

determine if the drug names could be confused with Effient and if the drug name confusion would likely result in a medication error.

Six names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix B).

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed name, Effient, could potentially be confused with any of the eighteen remaining names and lead to medication errors. This analysis determined that the name similarity between Effient and the identified names was unlikely to result in medication errors with any of the eighteen products identified for the reasons presented in Appendices C through I.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

Twenty-four names were evaluated for their potential similarity to the proposed name, Effient. The FMEA indicates that the proposed name is not likely to result in name confusion that could lead to medication errors.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Effient, is not vulnerable to name confusion that could lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Effient, for this product at this time. Additionally, DDMAC does not object to the proposed name, Effient, from a promotional perspective.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

5.1 COMMENTS TO THE DIVISION

We would appreciate feedback on the final outcome of this review. We are willing to meet with the Division for further discussion, if needed. Please copy DMEPA on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Sean Bradley, project manager, at 301-796-1332.

5.2 COMMENTS TO THE APPLICANT

5.2.1 *Proprietary Name*

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

Effient 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.

6 REFERENCES

1. OSE Review # 2007-387

Fava W. Proprietary Name Review, Division of Medication Errors and Technical Support, FDA; dated March 23, 2007.

2. OSE Review # 2008-79

Turner T. Proprietary Name, Label, and Labeling Review, Division of Medication Error Prevention, FDA; dated May 29, 2008.

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

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

4. 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.

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

Drug Facts and Comparisons is a compendium organized by therapeutic Course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

6. AMF Decision Support System [DSS]

DSS is a government database used to track individual submissions and assignments in review divisions.

7. Division of Medication Error 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.

8. 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 and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologicals, discontinued drugs and “Chemical Type 6” approvals.

9. *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.

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

USPTO provides information regarding patent and trademarks.

11. *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.

12. *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 tradenames that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

13. *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.

14. *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.

15. *USAN Stems* (*<http://www.ama-assn.org/ama/pub/category/4782.html>*)

USAN Stems List contains all the recognized USAN stems.

16. *Red Book Pharmacy's Fundamental Reference*

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

17. *Lexi-Comp* (*www.lexi.com*)

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

18. *Medical Abbreviations Book*

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

APPENDICES

Appendix A:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. We also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine 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* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has led to medication errors. The Medication Error Staff apply their 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, we will consider the Sponsor’s intended pronunciation of the proprietary name. However, because the Sponsor has little control over how the name will be spoken in practice, we also consider a variety of pronunciations that could occur in the English language.

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

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> 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 Downstrokes Cross-strokes	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

		Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix B: Products withdrawn and/or discontinued from the market

Proprietary Name	Similarity to Effient	Availability of generic equivalent
Efidac 24 (chlorpheniramine maleate)	Look	None
Efidac 24 (pseudoephedrine hydrochloride/brompheniramine maleate)	Look	None