Cospot PF	Cosopt PS
Cosopt PF	Gosopt PF	Cosopt PS
Cosopt PF	Cosopt pf	Cosopt-TS
Cosopt PF	Cosopt pf	Cospt PF
Cosopt		Cosart ps
Cosopt PF		Cosopt PS
Cosopt pf		Cosopt pf
Cosopt pf		Cosopt pf
Cosopt pf		Cosopt ps
		Cosphe PF

**Appendix D:** Drug names that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Cosopt PF
Casopitant	Look-alike
Cellcept	Look-alike
Cesamet	Look-alike
Cipro HC	Look-alike
Cosamin DS	Sound-alike
Cosantix	Look-alike
Trusopt	Look-alike

**Appendix E:** Names of products withdrawn from the market or not marketed in the U.S.

Proprietary Name	Similarity to Cosopt PF	Status
Ocucoat PF	Look-alike	Name found in POCA search, but is only marketed in Israel.

**Appendix F:** Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors

Product name with potential for confusion	Similarity to Cosopt PF	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
<b>Cosopt PF (dorzolamide hydrochloride/timolol maleate) ophthalmic solution</b>	N/A	2%/0.5%	<b>Instill 1 drop into affected eye twice daily</b>	N/A
Cortef (Hydrocortisone) tablet	Look-alike	5 mg, 10 mg, 20 mg	<p><i>Adults &amp; Pediatric:</i></p> <p><b>Adrenal hyperplasia (congenital)</b> 10 mg/m<sup>2</sup>/day to 20 mg/m<sup>2</sup>/day in 3 divided doses</p> <p><i>Adults only:</i></p> <p><b>Adrenal insufficiency (chronic)/physiologic replacement:</b> 20 mg/day to 30 mg/day</p> <p><b>Anti-inflammatory or immunosuppressive:</b> 15 mg to 240 mg every 12 hours</p> <p><i>Children:</i></p> <p><b>Physiologic replacement:</b> 0.5 mg/kg/day to 0.75 mg/kg/day or 20 mg/m<sup>2</sup>/day to 25 mg/m<sup>2</sup>/day every 8 hours</p>	<p><u>Orthographic:</u> <i>When scripted, Cortef contains three upstrokes, whereas the root name, Cosopt, contains two upstrokes. Also, the suffix in Cortef is “tef”, whereas the suffix in Cosopt is “opt”.</i></p> <p><u>Route of Administration:</u> <i>Topical vs. oral</i></p> <p><u>Dosage Form:</u> <i>Ophthalmic solution vs. tablet</i></p> <p><u>Strength:</u> <i>2%/0.5% (or no designated strength due to single strength formulation) vs. 5 mg, 10 mg, or 20 mg</i></p> <p><u>Usual dose:</u> <i>1 drop vs. 10 mg/m<sup>2</sup>, 15 mg, 20 mg, 0.5 mg/kg, or 2.5 mg/kg</i></p>

Product name with potential for confusion	Similarity to Cosopt PF	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Cosopt PF (dorzolamide hydrochloride/timolol maleate) ophthalmic solution	N/A	2%/0.5%	Instill 1 drop into affected eye twice daily	N/A
			<p><i>Infants and Children:</i></p> <p><b>Anti-inflammatory or immunosuppressive:</b></p> <p>2.5 mg/kg/day to 10 mg/kg/day or 75 mg/m<sup>2</sup>/day to 300 mg/m<sup>2</sup>/day every 6 to 8 hours</p>	
Gengraf (Cyclosporine) capsule	Look-alike	25 mg, 50 mg, 100 mg	<p><i>Type of transplant:</i></p> <p>Renal: 9 ± 3 mg/kg/day, divided twice daily</p> <p>Liver: 8 ± 4 mg/kg/day, divided twice daily</p> <p>Heart: 7 ± 3 mg/kg/day, divided twice daily</p> <p><b>Rheumatoid arthritis:</b> Initial dose: 2.5 mg/kg/day, divided twice daily</p> <p><b>Psoriasis: Initial dose:</b> 2.5 mg/kg/day, divided twice daily</p>	<p><u>Route of Administration:</u> <i>Topical vs. oral</i></p> <p><u>Dosage Form:</u> <i>Ophthalmic solution vs. capsule</i></p> <p><u>Strength:</u> <i>2%/0.5% (or no designated strength due to single strength formulation) vs. 25 mg, 50 mg, 100 mg</i></p> <p><u>Usual dose:</u> <i>1 drop vs. 7 ± 3 mg/kg, 8 ± 3 mg/kg, 9 ± 3 mg/kg, or 2.5 mg/kg/day</i></p>

Product name with potential for confusion	Similarity to Cosopt PF	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Cosopt PF (dorzolamide hydrochloride/timolol maleate) ophthalmic solution	N/A	2%/0.5%	Instill 1 drop into affected eye twice daily	N/A
Isoptin SR (Verapamil hydrochloride) tablet	Look-alike	120 mg, 180 mg, 240 mg	1 tablet by mouth every morning	<p><u>Orthographic:</u> When scripted, the downstroke, “p” in the root name, Isoptin is in the infix, whereas the downstroke, “p” in the root name, Cosopt, is in the suffix. Additionally, the modifier, “SR”, in Isoptin SR does not look like the modifier, “PF”, in Cosopt PF.</p> <p><u>Route of Administration:</u> Topical vs. oral</p> <p><u>Dosage Form:</u> Ophthalmic solution vs. tablet</p> <p><u>Strength:</u> 2%/0.5% (or no designated strength due to single strength formulation) vs. 120 mg, 180 mg, or 240 mg</p> <p><u>Frequency:</u> Twice daily vs. once daily</p>
Lusonal (Phenylephrine) oral solution  OTC product	Look-alike	7.5 mg/ 5 mL (480 mL)	10 mg to 20 mg every 4 hours as needed for ≤ 7 days	<p><u>Orthographic:</u> When scripted, Lusonal contains no downstrokes, whereas the root name, Cosopt, contains one downstroke, “p”.</p> <p><u>Phonetic:</u> When Lusonal is pronounced, the sound of the “L” at the beginning of the name is distinctly different from “C” in the root name, Cosopt.</p> <p><u>Route of Administration:</u> Topical vs. oral</p> <p><u>Dosage Form:</u> Ophthalmic solution vs. oral solution</p> <p><u>Usual Dose:</u> 1 drop vs. 10 mg to 20 mg</p> <p><u>Frequency:</u> Twice daily vs. every 4 hours</p>

**Appendix G:** Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease the risk of medication error

<b>Proposed Name:</b>	<b>Strength:</b>	<b>Usual Dose and Administration:</b>
<b>Cosopt PF (dorzolamide hydrochloride/ timolol maleate) ophthalmic solution</b>	<b>2%/0.5%</b>	<b>Instill 1 drop into affected eye twice daily</b>
<b>Failure: Name confusion</b>	<b>Causes (can be multiple)</b>	<b>Prevention of Failure</b>
<p>Azopt (Brinzolamide) ophthalmic suspension</p> <p><b>Strength:</b> 1%</p> <p><b>Usual Dose and Administration:</b></p> <p>Instill one drop into affected eye(s) three times daily</p>	<p><b>Orthographic Similarities:</b></p> <p>The root name, Cosopt, is orthographically similar to Azopt due to the following:</p> <ol style="list-style-type: none"> <li>1. Azopt begins with “A”, which may look like “C” when scripted. Cosopt PF begins with “C”, which may look like “A” when scripted.</li> <li>2. Both names end with “opt”.</li> <li>3. If Azopt is written without a downstroke “z,” then it would be similar to Cosopt having two upstrokes, one downstroke, and one cross-stroke.</li> </ol> <p><b>Numerical Overlap in Dose:</b></p> <p>Both Azopt and Cosopt PF may be written as “Use as directed” or “1 drop” if there is no strength designation.</p>	<p>Difference in product characteristics, which minimize the likelihood of medication error in the usual practice setting.</p> <p><b>Rationale:</b></p> <p>There are no reported cases of name confusion between Azopt and Cosopt.</p> <p>If Azopt is written with a downstroke “z,” then it would not look similar to Cosopt. Azopt would have two downstrokes, “z” and “p”, compared with one downstroke, “p”, in Cosopt.</p> <p>Azopt is to be administered at a frequency of three times daily, whereas Cosopt PF is to be administered twice daily.</p> <p>The modifier “PF” will help to distinguish the names from each other.</p>

**Appendix H:** Excluded AERS reports (ISR#s)

3141835	3999620	4551168	5340684	6545997
3143043	4037011	4571708	5352179	6550585
3316634	4052204	4582216	5356434	6565936
3406432	4090727	4612479	5403335	6600636
3442465	4156235	4617611	5465682	6646221
3515169	4166975	4629247	5465725	6651667
3569189	4176161	4653367	5507805	6666713
3651685	4179937	4677967	5723030	6750399
3673136	4187365	4678680	5805170	6792589
3724347	4195110	4678713	5904810	6868840
3724363	4225184	4692998	5924668	6874458
3724370	4251511	4700935	5928770	6914591
3724373	4268545	4701244	5969064	6917622
3724374	4288909	4705171	6023377	6946768
3734722	4299832	4737870	6101427	7023639
3734726	4324585	4738358	6120589	7049542
3760225	4336638	4797438	6298853	7050646
3791669	4396873	4848389	6309163	7052032
3817844	4452104	4849922	6330235	7116833
3898850	4458100	4943088	6332893	7131129
3898853	4467130	5055206	6333171	7150577
3920159	4511834	5118061	6355630	7179725
3935459	4512886	5133629	6425122	7245228
3938138	4536688	5143387	6501669	7276421
3967251	4549477	5205373	6531946	7285025
3992077				

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KELLIE A TAYLOR  
05/13/2011

CAROL A HOLQUIST  
05/13/2011