

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**203389Orig1s000**

**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: March 12, 2013

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): Procysbi (Cysteamine Bitartrate) Delayed-release Capsules  
25 mg and 75 mg

Application Type/Number: NDA 203389

Applicant/sponsor: Raptor Pharmaceuticals Inc.

OSE RCM #: 2012-1482

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## **1 INTRODUCTION**

This re-assessment of the proposed proprietary name, Procysbi 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, *Procysbi*, acceptable in OSE Review RCM # 2012-908 dated June 28, 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 # 2012-908. 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 Procysbi and 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 February 26, 2013. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on November 2, 2012 and had no concerns regarding the proposed name from a promotional perspective.

## **3 CONCLUSIONS**

The re-evaluation of the proposed proprietary name, Procysbi, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Procysbi, 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 Office of the Division of Gastroenterology and Inborn Error Products 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 Phong Do, OSE project manager, at 301-796-4795.

## 4 REFERENCES

1. **OSE Reviews** Tobenkin, Anne., OSE RCM #2012-908, Proprietary Name Review for Procysbi (NDA 203389), June 28, 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.

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/s/  
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03/12/2013

LUBNA A MERCHANT  
03/12/2013

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

**Proprietary Name Review**

Date: June 28, 2012

Reviewer: Anne Crandall Tobenkin, Pharm.D.  
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, Pharm.D., M.S.  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, R.Ph.  
Division of Medication Error Prevention and Analysis

Drug Name(s): Procysbi (Cysteamine Bitartrate) Delayed-release Capsules

Strengths: 25 mg and 75 mg

Application Type/Number: NDA 203389

Applicant/Sponsor: Raptor Pharmaceuticals Inc.

OSE RCM #: 2012-908

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## 1 INTRODUCTION

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

### 1.1 REGULATORY HISTORY

This product as initially submitted with the name, (b) (4), which was found unacceptable in OSE review # 2010-2552. Subsequently, the name was withdrawn and a new proprietary name, (b) (4) was submitted and found unacceptable in OSE review # 2011-2521. Both names were reviewed in the IND phase (IND 103694). The application has since converted to an NDA, with a PDUFA goal date of September 30, 2012. The NDA was submitted in accordance with section 505(b)(2) with Cystagon as the Reference Listed Drug.

### 1.2 PRODUCT INFORMATION

The following table includes product information provided in the April 9, 2012 proprietary name submission and product information for the currently marketed cysteamine product, Cystagon.

<b>Product</b>	<b>Procysbi (NDA 203389)</b>	<b>Cystagon (NDA 020392)</b>
Established Name	Cystamine Bitartrate	Cysteamine Bitartrate
Indication of Use	Management of nephrotic cystinosis	Management of nephrotic cystinosis
Route of Administration	Oral	Oral
Dosage Form	Delayed-release capsule	Capsule
Strength	25 mg, 75 mg	50 mg, 150 mg
Dose* * Maintenance dose should be reached after 4 to 6 weeks of incremental dosage increases	(b) (4) <u>Starting dose:</u> (b) (4) by mouth every 12 hours <u>Maintenance dose:</u> 0.65 grams/ m <sup>2</sup> by mouth twice daily (b) (4)	Children up to 12 years: 1.3 grams/m <sup>2</sup> /day given in four divided doses  Patients over age 12 (or over 110 lbs): 2 grams/day given in four divided doses

<b>Table 1: Procysbi and Cystagon Product Characteristics</b>		
<b>Product</b>	<b>Procysbi (NDA 203389)</b>	<b>Cystagon (NDA 020392)</b>
How Supplied	25 mg: bottles of 60 capsules 75 mg: bottles of 250 capsules	Bottles of 500 capsules
Storage	Protect from light and moisture	Protect from light and moisture
Container and Closure Systems	HDPE bottle, (b) (4) *Procysbi should only be dispensed in the original packaging	HDPE bottle, (b) (4) child-resistant (b) (4) closure
Distribution	Controlled distribution system using single specialized pharmacy and distributor	N/A

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Error Products (DGIEP) 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*

The June 1, 2012 United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

#### 2.2.2 *Components of the Proposed Proprietary Name*

Per the Applicant, the proposed name Procysbi, has no derivation and is a "blank canvas". Procysbi is a delayed-release formulation. Procysbi is not currently marketed as an immediate release formulation but there is an existing, currently marketed Cysteamine product called Cystagon. Therefore, we considered whether or not the product needed a modifier to emphasize the delayed-release nature of the product.

First, we considered errors that could occur due to confusion between the different release formulations of the same drug product. These include: wrong technique errors involved patients or practitioners, chewing, splitting, or crushing the extended-release

oral dosage forms when these products were intended to be administered intact or capsules opened and mixed with certain foods or liquids, wrong frequency errors involved the administration of the delayed-release dosage form at intervals more frequent than labeled, (e.g. taking a twice daily drug four times a day) and wrong technique and wrong frequency errors occurred despite the presence of clear labeling directives to administer the products intact and at the given intervals.

With respect to wrong technique errors, we do not believe Procysbi poses the same risk for wrong technique errors that was identified above because the capsule can be opened and sprinkled in certain liquids or food for administration, unlike the other products that are intended to be only administered intact.

We reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms That Should Not Be Crushed" to identify if a modifier exists that could possibly convey that a delayed-release dosage form can be manipulated (note, the list refers to delayed-release as "slow-release"). We conclude that there is no standard single modifier currently on the market today that speaks to whether a delayed-release product can or cannot be manipulated prior to administration.

Moreover, with respect to the potential for wrong frequency of administration errors, we do not anticipate that Procysbi is prone to be administered at the wrong frequency of administration. The existing formulation, which is immediate release, is administered four times daily vs. the proposed product which is administered twice daily. Adding a modifier to communicate the delayed-release nature of the product, may cause further confusion by wrongly insinuating that administration is once daily, as some currently marketed delayed-release formulations recommend. Therefore, we find that the risk of Procysbi being administered at the wrong frequency is minimal, irrespective of the inclusion of a modifier in the proprietary name.

In addition, the strengths of Procysbi do not directly overlap with the strengths of the currently marketed immediate-release formulation of this drug product. Therefore, we believe the differences in strength also minimize the risk of confusion when the products are prescribed in the case that the formulation descriptor (i.e. delayed-release) is omitted or overlooked.

Given the totality of the factors considered above, there is no compelling evidence to support the necessity to request a modifier for the proposed proprietary name, Procysbi, at this time.

### ***2.2.3 Medication Error Data Selection of Cases***

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

The May 31, 2012 search of the Adverse Event Reporting System (AERS) database used the following mames: Cystagon (Trade name), Cysteamine (Active name) and Cystago% (Verbatim term) and Reaction Terms: Medication Errors (HLGT) and Product Quality Issues (HLGT).

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, no reports were not included in the final analysis for the following reason: vomiting due to smell of Cystagon capsules.

#### ***2.2.4 FDA Name Simulation Studies***

Thirty three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. About 50% of the participants interpreted the name correctly as Procysbi. Significant trends in the written studies included misinterpreting 'b' for 'li', 't', 'br' or 'k'. Significant trends in the voice study included misinterpreting 'c' for 's', 'sc' or 'th', 'y' for 'i', 's' for 'z', 'b' for 'p' and 'y' for 'i'. 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 20, 2012 e-mail, the Division of Gastroenterology and Inborn Error Products (DGIEP) 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, Procysbi. Table 2 (on the next page) lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Procysbi, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

**Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)**

<b>Orthographic Similarity to Procysbi</b>		
<b>Procycle (EPD)</b>	<b>Perjeta*** (EPD)</b>	<b>Prasurgel (EPD)</b>
<b>Rocephin (EPD)</b>	<b>Promiseb (EPD)</b>	<b>Pro-cof (EPD)</b>
<b>Procentra (EPD)</b>	<b>Procanbid (EPD)</b>	<b>Procardia (XL) (EPD)</b>
<b>Provigil (EPD)</b>	<b>Prevacid (EPD)</b>	<b>Priscoline (EPD)</b>
<b>Prinzide (EPD)</b>	<b>Periogard (EPD)</b>	<b>Pramegel (EPD)</b>
<b>Pre-protein (EPD)</b>	<b>Dermafilm (EPD)</b>	<b>Duragesic (EPD)</b>
<b>Durezol (EPD)</b>	<b>Perfecta (EPD)</b>	<b>Pergonal (EPD)</b>
<b>Perifresh (EPD)</b>	<b>Periguard (EPD)</b>	<b>Pro-fast SA (EPD)</b>
<b>Profenal (EPD)</b>	(b) (4)	(b) (4)
<b>Procydin (SE)</b>	<b>Prograf (SE)</b>	<b>Prazosin (SE)</b>
<b>Pregnyl (SE)</b>	<b>Probenecid (SE)</b>	(b) (4)
<b>Proventil (SE)</b>	<b>Benlysta (SE)</b>	
<b>Look-Alike and Sound-Alike to Procysbi</b>		
(b) (4)	<b>Procysbi (EPD)</b>	<b>Prezista (EPD)</b>
<b>Sound-Alike to Procysbi</b>		
<b>Prostigmin (EPD)</b>		

Our analysis of the 39 names contained in Table 2 considered the information obtained in the previous sections along with their product characteristics. We determined all 39 names will not pose a risk for confusion as described in Appendix D through E.

### ***2.2.7 Failure Modes and Effects Analysis of Product***

The proposed established name (Cysteamine bitartrate) and proposed strengths (25 mg and 75 mg) are incongruent because the established name is expressed in terms of the salt of the active moiety and the strengths are based on the free base of the active moiety. Although the currently marketed Cysteamine bitartrate product also expresses the established names in the same way, we are aware the Agency has revised how the established name and strength are expressed, therefore, we defer to the expertise of ONDQA regarding this issue.

Furthermore, the usual maintenance doses range between (b) (4) twice daily. As a result, a patient will have to administer several capsules to obtain a desired dose, which may put a significant pill burden on a patient and reduce adherence to therapy. (b) (4)

(b) (4) Having to swallow this many capsules may impact patient compliance.

### ***2.2.8 Communication of DMEPA's Final Decision to Other Disciplines***

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Error Products (DGIEP) via e-mail on June 25, 2012. Per e-mail correspondence from the DGIEP, they stated no additional concerns with the proposed proprietary name, Procysbi.

## **3 CONCLUSION**

The proposed proprietary name is acceptable from both a promotional and safety perspective. Additionally, we conclude the product strengths require revision to decrease pill burden for patients as well as increase patient compliance (see Comments to Division).

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412.

### **3.1 COMMENTS TO THE DIVISION**

DMEPA recommends developing higher strengths of Cysteamine Bitartrate Delayed-release Capsules strengths to accommodate the need for larger doses and to decrease pill burden. However, these new strengths should not overlap with the reference listed product, Cystagon, because both Cystagon and Procysbi contain the same active ingredient and if products are ordered by the established name, the fact that one product is immediate-release and the other is delayed-release may be overlooked, which may result in the wrong drug error.

### **3.2 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Procysbi, and have concluded that this name is acceptable. However, if any of the proposed product

characteristics as stated in your April 9, 2012 submission are altered, the name must be resubmitted for review.

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

## 4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

9. **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.

10. **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.

11. **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.

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](http://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](http://www.lexi.com))**

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

15. **Medical Abbreviations ([www.medilexicon.com](http://www.medilexicon.com))**

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

16. **CVS/Pharmacy ([www.CVS.com](http://www.CVS.com))**

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

17. **Walgreens ([www.walgreens.com](http://www.walgreens.com))**

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

18. **Rx List ([www.rxlist.com](http://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](http://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.<sup>1</sup>

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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<sup>1</sup> 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.<sup>2</sup>

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).

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<sup>2</sup> 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.

<b>Type of Similarity</b>	<b>Considerations when Searching the Databases</b>		
	<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"> <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/Similar shape 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, 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.<sup>3</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

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<sup>3</sup> 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, Procysbi	Scripted May Appear as:	Spoken May Be Interpreted as:
P	R, D	“B”
r	i, v, s, n	
o	a, e, c	
c	o, i	“s”, “z”, “sc”
y	g, j, z	“i”
s	n, r,	“z”, “s”
b	lo, la, h, k	“t”
i	e, u, r	“e”, “y”

**Appendix C: Prescription Simulation Samples and Results**

**Figure 1. Prescription Simulation Study (Conducted on April 20, 2012)**

Handwritten Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Procysbi 900 mg po BID</i></p>	<p>Procysbi 75 mg 900 mg po bid # 720</p>
<p><u>Outpatient:</u></p> <p><i>Procysbi 75mg # 720 Sig. 900mg by mouth BID</i></p>	

**FDA Prescription Simulation Responses for Procysbi**

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
PROCYSBI	PROCYSTI	PROSIPI
PROCYSBI	PROCYSBI	PROSISBY
PROCYSBI	PROCYSBRI	PROSISBEE
PROCYSBI	PROCYSBI	PROSIZBY
PROCYSBI	PROCYSBI	PROSISPY
PROCYRBI	PROCYSKI	PROSISBY
PROCYSBI	PROCYSTI	PROCISBE
PROCYSBI	PROCYSBI	PROTHISBE
PROCYSBI	PROCYSBI	PROCISPY
PROCYSLIR		PROSYSBI
PROCYSBI		PROSCIZBY
PROCYSBI		PROSETBE

**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 Procysbi	Failure preventions
Dura-Gest	n/a	Orthographic	Name found in RedBook, but not connected with a product, also not found in other commonly used drug databases
Pergonal	n/a	Orthographic	Name found in RedBook, but not connected with a product, also not found in other commonly used drug databases
Procysbi	Cysteamine	Orthographic and phonetic	Associated with product evaluated in this review
	(b) (4)	Orthographic and phonetic	All INDs associated with name are either withdrawn, on hold (1998) or inactive (1994)
(b) (4)			
Perifresh	n/a	Orthographic	No rinse-spray cleanser. Not likely to be confused with prescription product.
Procycle	Multivitamin	Orthographic and phonetic	Unable to find product characteristics

**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><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Prezista (Darunavir)</b></p> <p>- 75 mg, 150 mg, 400 mg, 600 mg oral tablet, 100 mg/mL oral solution</p> <p>- 375 mg to 800 mg by mouth or 2 mL to 6 mL once daily, or 200 mg to 600 mg twice daily. MUST be taken with Ritonavir.</p>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pr”</li> <li>- Both names have a downstroke in the middle of the name (scripted “z”)</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Phonetic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names have similar sounding first syllable “Pro” vs. “Pre”</li> <li>-Both names have similar sounding middle syllable “cys” vs. “zis”</li> <li>- Both names are three syllables</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (75 mg)</li> <li>- Route of administration (oral)</li> <li>- Frequency of administration (twice daily)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has three letters between the first upstroke and downstroke vs. Prezista has two letters in between the upstroke and downstroke making the name appear different when scripted</li> <li>- Procysbi has one letter in between the downstroke and upstroke vs. Prezista has two letters in between the downstroke and upstroke making the name appear different when scripted</li> </ul> <p><b>Phonetic differences</b></p> <ul style="list-style-type: none"> <li>- The final syllable in Procysbi has the sound “bee” vs. Prezista has the sound “tah” making the names sound different when pronounced</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Prezista is an HIV medication which must be prescribed with Ritonavir</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Prinzide (Lisinopril and Hydrochlorothiazide)</b></p> <p>- 10 mg/12.5 mg, 20 mg/12.5 mg, 20 mg/25 mg oral tablets</p> <p>- One or two tablets by mouth once daily, up to 40 mg/50 mg per day</p>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (solid oral: capsule, tablet)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg, 75 mg vs. 10 mg/12.5 mg, 20 mg/12.5 mg, 20 mg/25 mg, both strengths must be included to differentiate which strength tablet)</li> </ul>
<p><b>Prograf (Tacrolimus)</b></p> <p>- 0.5 mg, 1 mg, 5 mg oral capsule</p> <p>- 0.02 mg/kg to 0.15 mg/kg by mouth every 12 hours</p> <p>- 5 mg/mL injection solution</p>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pro”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (capsule)</li> <li>- Frequency of administration (every 12 hours)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has three letters in between the first upstroke and downstroke vs. Prograf has two letters making the name appear shorter when scripted</li> <li>- Suffix in Procysbi “sbi” appears different when scripted vs. suffix in Prograf “raf” because there is no letter following the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg and 75 mg vs. 0.5 mg, 1 mg, 5 mg, although obtainable would take an inordinate amount of capsules to obtain prescribed dose)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every 12 hours</p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Perjeta*** (Pertuzumab)</b></p> <ul style="list-style-type: none"> <li>- 420 mg/14 mL injection</li> <li>- 840 mg administered as a 60 minute intravenous infusion, followed every 3 weeks thereafter by a dose of 420 mg administered over a period of 30 to 60 minutes.</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi does not have a cross-stroke vs. Perject has a cross-stroke towards the end of the name making the name appear different</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (must in be increments of 25 mg or 75 mg vs. 420 mg or 840 mg)</li> <li>- Frequency of administration (every 12 hours vs. load doses followed by every 3 weeks)</li> </ul>
<p><b>Prasurjel (Proprietary name: Effient)</b></p> <ul style="list-style-type: none"> <li>- 5 mg, 10 mg oral tablet</li> <li>- 60 mg by mouth once followed by 5 mg or 10 mg once daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke towards the end of the names</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dosage form (oral solid: capsule, tablet)</li> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has the downstroke as the fifth letter vs. Prasurjel has a downstroke as the seventh letter giving the name a different shape</li> <li>- Procysbi has a letter after the final upstroke vs. Prasurjel ends with an upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. once daily)</li> <li>- Dose (b) (4) vs. 5 mg or 10 mg)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every 12 hours</p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily (b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Rocephin (Ceftriaxone)</b></p> <ul style="list-style-type: none"> <li>- 250 mg, 500 mg, 1 g, 2 g, 10 g powder for injection, 1 g, 2 g injection solution</li> <li>- 1 g to 2 g intravenously or intramuscularly once daily or twice daily or 50 mg/kg intravenously or intramuscularly once daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- “Pr” and “R” appear similar when scripted</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose (mg overlap)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “sbi” appears different when scripted vs. “hin” because there are two letters after the final upstroke</li> <li>- Procysbi has a letter in between the downstroke and upstroke vs. Rocephin has the downstroke and upstroke next to one another giving the name a different shape.</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral vs. intravenous or intramuscular)</li> </ul>
<p><b>Promiseb (Shea nut)</b></p> <ul style="list-style-type: none"> <li>- Topical lotion</li> <li>- Apply as needed to dry skin</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both name begin with “P”</li> <li>- Both names have an upstroke toward the end of the names</li> <li>- Both names are similar in length</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke in the middle of the name vs. Promiseb does not have a downstroke</li> <li>- Procysbi has a name after the upstroke vs. Promiseb ends with an upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (b) (4) vs. amount needed to cover affected area</li> <li>- Strength (no numerical overlap: 25 mg and 75 mg vs. single strength, not required on prescription)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every 12 hours</p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily (b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Pro-cof (Hydrocodone and Potassium Guaiaculfonate)</b></p> <ul style="list-style-type: none"> <li>- 5 mg/300 mg/5 mL oral solution</li> <li>- 5 mL to 7.5 mL by mouth as needed every 4 to 6 hours</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pro”</li> <li>- Both names end with an upstroke</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke in the middle of the name vs. Pro-cof does not have a downstroke in the middle of the name, giving the names a different shape</li> <li>- Procysbi has eight letters vs. Pro-cof has six letters making it appear shorter when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (b) (4) vs. 5 mL to 7.5 mL)</li> <li>- Frequency of administration (every 12 hours vs. every 4 to 6 hours as needed)</li> </ul>
<p><b>Procentra (Dextroamphetamine)</b></p> <ul style="list-style-type: none"> <li>- 5 mg/5 mL oral solution</li> <li>- 5 mg to 60 mg by mouth per day in divided doses</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Proc”</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke in the middle of the name vs. Procentra does not have a downstroke in the name giving it a different shape</li> <li>- Procysbi has one letter after the final upstroke vs. Procentra has two letters after the final upstroke giving the name a different shape</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every</p> <p><b>12 hours</b></p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Procanbid (Procainamide)</b> Procanbid not marketed, no generic oral formulations available</p> <ul style="list-style-type: none"> <li>- 500 mg, 1000 mg Extended-release tablets</li> <li>- 50 mg/kg by mouth per day in two divided doses</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- both names begin with “Proc”</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose overlap (500 mg, 1000 mg)</li> <li>- Frequency of administration (twice daily)</li> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has two upstrokes vs. Procanbid has three upstrokes giving the name a different shape when scripted</li> <li>- Procysbi has a downstroke vs. Procanbid has no downstroke making the name appear different when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>
<p><b>Procardia (Nifedipine)</b></p> <ul style="list-style-type: none"> <li>- 10 mg, 20 mg oral capsules</li> <li>- 10 mg to 30 mg by mouth three times daily</li> </ul> <p><b>Procardia XL (Nifedipine)</b></p> <ul style="list-style-type: none"> <li>- 30 mg, 60 mg, 90 mg oral tablet</li> <li>- 30 mg to 90 mg by mouth once daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Proc”</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (oral solid: capsule, tablet)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke vs. Procardia does not have a downstroke giving the name a different shape</li> <li>- Procysbi has one letter after the final upstroke vs. Procardia has two letters after the final upstroke making the name appear longer when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. once daily or three times daily)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Provigil (Modafanil)</b></p> <ul style="list-style-type: none"> <li>- 100 mg, 200 mg oral tables</li> <li>- 100 mg to 400 mg by mouth once daily in the morning</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pro”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke at the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (oral solid: capsule, tablet)</li> <li>- Dose (mg overlap)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi suffix, “bi” appears orthographically different vs. Provigil suffix “il” because there is no letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>
<p><b>Prevacid (Lansoprazole)</b></p> <ul style="list-style-type: none"> <li>- 15 mg, 30 mg delayed-release capsule, delayed release granules for suspension, and orally disintegrating tablets</li> <li>- 15 mg or 30 mg by mouth once daily</li> <li>- 30 mg powder for injection</li> <li>- 30 mg infusion over 30 minutes once daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names are similar in length</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (capsules)</li> <li>- Strength (obtainable mg)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke vs. Prevacid does not have a downstroke making the name have a different shape</li> <li>- Procysbi suffix “bi” appears orthographically different vs. Provigil suffix “il” because there is a letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> _____ (b) (4)</p> <p><b>Starting dose:</b> _____ (b) (4) by mouth every</p> <p><b>12 hours</b></p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Priscoline (Tolazoline)</b></p> <ul style="list-style-type: none"> <li>- generic formulations only available in veterinarian drugs, NDA withdrawn</li> <li>- 25 mg/mL injection solution</li> <li>- 10 mg to 50 mg intramuscularly or intravenously four times daily</li> <li>- 25 mg oral tablet</li> <li>- 25 mg to 50 mg by mouth four times daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke vs. Priscoline has no downstroke giving the name a different shape when scripted</li> <li>- Procysbi has eight letters vs. Priscoline has 10 letters making the name appear longer when scripted</li> <li>- Procysbi has one letter after the final upstroke vs. Priscoline has three letters after the final upstroke giving the name a different shape when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. four times daily)</li> </ul>
<p><b>Pramegel (Menthol and Promaxine)</b></p> <ul style="list-style-type: none"> <li>- 1%/0.5% topical gel</li> <li>- Apply liberally to affected area three to four times daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pr”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “bi” appears orthographically different vs. suffix “el” because there is no letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg, 75 mg vs. 1%/0.5%, single strength, not required on prescription and no numerical overlap or mg similarity)</li> <li>- Frequency of administration (every 12 hours vs. three to four times daily)</li> <li>- Dose _____ (b) (4) vs. liberally to cover affected area)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Preprotein</b> (Protein powder supplement)</p> <ul style="list-style-type: none"> <li>- Oral powder, tablets</li> <li>- Take 1 to 3 scoops or two tablets daily as directed by physician</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names being with “Pr”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke in toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has eight letters vs. Pre-protein has ten letters making it appear longer when scripted</li> <li>- Procysbi has one letter after the final upstroke vs. Pre-protein has three letters after the final upstroke giving the name a different shape when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg and 75 mg vs. single strength, strength not required on prescription and not strength overlap)</li> </ul>
<p><b>Dermafilm</b></p> <ul style="list-style-type: none"> <li>- 4 x 4 extra thin dressing</li> <li>- Apply as needed</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- “P” and “D” appear similar when scripted</li> <li>- Both names have a downstroke in the middle of the name (scripted “f”)</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has two upstrokes in the name vs. Dermafilm has three upstrokes giving the name a different shape when scripted</li> <li>- Procysbi appears shorter when scripted vs. Dermafilm because of the presence of wider letters such as “m”</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg and 75 mg vs. no strength)</li> <li>- Dose (b) (4) vs. enough to cover area</li> <li>- Frequency of administration (every 12 hours vs. as needed)</li> </ul>

<p><b>Proposed name: Procsybi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every 12 hours</p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Durezol (Difluprednate)</b></p> <ul style="list-style-type: none"> <li>- 0.5% ophthalmic emulsion</li> <li>- Administer one drop in the affected eye four times daily after surgery, then twice daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- “P” and “D” appear similar when scripted</li> <li>- Both names have a downstroke in the middle of the name (scripted “z”)</li> <li>- Both names have a downstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “bi” appears orthographically different vs. suffix “ol” because there is no letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (b) (4) vs. one drop)</li> <li>- Strength (25 mg, 75 mg vs. 0.5%, single strength not required on prescription and no numerical overlap or mg similarity)</li> </ul>
<p><b>Perfecta (Petrolatum)</b></p> <ul style="list-style-type: none"> <li>- ointment</li> <li>- Apply to affected area as needed</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names being with “P”</li> <li>- Both names have a downstroke in the middle of the name (scripted “f”)</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procsybi has two upstrokes in the name vs. Perfecta has three upstrokes in the name giving the name a different shape</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg, 75 mg vs. single strength, not required on prescription)</li> <li>- Dose (b) (4) vs. liberally to affected area)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> _____ (b) (4)</p> <p><b>Starting dose:</b> _____ (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Periguard (Aloe vera, lanolin, mineral oil and vitamins)</b></p> <ul style="list-style-type: none"> <li>- 100 g tube</li> <li>- Apply as directed to affected area as needed</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke towards the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has one letter in between the downstroke and final upstroke vs. Periguard has three letters giving the name a different shape when scripted</li> <li>- Suffix “sbi” in Procysbi appears different when scripted vs. “ard” in Periguard because there is no letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose _____ (b) (4) _____ vs. amount needed to cover area)</li> <li>- Strength (25 mg and 75 mg vs. no strength associated with product)</li> </ul>
<p><b>Periogard (Chlorhexidine)</b></p> <ul style="list-style-type: none"> <li>- 0.12% oral rinse</li> <li>- Rinse 15 mL in mouth for 30 seconds twice daily. Do not swallow.</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> <li>- Route of administration (oral)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “sbi” in Procysbi appears different when scripted vs. “ard” in Periogard because there is no letter after the final upstroke</li> <li>- Procysbi has one letter in between the downstroke and upstroke vs. Periogard has two letters in between the downstroke and upstroke making the name appear different when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose _____ (b) (4) _____ vs. 15 mL)</li> <li>- Strength (25 mg and 75 mg vs. 0.12%, single strength, not required on order, no numerical overlap or mg similarity)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Pro-fast SA (Phentermine)</b> Pro-fast SA off market, generic available</p> <ul style="list-style-type: none"> <li>- 8 mg, 18.75 mg, 37.5 mg extended release tablet/tablet</li> <li>- 8 mg to 37.5 mg by mouth once daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pro”</li> <li>- Both have a downstroke in the middle of the name (scripted “f”)</li> <li>- Both names have an upstroke at the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (oral solid: capsule, tablet)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has two upstrokes vs. Profast (without modifier) has three upstrokes giving the name a different shape when scripted</li> <li>- Suffix “sbi” in Procysbi vs. “ast” in Profast (without modifier) appears different when scripted because there is a letter following the final upstroke or has multiple letters after the upstroke (with modifier, “SA”)</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg, 75 mg vs. 8 mg, 18.75 mg, 37.5 mg, no mg overlap or numerical similarity)</li> </ul>
<p><b>Profenal (Suprofen)</b></p> <ul style="list-style-type: none"> <li>- 1% ophthalmic solution</li> <li>- Two drops in the affected eye before surgery and then every 4 hours after surgery</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “P”</li> <li>- Both names have a downstroke in the middle of the name (scripted “f”)</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “bi” appears orthographically different vs. suffix “al” because there is no letter after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (b) (4) vs. two drops)</li> <li>- Strength (25 mg, 75 mg vs. 1%, single strength not required on prescription and no numerical overlap or mg similarity)</li> <li>- Frequency of administration (every 12 hours vs. every 4 hours)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Prostigmin (Neostigmin)</b></p> <ul style="list-style-type: none"> <li>- 15 mg oral tablet</li> <li>- 15 mg to 150 mg by mouth three times daily</li> <li>- 1 mg/mL, 0.5 mg/mL injection</li> <li>- 1 mL subcutaneously or intramuscularly followed by 0.5 mL every 3 to 6 hours for up to 3 days if needed</li> </ul>	<p><b>Phonetic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with the same first syllable, “Pro”</li> <li>- Both names have three syllables</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose (obtainable)</li> <li>- Route of administration (oral)</li> <li>- Dosage form (solid oral: capsule, tablet)</li> </ul>	<p><b>Phonetic differences</b></p> <ul style="list-style-type: none"> <li>- Different second syllable sound “sis” in Procysbi vs. “stig” in Prostigmin</li> <li>- Procysbi final syllable has sound “bee” vs. “min” in Prostigmin</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. three times daily)</li> </ul>
<p><b>Proventil (Albuterol)</b></p> <ul style="list-style-type: none"> <li>- 90 mcg/actuation inhaler</li> <li>- 1 to 2 puffs every 4 to 6 hours as needed</li> <li>- 0.63 mg/3 mL, 1.25 mg/3 mL inhalation solution</li> <li>- One ampule via nebulizer every 4 to 6 hours as needed</li> <li>- 4 mg oral tablets</li> <li>- 2 mg to 4 mg by mouth every 6 to 8 hours</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pro”</li> <li>- Both names have an upstroke at then end of the name</li> <li>- Both names are similar in length</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (solid oral: capsule, tablet)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has two upstrokes in the name vs. Proventil has three upstrokes giving the name a different shape</li> <li>- Procysbi has a downstroke vs. Proventil has no downstrokes giving the name a different shape when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg, 75 mg vs. 90 mcg, 0.63 mg/3 mL, 1.25 mg/mL or 4 mg, no numerical overlap or mg similarity)</li> <li>- Frequency of administration (every 12 hours vs. every 4 to 6 hours as needed)</li> <li>- Dose (25 mg to 1400 mg vs. 1 to 2 puffs or 2 to 4 mg, no numerical similarity or mg overlap)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every <b>12 hours</b></p> <p><b>Maintenance dose:</b> <b>650 mg/ m<sup>2</sup> by mouth twice daily</b></p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Procydin (Proanthocyanidin)</b></p> <ul style="list-style-type: none"> <li>- Single strength antioxidant</li> <li>- Three capsules by mouth daily</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Procy”</li> <li>- Both names have one upstroke toward the end of the name</li> <li>- Both names are similar in length</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Route of administration (oral)</li> <li>- Dosage form (capsule)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “sbi” in Procysbi vs. “din” in Procydin appears different when scripted because there are two letters after the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Strength (25 mg and 75 mg vs. no designated strength)</li> </ul>
<p><b>Prazosin</b></p> <ul style="list-style-type: none"> <li>- 1 mg, 2 mg, 5 mg oral capsules</li> <li>- 1 mg to 5 mg by mouth two to three times a day, up to 15 mg per day</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pr”</li> <li>- Both names have a downstroke in the middle of the name (scripted “z”)</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> <li>- Route of administration (oral)</li> <li>- Dosage form (capsules)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has an upstroke toward the end of the name vs. Prazosin has no upstroke at the end of the name giving the name a different shape</li> <li>- Procysbi has three letters in between the first upstroke and downstroke vs. Prazosin has two letters in between making the name appear different when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Dose (b) (4) vs. 1 mg to 5 mg, smallest available strength for Procysbi exceeds the maximum daily recommended dose and the largest dose of Prazosin is not available in strengths of Procysbi)</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> _____ (b) (4)</p> <p><b>Starting dose:</b> _____ (b) (4) by mouth every</p> <p><b>12 hours</b></p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p> <p>(b) (4)</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p><b>Pregnyl (Chorionic gonadotropin)</b></p> <ul style="list-style-type: none"> <li>- 10,000 units for injection</li> <li>- 500 units to 5000 units intramuscularly two to three times a week for 3 to 5 weeks or 300 mg to 1500 mg subcutaneously or intramuscularly three times a week or 10,000 units once intramuscularly</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pr”</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke at the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose (mg overlap)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Suffix “ybi” in Procysbi vs. suffix “ynl” in Pregnyl appears different when scripted due to letter following the final upstroke</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. two or three times a week or once)</li> <li>- Route of administration (oral vs. subcutaneous or intramuscular)</li> </ul>
<p><b>Probenecid</b></p> <ul style="list-style-type: none"> <li>- 500 mg oral tablet</li> <li>- 250 mg by mouth twice daily for the first week then 500 mg by mouth twice daily or 1 g by mouth once or twice with antibiotics</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- Both names begin with “Pr”</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (twice daily)</li> <li>- Dose (mg overlap)</li> <li>- Route of administration (oral)</li> <li>- Dosage form (solid oral: capsule, tablet)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has a downstroke vs. Probenecid does not have a downstroke making the name appear different when scripted</li> <li>- Procysbi is composed of eight letters vs. 10 letters making the name appear longer when scripted</li> <li>- Procysbi has two upstrokes vs. Probenecid has three upstrokes giving the name a different shape</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- none</li> </ul>

<p><b>Proposed name: Procysbi (Cysteamine Bitartrate)</b></p> <p><b>Strength(s): 25 mg and 75 mg Delayed-release Capsule</b></p> <p><b>Usual dose:</b> (b) (4)</p> <p><b>Starting dose:</b> (b) (4) by mouth every 12 hours</p> <p><b>Maintenance dose:</b> 650 mg/ m<sup>2</sup> by mouth twice daily</p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Prevention of Failure Mode</b></p>
(b) (4)		
<p><b>Benlysta (Belimumab)</b></p> <ul style="list-style-type: none"> <li>- 120 mg, 400 mg powder for injection</li> <li>- 10 mg/kg intravenously over 1 hour every 2 weeks (for 3 doses) then every 4 weeks thereafter</li> </ul>	<p><b>Orthographic similarities</b></p> <ul style="list-style-type: none"> <li>- “P” and “B” appear similar when scripted</li> <li>- Both names have a downstroke in the middle of the name</li> <li>- Both names have an upstroke toward the end of the name</li> </ul> <p><b>Overlapping product characteristics</b></p> <ul style="list-style-type: none"> <li>- Dose (mg overlap)</li> </ul>	<p><b>Orthographic differences</b></p> <ul style="list-style-type: none"> <li>- Procysbi has two upstrokes vs. Benlysta has three upstrokes giving the name a different shape when scripted</li> </ul> <p><b>Product characteristic differences</b></p> <ul style="list-style-type: none"> <li>- Frequency of administration (every 12 hours vs. every 2 or 3 weeks)</li> </ul>

**Proposed name: Procysbi  
(Cysteamine Bitartrate)**

**Strength(s): 25 mg and 75 mg  
Delayed-release Capsule**

**Usual dose:**

(b) (4)

**Starting dose:**

(b) (4)

**by mouth every**

**12 hours**

**Maintenance dose:**

**650 mg/ m<sup>2</sup> by mouth twice  
daily**

(b) (4)

**Failure Mode: Incorrect  
Product Ordered/  
Selected/Dispensed or  
Administered because of  
Name confusion**

**Prevention of Failure Mode**

(b) (4)

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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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ANNE C TOBENKIN  
06/28/2012

LUBNA A MERCHANT  
06/28/2012

CAROL A HOLQUIST  
06/28/2012