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RESEARCH**

APPLICATION NUMBER:
202428Orig1s000

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

Date: April 30, 2012

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Drug Name and Strength: Fabior (Tazarotene) Foam, (b) (4)

Application Type/Number: NDA 202428

Applicant/Sponsor: Stiefel

OSE RCM #: 2012-431

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Fabior, 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 application is currently under review with the Division of Dermatology and Dental products with a goal date of May 29, 2012.

1.2 PRODUCT INFORMATION

The following product information is provided in the February 15, 2012 proprietary name submission.

- Active Ingredient: Tazarotene
- Indication of Use: Topical treatment of (b) (4) acne vulgaris in patients 12 years of age and older
- Route of Administration: Topical
- Dosage Form: Foam
- Strength: 0.1%
- Dose and Frequency: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening
- How Supplied: 10 g (sample), 50 g, and 100 g aluminum cans
- Storage: 25°C (77°F). Store upright. Do not allow to freeze. Do not expose to heat or store at temperatures above 120°F (49°C)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Dermatology and Dental Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On March 19, 2012 the 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

The Applicant did not submit an intended meaning or derivation for the proposed name, Fabior. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Thirty-two practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Twenty-two participants interpreted the name correctly (inpatient study n=8, outpatient study n=8, voice study n=6). In the outpatient study three participants misinterpreted the letter ‘i’ for the letter ‘o’ and two participants misinterpreted the letter ‘b’ for the letter ‘l’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, February 24, 2012 e-mail, the Division of Dermatology and Dental Products (DDDP) indicated that the review team did not have any concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 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, Fabior. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Fabior, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation or by (b) (4) not identified by DMEPA and require further evaluation.

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

Look Similar					
Name	Source	Name	Source	Name	Source
Famvir	Both	Forteo	Both	Forfivo XL	FDA
Talwin	FDA	Tobrex	FDA	Fentora	FDA
Flolan	FDA	Librax	FDA	(b) (4)	FDA
Butrans	FDA	Folacin	FDA	Tricor	FDA
Tambocor	FDA	FaBB	FDA	Fiberall	FDA
FiberLax	FDA	Rebif	FDA	Rebetol	FDA
Robafen	FDA	Robinul	FDA	Halcion	FDA
Tobi	FDA	(b) (4)	FDA	Febrol	Both

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Folvron	FDA	Fulvicin P/G	FDA	Tilia	FDA
Latisse	FDA	Tribenzor	FDA	(b) (4)	FDA
Fortaz	FDA	Talacen	FDA	Jolessa	FDA
Robaxin	FDA	Benefiber	(b) (4)	Calcor	(b) (4)
Crestor	(b) (4)	Fabrazyme	(b) (4)	Fanapt	(b) (4)
Fansidar	(b) (4)	Feiba	(b) (4)	Felbatol	(b) (4)
Flector	(b) (4)	Flexeril	(b) (4)	Folmor	(b) (4)
Relistor	(b) (4)	Zaditor	(b) (4)	Sabril	FDA
Zofran	FDA	Tebonin	FDA		
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Fabior	FDA	Fabiol	FDA	Fibricor	Both

Our analysis of the 53 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined that none of the names will not pose a risk for confusion as described in Appendix D and E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Dermatology and Dental Products via e-mail on March 23, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on March 26, 2012, stated they have no objections with the proposed proprietary name, Fabior.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Fabior, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 15, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

We consider this a final review; however, if the approval of the NDA is delayed beyond 90 days the proposed proprietary name will be re-reviewed. The conclusions upon re-review are subject to change.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

11. ***Access Medicine*** (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. ***Medical Abbreviations*** (www.medilexicon.com)

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

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

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

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

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

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

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-	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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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

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, Fabior	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘F’	T, L, Z, I, P, S, J	n/a
Lower case ‘a’	Any vowel, ci	Any vowel
Lower case ‘b’	l, d, f, h, k, t	p
Lower case ‘i’	Any vowel	Any vowel
Lower case ‘o’	Any vowel	Any vowel
Lower case ‘r’	s, n, e, v, z	n/a

Appendix C: Prescription Simulation Samples and Results

Figure 1. Fabior Study (Conducted on February 24, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> Fabior UAD	Fabior 0.1% Use as Directed Disp: 50 grams
<u>Outpatient Prescription:</u> Fabior 0.1% UAD #50g	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

84 People Received Study

32 People Responded

Study Name: Fabior

Total	8	9	15	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
FABINOR	0	0	1	1
FABIOR	8	4	8	20
FABIOR 0.1%	0	1	0	1
FABIOR 1%	0	1	0	1
FABIVOR	0	0	1	1
FABROR	0	0	3	3
FABUOR	0	1	0	1
FABYUR	0	1	0	1
FALICOR	0	0	1	1
FALIVOR	0	0	1	1
FAVIORE	0	1	0	1

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 Fabior or Source	Failure preventions
1	Benefiber	n/a (multiple products with different ingredients)	(b)(4)	The name pair have sufficient orthographic differences
2	Butrans	Buprenorphine	Look alike	The name pair have sufficient orthographic differences
3	Crestor	Rosuvastatin calcium	(b)(4)	The name pair have sufficient orthographic differences
4	Fabb	Folic acid, Cyanocobalamine, and Pyridoxine	Look alike	The name pair have sufficient orthographic differences
5	Fabiol	n/a	Look and	Found in Saegis. Name trademarked in

	Proprietary Name	Active Ingredient	Similarity to Fabior or Source	Failure preventions
			sound alike	Romania. Fabiol is a pharmaceutical company in Romania.
6	Fabior	Tazarotene	Look and sound alike	Proprietary name under review
7	Fabrazyme	Agalsidade beta	(b) (4)	The name pair have sufficient orthographic differences
8	Famvir	Famciclovir	Look alike	The name pair have sufficient orthographic differences
19	Fanapt	Iloperidone	(b) (4)	The name pair have sufficient orthographic differences
10	Fansidar	Pyrimethamine and Sulfadoxine	(b) (4)	The name pair have sufficient orthographic differences
11	Felbatol	Felbamate	(b) (4)	The name pair have sufficient orthographic differences
12	Fentora	Fentanyl citrate	Look alike	The name pair have sufficient orthographic differences
13	Fiberall	Psyllium	Look alike	The name pair have sufficient orthographic differences
14	Fiberlax	Polycarbophil	Look alike	The name pair have sufficient orthographic differences
15	Flector	Diclofenac epolamine	(b) (4)	The name pair have sufficient orthographic differences
16	Flexeril	Cyclobenzaprine HCl	(b) (4)	The name pair have sufficient orthographic differences
17	Forfivo XL	Bupropion HCl	Look alike	The name pair have sufficient orthographic differences
18	Fulvicin P/G	Griseofulvin	Look alike	The name pair have sufficient orthographic differences
19	Jolessa	Levonorgestrel and Ethinyl Estradiol	Look alike	The name pair have sufficient orthographic differences
20	Latisse	Bimatoprost	Look alike	The name pair have sufficient orthographic differences
21	Rebetol	Ribavirin	Look alike	The name pair have sufficient orthographic differences
22	Rebif	Interferon Beta-1A	Look alike	The name pair have sufficient orthographic differences
23	Relistor	Methylnaltrexone Bromide	(b) (4)	The name pair have sufficient orthographic differences
24	Robafen	Guaifenesin	Look alike	The name pair have sufficient orthographic differences
25	Robaxin	Methocarbamol	Look alike	The name pair have sufficient orthographic differences
26	Talacen	Acetaminophen and Pentazocine HCl	Look alike	The name pair have sufficient orthographic differences
27	Tambocor	Flecainide acetate	Look alike	The name pair have sufficient orthographic differences
28	Tebonin	Ginkgo bilboa	Look alike	The name pair have sufficient

	Proprietary Name	Active Ingredient	Similarity to Fabor or Source	Failure preventions
				orthographic differences
29	Tilia Fe	Norethindrone Acetate and Ethinyl Estradiol and Fumarate	Look alike	The name pair have sufficient orthographic differences
30	Tobi	Tobramycin	Look alike	The name pair have sufficient orthographic differences
31	Tribenzor	Amlodipine besylate, Hydrochlorothiazide, and Olmesartan medoxomil	Look alike	The name pair have sufficient orthographic differences
32	Zaditor	Ketotifen fumarate	(b) (4)	The name pair have sufficient orthographic differences

(b) (4)

34	Robinul	Glycopyrrolate	Look alike	The name pair have sufficient orthographic differences

(b) (4)

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.

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1 Calcor (Calcium carbonate, Magnesium, Potassium Bicarbonate, Boron, L-Lysine, Silicon, L-Threonine) Tablets 500 mg/140 mg/100 mg/ 2 mg/ 2 mg/ 2 mg/ 2 mg <u>Dose</u> One tablet daily	<u>Orthographics</u> Both names have 6 letters share the ‘a’ in the same position and the ending ‘or’. Both names contain an upstroke in the third position <u>Strength</u> Both products are single strength and thus no strength is required on a prescription <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> The capital letter ‘F’ in Fabior looks different than the capital letter ‘C’ in Calcor which may help differentiate the names. <u>Dose</u> Thin layer or 1 application vs. 1 tablet
2 Famvir (Famciclovir) Tablets 125 mg, 250 mg, 500 mg <u>Dose</u> 250 mg to 1500 mg as a single dose or 1000 mg twice daily for 1 day or 250 mg to 500 mg daily for 7 days or 500 mg every 8 hrs for 7 days	<u>Orthographics</u> Both names contain 6 letters, begin with the same letters ‘Fa’ and end in the letter ‘r’.	<u>Strength</u> Fabior is a single strength product vs. Feiba is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Dose</u> Thin layer or 1 application vs. xx mg or xx tablets

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3 Febrol (Acetaminophen) Oral solution 325 mg/5 mL <u>Dose</u> Adult: 325 to 650 mg (or 5 to 10 mL) every 4 to 6 hours. Children 2 years and older: weight base dosing every 4 to 6 hours.	<u>Orthographics</u> Both names contain 6 letters and share the same letters 'F', 'b' and 'o' in the same positions. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription.	<u>Dose</u> Thin layer or 1 application vs. xx mg or xx mL <u>Frequency of Administration</u> Once daily in the evening vs. every 4 to 6 hours pm
4 Feiba NF (Anti-inhibitor Coagulant Complex) Injection Kit 500 Units per vial 1000 Units per vial 2500 Units per vial <u>Dose</u> 50 to 100 Units per kg of body weight at 6 to 12 hours intervals until clear signs of clinical improvement appear	<u>Orthographics</u> Both names contain the letter 'F' in the same position. The letter 'a' in Fabior may look like the letter 'e' in Feiba. Both names contain the up stroke letter 'b' in a similar position.	<u>Strength</u> Fabior is a single strength product vs. Feiba is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Dose</u> Thin layer or 1 application vs. xx Units <u>Frequency of administration</u> Once daily in the evening vs. every 6 to 12 hours until clinical improvement appear
5 Fibricor (Fenofibric acid) Tablets 35 mg, 105 mg <u>Dose</u> 35 to 105 mg daily or 1 tablet daily	<u>Orthographics</u> Both names have the letters 'F' and 'b' in the same positions and the letters 'or' at the end of the name. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> Fabior contains 6 letters vs. 8 letters in Fibricor; thus, Fabior appears shorter when scripted. <u>Strength</u> Fabior is a single strength product vs. Fibricor is available in two strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Dose</u> Thin layer or 1 application vs. xx mg or xx mL

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6 Flolan (Epoprostenol sodium) for Injection Strength: 0.5 mg and 1.5 mg <u>Dose</u> Initiate at an infusion rate of 2 ng/kg/min. Increase dose if symptoms of PAH persist or recur by 1-2 ng/kg/min. increments at intervals of 24-48 hours or longer.	<u>Orthographics</u> Both names contain six letters, begin with the letter 'F' and have an upstroke in a similar position.	<u>Orthographics</u> Fabior has 2 upstrokes vs. Flolan has 3 upstrokes, which gives the names different shapes when scripted. <u>Strength</u> Fabior is a single strength product vs. Flolan is available in two strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Dose</u> Thin layer or 1 application vs. xx mg/min. <u>Frequency of administration</u> Once daily in the evening vs. continuous infusion through central venous catheter
7 Folacin (Folic Acid) Tablets 0.8 mg <u>Dose:</u> 0.8 mg or 1 tablet daily	<u>Orthographics</u> Both names share the letter 'F' in the same position. The letter 'o' in Folacin may look like the letter 'a' in Fabior. Both names have an upstroke in the same position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> The ending letter 'ior' look different than the ending letters 'acin' which may help differentiate the names when scripted. <u>Dose</u> Thin layer or 1 application vs. xx mg or 1 tablet

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
8 Folmor (Folic acid, B6, B12, and Primorine) Tablets 2.5 mg/25 mg/2 mg/875 mg <u>Dose</u> 1 tablet daily	<u>Orthographics</u> Both names contain 6 letters and share the letter ‘F’ in the same position. The first letter ‘o’ in Folmor may look like the letter ‘a’ in Fabior. Both names have an upstroke in the same position. Both names end in ‘or’. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> The letters following the upstroke in each name look different when scripted (‘i’ vs. ‘m’) which may help differentiate the names. <u>Dose</u> Thin layer or 1 application vs. xx mg or 1 tablet
9 Folvron (Ferrous sulfate and Folic acid) Capsules 182 mg/0.33 mg <u>Dose</u> 1 capsule daily	<u>Orthographics</u> Both names share the letter ‘F’ in the same position. The first letter ‘o’ in Folvron may look like the letter ‘a’ in Fabior. Both names have an upstroke in the same position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> The letters following the upstroke in each name look different when scripted (‘i’ vs. ‘vr’) which may help differentiate the names. <u>Dose</u> Thin layer or 1 application vs. xx mg or 1 tablet

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
10 Fortaz (Ceftazidime) Injection 500 mg, 1 g, 2 g, 6 g <u>Dose</u> Adults: 250 mg to 2 g intravenously or intramuscularly every 8 to 12 hours Lung infections dose: 30-50 mg/kg intravenously every 8 hours to a maximum of 6 grams per day Neonates (0-4 weeks): 30 mg/kg intravenously every 12 hours Infants and children (1 month – 12 years): 30-50 mg/kg intravenously every 8 hours to a maximum of 6 grams per day	<u>Orthographics</u> Both names contain six letters and begin with the letter 'F'. The letter 'a' in Fabior may look like the letter 'o' in Fortaz. Both names contain an upstroke in a similar position.	<u>Strength</u> Fabior is a single strength product vs. Fortaz is available in two strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Route of Administration</u> Topical vs. intravenous or intramuscular. Therefore a prescription for Fortaz must include the route of administration <u>Dose</u> Thin layer or 1 application vs. xx mg

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
11 Forteo (Teriparatide) Injection 20 mcg per dose <u>Dose</u> 20 mcg subcutaneously daily	<u>Orthographics</u> Both names contain 6 letters and share the letter 'F' in the same position. The first letter 'o' in Forteo may look like the letter 'a' in Fabior. Both names have an upstroke in a similar position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> Fabior has 1 letter separating the capital letter 'F' from the upstroke letter 'b' vs. Forteo has 2 letters separating the capital letter 'F' from the upstroke letter 't' which gives the names a different shape when scripted. In addition, the upstroke in Forteo is a cross stroke which may further differentiate the names when scripted. <u>Dose</u> Thin layer or 1 application vs. 20 mcg
12 Halcion (Triazolam) Tablets 0.125 mg and 0.25 mg <u>Dose</u> 0.125 to 0.5 mg at bedtime	<u>Orthographics</u> Both names share the same letters 'a' and 'o' in the same position. Both names have an upstroke in the same position. The ending letters 'ior' may look like 'ion'. <u>Frequency of Administration</u> Both products are dosed once daily	<u>Orthographics</u> The capital letter 'F' in Fabior may look different than the capital letter 'H' in Halcion. <u>Dose</u> Thin layer vs. xx mg or 1 tablet

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
13	Librax (Chlordiaepoxide HCl and clidinium bromide) Capsules 5 mg/2.5 mg <u>Dose</u> 1 – 2 capsules three to four times daily before meals and at bedtime	<u>Orthographics</u> Both names contain 6 letters and the letters ‘F’ and ‘L’ may look similar when scripted. Both names contain an upstroke letter ‘b’ in the same position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription.	<u>Dose</u> Thin layer or 1 application vs. xx capsules <u>Frequency of administration</u> Once daily in the evening vs. 3-4 times daily before meals and at bedtime
14	Sabril (Vigabratin) <u>Tablets</u> 500 mg <u>Powder for oral solution</u> 500 mg <u>Dose</u> Adult: 1 to 3 tablets twice daily Pediatric: 50 mg/kg/day to 150 mg/kg/day	<u>Orthographics</u> Both names contain 6 letters and the letters ‘F’ and ‘S’ may look similar when scripted. Both names share the letters ‘ab’ in the same position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription.	<u>Dosage Form</u> Foam vs. tablets and oral solution. Therefore, a prescription for Sabril must specify the dosage form. <u>Dose</u> Thin layer or 1 application vs. xx mg or xx tablets or xx mL

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
15 Talwin (Pentazocine Lactate) Injection 30 mg/mL <u>Dose</u> Adults, excluding patients in labor: Single parenteral dose is 30 mg every 3 to 4 hours. Maximum daily dose is 360 mg. Patients in labor: Single 30 mg intramuscular dose. An intravenous 20 mg dose when contractions become regular and may be given two or three times at two- to three-hour intervals, as needed. Pediatric patients excluding patients less than 1 year old: Single parenteral dose as premedication for sedation is 0.5 mg/kg by intramuscular route.	<u>Orthographics</u> Both names contain 6 letters and the letters 'F' and 'T' may look similar when scripted. Both names have the same letters 'a' and an upstroke in the same positions. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription.	<u>Route of administration</u> Topical vs. intramuscular, intravenous, or subcutaneous. Thus, a prescription for Talwin must include the route of administration. <u>Dose</u> Thin layer or 1 application vs. xx mg or xx mL <u>Frequency of administration</u> Once daily in the evening vs. single dose or in 2-3 hours intervals as needed <u>Setting of Use</u> Talwin is used in the inpatient setting only (i.e. operating room) for the relief of moderate to severe pain, for preoperative or preanesthetic medication and as a supplement to surgical anesthesia.

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16	Tobrex (Tobramycin) <u>Ophthalmic ointment</u> 0.3% <u>Ophthalmic solution</u> 0.3% <u>Dose</u> <i>Ointment:</i> Mild to moderate: Apply a half-inch ribbon into the affected eye(s) two to three times per day. Severe: Apply a half-inch ribbon into the affected eyes every 3 to 4 hours. <i>Solution:</i> Mild to moderate: 1-2 drops into the affected eye(s) every 4 hours. Severe: 2 drops into the affected eye(s) hourly	<u>Orthographics</u> Both names contain 6 letters and the letters 'F' and 'T' may look similar when scripted. The letter 'a' in Fabior may look like the letter 'o' in Tobrex. Both names have the same upstroke letter 'b' in the same position. <u>Strength</u> Both products are single strength and thus no strength is required on the prescription.	<u>Dosage form</u> Topical vs. ophthalmic ointment and ophthalmic solution. Therefore, a prescription for Tobrex must specify the dosage form. <u>Frequency of administration</u> Once daily in the evening vs. every 3-4 hours or hourly
17	Tricor (Febofibrate) Tablets 48 mg and 145 mg <u>Dose</u> 48 to 145 mg daily	<u>Orthographics</u> Both names contain 6 letters. The capital letter 'F' may look like the capital letter 'T' when scripted. Both names end in the letters 'or'. <u>Frequency of administration</u> Once daily	<u>Orthographics</u> Fabior contains an upstroke letter in the third position that is not present in Tricor and may help differentiate the names when scripted. <u>Dose</u> Thin layer or 1 application vs. xx mg or 1 tablet

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names

(b) (4)

Proposed name: Fabior Dosage Form(s): Foam Strength(s): 0.1% Usual Dose: Apply a small amount. Lightly cover the entire affected area with a thin layer once daily in the evening.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
19 Zofran (Ondansetron HCl) <u>Tablets</u> 4 mg, 8 mg <u>Orally disintegrating tablets</u> 4 mg, 8 mg <u>Oral Solution</u> 4 mg/5 mL <u>Injection</u> 40 mg in 20 mL (2 mg/mL) Dose for oral formulations: <i>Prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy:</i> 24 mg (three 8 mg tabs) 30 minutes before starting chemotherapy. <i>Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy:</i> One 8 mg tablet or 10 mL oral solution given twice daily. The first dose is given 30 minutes before starting chemotherapy, with a subsequent dose 8 hours after the first dose. One 8 mg tablets or 10 mL oral solution twice daily for 1 to 2 days after completion of chemotherapy. Pediatric patients 4 to 11 years old the dose is 4 mg three times daily. First dose is administered 30 minutes before chemotherapy starts. Subsequent doses 4 and 8 hours after the first dose. One 4 mg tablet or 10 mL oral solution should be administered 3 times a day for 1 to 2 days after completion of chemotherapy. <i>Postoperative nausea and vomiting</i> 16 mg given as two 8 mg tablets or 20 mL oral solution 1 hour before induction of anesthesia.	<u>Orthographics:</u> Both names contain 6 letters and the letters 'F' and 'Z' may look similar when scripted. The letter 'a' in Fabior may look like the letter 'o' in Zofran. Both names have an upstroke letter in the same position.	<u>Dosage Form</u> Foam vs. tablets, orally disintegrating tablest, oral solution and injection. Therefore, a prescription for Zofran must specify the dosage form. <u>Strength</u> Fabior is a single strength product vs. Zofran is available in multiple strengths, which would be required in a prescription. In addition, there is no overlap in strength or dose. <u>Route of administration</u> Topical vs. oral or injection. Therefore, a prescription for Zofran must include the route of administration <u>Dose</u> Thin layer or 1 application vs. XX mg or XX mL or XX tabs. <u>Frequency of administration</u> Once daily in the evening vs. 30 minutes before chemotherapy starts or twice daily or three times daily

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