CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

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Through:	Melina Griffis RPh, Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis
From:	Lubna Najam, MS, PharmD., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Teflaro (Ceftaroline Fosamil) for Injection, 400 mg per Vial and 600 mg per Vial
Applicant:	Cerexa Inc.
OSE RCM #:	2010-1546

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EXECUTIVE SUMMARY

This review summarizes the analysis of the proposed proprietary name, Teflaro for Ceftaroline Fosamil, for Injection. Our evaluation 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 Teflaro conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

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.

1. BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Cerexa Inc. dated July 14, 2010 for an assessment of the proposed proprietary name, Teflaro, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by (b) (4) in support of their proposed proprietary name. The Labels and Labeling included in this submission were reviewed separately in OSE review # 2010-65.

1.2 PRODUCT INFORMATION

Teflaro (Ceftaroline Fosamil for injection) belongs to a novel cephalosporin class of beta-lactams. The bactericidal action of Teflaro results from inhibition of cell wall biosynthesis. Teflaro is indicated for the treatment of patients with complicated skin and community acquired pneumonia infections caused by susceptible isolates of gram-positive and gram-negative organisms. The recommended dose of Teflaro is administered by intravenous infusion over 1 hours. The recommended dose is as follows.

Infection	Dosage	Frequency	Recommended Duration
Complicated Skin and Skin Structure Infection (cSSSI)	600 mg	q12h	5-14 days
Community-Acquired Bacterial Pneumonia (CABP)	600 mg	q12h	5-7 days
		(b) (4)	

For patients with renal impairment, the recommended dose is 400 mg every 12 hours.

Teflaro should be reconstituted with 20 mL Sterile Water for Injection, USP. The entire volume of reconstituted solution must be further diluted in ≥ 250 mL of 0.9% Sodium Chloride or 5% Dextrose Injection, USP; 2.5% Dextrose and 0.45% Sodium Chloride Injection, USP; or Lactated Ringer's Injection, USP before infusion.

Teflaro will be supplied in single use vials of 400 mg and 600 mg in a carton containing 10 vials.

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, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Teflaro.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'T' 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.[1,2]

To identify drug names that may look similar to Teflaro, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (three, letters 'T,' 'f,' and 'l'), down strokes (one, 'f' if scripted), cross strokes (one, letter 't'), and dotted letters (none). Additionally, several letters in Teflaro may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Teflaro.

When searching to identify potential names that may sound similar to Teflaro, the DMEPA staff search for names with similar number of syllables (three), stresses (TEf-la-ro or Te-fla-ro), and placement of vowel and consonant sounds. (See Appendix B) The Applicant's intended pronunciation (te'-fla-ro) was also taken into consideration. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 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 and verbal prescription was communicated during the FDA prescription studies.

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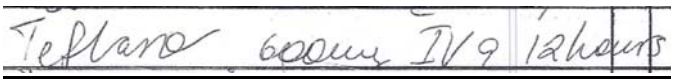
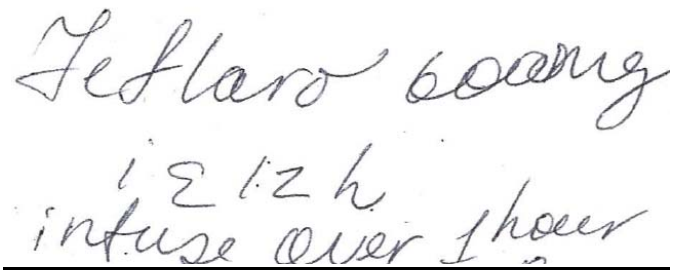
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

Figure 1. Teflaro Study (conducted on July 22, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient prescription: 	Teflaro 600 mg IV q12 hours
Outpatient prescription: 	

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings. After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3. RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 15 names as having some similarity to the name Teflaro. Fourteen of the names were thought to look like Teflaro. These include: Teslac, Tekturna, (b) (4) Tamiflu, Feldene, Tetterine, Zeftera***, Zictifa***, Fentora, Lofibra, Lutera,

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Aclaro, Fibricor, and Tabloid. The remaining name: Teflaro was thought to look and sound similar to Teflaro.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 26, 2010.

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 Teflaro.

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 PRESCRIPTION ANALYSIS STUDIES

A total of 30 practitioners responded, with one of the responses overlapping with an existing drug name (Tylenol). Tylenol was previously identified in section 3.1. Five (n=5) of the participants interpreted the name correctly as "Teflaro," with correct interpretation occurring in the written outpatient study. The remaining written responses misinterpreted the drug name. The letter 'T' was misinterpreted as the letter 'F', and the letter 'r' was misinterpreted as the letters 'n.' In the verbal studies, most of the responses were misspelled phonetic variations of the proposed name.

See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

The proprietary name risk assessment conducted by (b) (4) and submitted by Cerexa Inc. found the proposed proprietary name acceptable. (b) (4) identified and evaluated twenty-one drug names with some potential for confusion with the name Teflaro: Aclaro, Tekturna, Avapro, Bupivacaine, Cefaclor, Ceftin, Pylera, Rapaflo, Refacto, Stelara, Tazorac, Tegretol, Temodar, Tequin, Tessalon, Tetanus, Tetracycline, Texacort, Tofranil, Tri-Vi-Flor, and Zofran. Of the names identified by (b) (4), two were also identified by DMEPA during the database searches: Tekturna and Aclaro. The remaining 19 names were added to the safety evaluator assessment.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in identification of five additional names which were thought to look or sound similar to Teflaro represent a potential source of drug name confusion. The names identified to have look-alike similarities are Tylox, Tylenol, Tibolone, Befex, and (b) (4)

One name "Teflaro" was not evaluated further since it was identified on the U.S. Patent and Trademark Office website registered to the Applicant likely for this product. Thus,

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we evaluated a total of thirty eight names: five identified by the primary safety evaluator, 19 identified by (b) (4), and 14 identified in section 3.1 above.

3.6 COMMENTS FROM THE DIVISION OF ANTI-INFECTIVE AND OPHTHALMOLOGY PRODUCTS (DAIOP)

3.6.1 Initial Phase of Review

In response to the OSE, July 26, 2010 e-mail, Division of Anti-infective and Ophthalmology Products (DAIOP) did not forward any concerns on the proposed name at the initial phase of the name review.

3.6.2 Midpoint of Review

DMEPA notified the Division of Division of Anti-infective and Ophthalmology Products (DAIOP) Products via e-mail that we had no concerns with the proposed proprietary name, Teflaro, on October 7, 2010. Per e-mail correspondence from the DAIOP on October 7, 2010, they indicated the Division had no problem with the proposed proprietary name, Teflaro.

4. DISCUSSION

Teflaro is the proposed proprietary name for Ceftaroline Fosamil Injection. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Cerexa Inc. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC found the proposed proprietary name acceptable from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Anti-infective and Ophthalmology Products (DAIOP) concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

Thirty eight names were identified as having potential similarity to the proposed proprietary name, Teflaro. No other aspects of the name were considered to pose potential confusion with the name. Sixteen of the thirty eight names did not undergo Failure Mode and Effect Analysis (FMEA) for the following reasons: Eleven names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Teflaro (see Appendix D) and five names were of products discontinued, withdrawn, or not marketed in the U.S, and proposed proprietary names for products later approved under a different proprietary name(see Appendices E, F, and G).

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 22 names and lead to medication errors. This analysis determined that the name similarity between Teflaro and all of the identified names was unlikely to result in medication error for the reasons presented in Appendices H and I.

5. CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Teflaro, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Teflaro, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified via letter.

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.

If you have further questions or need clarifications, please contact Brantley Dorch, project manager, at 301-796-0150.

6. COMMENTS TO THE APPLICANT

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

Teflaro 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 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.

7. 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 Applicant 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)

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)

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)

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

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

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)

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. [3]

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. [4] 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

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

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

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.[5] DMEPA provides the product characteristics considered for this review in section one.

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 in 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 Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, 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.

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, 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.[6] 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 posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

"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 Applicant 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 Applicant 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. 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 Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants' 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 Applicant 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 Applicant 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

Letters in Name, Beyaz	Scripted may appear as	Spoken may be interpreted as
Capital 'T'	T, I, l, b, F	D
lower case 'e'	a, i, e, o	any vowel
lower case 'f'	g, j, b	v
lower case 'l'	I, b, h	el
lower case 'a'	e, o, u	any vowel
lower case 'r'	n	
lower case 'o'	a, e, o, u	any vowel

Appendix C: FDA Prescription Study Responses

Outpatient Prescription	Voice Prescription	Inpatient Medication Order
Teflaro	Tefloro	Teflane
Teflaro	??Teflauro	Tylenol
Teflaro	Tefloro	Teflane
Teflaro	Tefluoro	Teflane
Feflaro	Desloro	Teflano
Fedlaro	Teslaro	Teflano
Feflaro	Tefloro	Teflane
Teflaro	Tessloro	Teflane
Feflaro		Teflane
Teflano		Teflane
		Teflane
		Teflano

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

Proprietary Name	Similarity to Teflaro	Proprietary Name	Similarity to Teflaro
Avapro	Look	Temodar	Look
Bupivacaine	Look	Tessalon	Look
Rapaflo	Look	Tetracycline	Look
Stelara	Look	Texacort	Look
Tri-Vi-Flor	Look	Tegretol	Look
Zictifa***	Look		

Appendix E: Discontinued products with no available generics.

Proprietary Name	Similarity to Teflaro	Status
Teslac (Testolactone) Tablets and Injection	Look	Discontinued products with no available generics
Tequin (Gatifloxacin) Tablets	Look	Discontinued products with no available generics

Appendix F: Proposed proprietary names

Proprietary Name	Similarity to Teflaro	Status
(b) (4)	Look	Name was withdrawn by applicant and the product was approved under the new proprietary name Jenloga.

Appendix G: Proprietary names not marketed in the US

Proprietary Name	Similarity to Teflaro	Status
Tibolone	Look	Trade name for Synthetic steroid, marketed only in Europe
Refacto	Look	Trade name for Antihemophilic Factor VIII, marketed only in Canada

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

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

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tekturna (Aliskiren Hemifumarate) Tablets	Look alike	150 mg 300 mg	150- 300 mg or 1 tablet once daily	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dose: *150-300 mg vs. 400 or 600 mg* Dosage form: *Tablet vs. powder for injection* Strength: *150 mg and 300 mg vs. 400 mg and 600 mg* Frequency: *Once daily vs. every 12 hours*
(b) (4)	Look alike	(b) (4)	(b) (4)	(b) (4)

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

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tamiflu (Oseltamivir) Capsules and oral suspension	Look alike	Capsules: 30 mg, 40 mg and 75 mg Oral suspension: 12 mg/mL	Adults: 75 mg twice daily Pediatrics: <12 months: 3 mg/kg/dose once daily, 3-5 months: 20 mg once daily 6-11 months: 25 mg once daily Children: 1-12 years: ≤15 kg: 30 mg once daily, >15 kg to ≤23 kg: 45 mg once daily, >23 kg to ≤40 kg: 60 mg once daily and >40 kg: 75 mg once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The two upstroke 'f' and 'l' are in different positions in the two names* Route of Administration: *Oral vs. intravenous infusion* Dosage form: *Capsules or oral suspension vs. powder for injection*
Feldene (Piroxicam) Capsules	Look Alike	10 mg 20 mg	Adults 10-20 mg or 1 tablet once daily Pediatrics: 0.2-0.3mg/kg/day max of 15 mg/day	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. intravenous infusion* Dose: *10-20 mg vs. 400 or 600 mg* Dosage form: *Capsules vs. powder for injection* Strength: *10 mg and 20 mg vs. 400 mg and 600 mg* Frequency: *Once daily vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tetterine Cream	Look Alike	2%	1 application to affected areas twice daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tetterine contains 2 more letters and appears longer than Teflaro when scripted* Route of Administration: *Topical vs. intravenous infusion* Dose: *1 application vs. 400 or 600 mg* Strength: *2% vs. 400 mg and 600 mg* Dosage form: *Cream vs. powder for injection*
Fentora (Fentanyl) Buccal Tablets	Look alike	100 mcg 200 mcg 300 mcg 400 mcg 600 mcg 800 mcg	100 mcg-1200 mcg as needed for pain	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has a additional upstroke 'f' in the name which is absent in Fentora* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Buccal Tablet vs. powder for injection* Frequency: *As needed vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Lofibra (Fenofibrate) Capsules and tablets	Look alike	Capsules: 67 mg 134 mg 200 mg Tablets : 54 mg 160 mg	54 to 200 mg or 1 tablet once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The position of the third upstroke is different in the two names.* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablet and capsules vs. powder for injection* Frequency: *Once daily vs. every 12 hours*
Lutera (Ethinyl Estradiol and Levnorgestrel)	Look alike	0.02/0.1 mg	1 tablet once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has a additional upstroke 'f' which is absent in Lutera.* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablet vs. powder for injection* Dose: *1 tablet vs. 400 mg or 600 mg* Frequency: *Once daily vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Aclaro (Hydroquinone) Topical emulsion	Look alike	4%	1 application to affected areas BID	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has a additional upstroke 'f' which is absent in Aclaro* Route of Administration: *Topical vs. intravenous infusion* Dose: *1 application vs. 400 or 600 mg* Strength: *4% vs. 400 mg and 600 mg* Dosage form: *Topical emulsion vs. powder for injection*
Fibricor (Fenofibric acid) Tablets	Look alike	35 mg 105 mg	35 to 105 mg or 1 tablet once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has a additional upstroke 'f' which is absent in Fibricor.* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablet vs. powder for injection* Dose: *35 to 105 mg or 1 tablet vs. 400 or 600 mg* Strength: *35 mg and 105 mg vs. 400 mg and 600 mg* Frequency: *Once daily vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tabloid (Thioguanine) Tablets	Look alike	40 mg	Adults: 2-3mg/kg/day Pediatrics: 60mg/m^2/day for 14 days	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tabloid has a additional upstroke 'd' at the end which is absent in Teflaro.* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablet vs. powder for injection* Frequency: *Once daily vs. every 12 hours*
Tylox (Oxycodone and Acetaminophen) Capsules	Look alike	5/500 mg	1-2 capsules every 4-6 hours as needed for pain	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tylox contains only 5 letters and appears shorter than Teflaro, which contains 7 letters, when scripted* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Capsules vs. powder for injection* Dose: *1 to 2 capsules vs. 400 or 600 mg* Strength: *5/500 mg vs. 400 mg and 600 mg* Frequency: *Every 4 to 6 hours as needed vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tylenol (Acetaminophen) Tablets	Look alike	325 mg	1-2 tablets every 4-6 hours as needed for pain	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tylenol has an additional upstroke 'l' at the end which is absent in Teflaro* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablets vs. powder for injection* Dose: *1 to 2 tablets or 325 to 650 mg vs. 400 or 600 mg* Strength: *325 mg vs. 400 mg and 600 mg* Frequency: *Every 4 to 6 hours as needed vs. every 12 hours*
Beflex (Acetaminophen and Phenyltoloxamine) caplets	Look alike	500/55	1-2 caplets every 4-6 hours as needed	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Caplets vs. powder for injection* Dose: *1 to 2 caplets vs. 400 or 600 mg* Strength: *500/55 mg vs. 400 mg and 600 mg* Frequency: *Every 4 to 6 hours as needed vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Cefaclor Capsules and Oral suspension	Look alike	Capsules: 250 mg 500 mg Suspension: 125 mg/5 mL 250mg/5 mL 375mg/5 mL	Adults: 250-500 mg every 8 hours. Pediatrics Children >1 month: Dosing range: 20-40 mg/kg/day divided every 8-12 hours; maximum dose: 1 g/day Otitis media: 40 mg/kg/day divided every 12 hours Pharyngitis: 20 mg/kg/day divided every 12 hours	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *The upstroke 'l' is in different position in the two names* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Capsules and oral suspension vs. powder for injection* Strength: *250 mg , 500 mg, 125 mg/5 mL, 250mg/5 mL, 375mg/5 mL vs. 400 mg and 600 mg*
Ceftin (Cefuroxime Axetil) Tablets and suspension	Look alike	Tablets: 250 mg 500 mg. Suspension: 125 mg/5 mL 250mg/5 mL	Adults: 250 to 500 mg twice daily. Pediatrics: Epiglottitis 150mg/kg/day in 3 divided doses. Acute otitis media 30 mg/kg/day in 2 divided doses or 350 mg q12 hrs	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has seven letters and appears longer than Ceftin, which has six letter, when scripted* Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Tablets and oral suspension vs. powder for injection* Strength: *250 mg , 500 mg, 125 mg/5 mL, and 250mg/5 mL vs. 400 mg and 600 mg*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Pylera (Bismuth Subcitrate Potassium/ Metronidazole/ Tetracycline) Capsules	Look alike	140/125/125 mg	3 capsules four times daily for 10 days	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Route of Administration: *Oral vs. Intravenous infusion* Dosage form: *Capsules vs. powder for injection* Dose: *3 capsules vs. 400 or 600 mg* Strength: *400-125-125 mg vs. 400 mg and 600 mg* Frequency: *Four times daily vs. every 12 hours*
Tetanus (Tetanus Toxoid) Injection solution	Look alike	4 LFU/0.5 mL	0.5 mL given intramuscularly once	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has a additional upstroke 'f' which is absent in Tetanus* Strength: *4 LFU/0.5 mL vs. 400 mg and 600 mg* Dose: *0.5 mL vs. 400 or 600 mg* Frequency: *Once vs. every 12 hours*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Tazorac (Tazarotene) Cream and Gel	Look alike	0.05 % 0.1 %	1 application once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has two additional upstroke 'l' and 'f' which are absent in Tazorac* Route of Administration: *Topical vs. intravenous infusion* Dose: *1 application vs. 400 or 600 mg* Strength: *0.05 % and 0.1 %vs. 400 mg and 600 mg* Dosage form: *Cream and gel vs. powder for injection* Frequency: *Once daily vs. every 12 hours*
Tofranil (Imipramine) Tablets	Look alike	10 mg 25 mg 50 mg	Adults: 25-100 mg/day. Pediatrics: (unlabeled use): 1.5 mg/kg/day maximum dose of 5 mg/kg/day in 1-4 divided doses; Adolescents: Initial: 30-40 mg/day; maximum: 100 mg/day in single or divided doses. Enuresis: Children ≥6 years: 25 mg to 50 mg once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Tofranil has a upstroke 'l' at the end of the name and Teflaro has an upstroke 'l' in the middle of the name* Route of Administration: *Oral vs. intravenous infusion* Strength: *10 mg, 25 mg and 50 mg vs. 400 mg and 600 mg* Dosage form: *Tablets vs. powder for injection*

Product name with potential for confusion	Similarity to Teflaro	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Teflaro (Ceftaroline Fosamil) for Injection	**N/A**	**400 mg 600 mg**	**600 mg every 12 hours Renal adj: 400 mg every 12 hours**	**N/A**
Zofran (Ondansetron) Tablets, Injection solution and Infusion solution	Look alike	Tablets: 4 mg 8 mg 24 mg Injection solution: 4 mg/5 mL Infusion solution: 32 mg in 50 mL	4 mg to 32 mg once prior to chemotherapy or two to three times daily as needed	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Teflaro has an additional upstroke 'l' which is absent in Zofran.* Dose: *4 to 32 mg vs. 400 mg and 600 mg* Strength: *4 mg, 8 mg, 24 mg, 4 mg/5mL and 32 mg/50 mL vs. 400 mg and 600 mg*

Appendix I: Risk of medication errors due to product confusion minimized by dissimilarity of the names or specified product characteristics

Proposed name: Teflaro (Ceftaroline Fosamil) Powder for Injection	**Strength: 400 mg 600 mg**	**Usual Dose: 600 mg every 12 hours 400 mg every 12 hours**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Zeftera[***] (Ceftobiprole Medocaril) Powder for Injection How supplied/Strength: Powder for Injection: 500 mg Dose; 250 mg to 500 mg every 8 to 12 hours	**Orthographic Similarities:** Both names contain the downstroke 'f' and upstroke (t vs. l) in the same position. Both names contain the same number of letters. **Overlap in frequency:** Both drugs can be given every 12 hours **Overlap in indication:** Both drugs are cephalosporin antibiotics given to treat infections **Overlap in route:** Both drugs are given via intravenous infusion	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. **Rationale:** Teflaro is available in two strengths vs. Zeftera is available as single strength, none of the strengths overlap between the two products Teflaro is dosed as 400 mg or 600 mg vs. Zeftera is dosed as 250 mg or 500 mg. None of the doses overlaps between the two products.

[***] This is proprietary and confidential information that should not be released to the public.

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

/s/

LUBNA A MERCHANT
10/08/2010

DENISE P TOYER on behalf of MELINA N GRIFFIS
10/08/2010

DENISE P TOYER
10/08/2010