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RESEARCH**

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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 January 25, 2013

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Drug Name & Strength Delzicol (Mesalamine) Delayed-release Capsules, 400 mg

Application Type/Number NDA 204412

Applicant Warner Chilcott

OSE RCM # 2012-2373

:

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

CONTENTS

1	INTRODUCTION.....	1
1.1	Regulatory History.....	1
1.2	Product Information.....	1
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	4
4	REFERENCES.....	5
	APPENDICES.....	8

1 INTRODUCTION

This review evaluates the proposed proprietary name, Delzicol, 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

Delzicol is a revised formulation of Asacol (Mesalamine) Delayed-release Tablets (NDA 019651). Asacol was first approved in January, 1992. Asacol contains the excipient, dibutyl phthalate (DBP) which is associated with reproductive system aberrations compatible with disruption of androgenic dependent development in rats. Additionally, DBP and its primary metabolite are excreted into human milk. As a result of these findings, the Asacol prescribing information was updated and the Agency requested that the Applicant revise the formulation to remove DBP.

The following are the proposed names which have been reviewed by DMEPA:

(b) (4) - found to be unacceptable because of its inclusion of (b) (4) in the name and also because of its inclusion of the letters (b) (4) which is a well known abbreviation for the marketed drug, (b) (4). Thus, (b) (4) may mislead the reader to believe the product is an (b) (4). These concerns were communicated to the Sponsor and the name was withdrawn on September 26, 2012.

(b) (4) – found to be unacceptable due to its orthographic similarity to the marketed name, (b) (4)

(b) (4) – found by the Office of Prescription Drug Products (OPDP) to be promotional because it is overly fanciful.

Thus, the alternative proposed proprietary name, Delzicol is being reviewed.

1.2 PRODUCT INFORMATION

The following product information is provided in the January 18, 2013 proprietary name submission.

- Active Ingredient: Mesalamine
- Indication of Use: Treatment of mildly to moderately active ulcerative colitis and maintenance of remission of ulcerative colitis
- Route of Administration: Oral
- Dosage Form: Delayed-release Capsules
- Strength: 400 mg
- Dose and Frequency: 800 mg by mouth three times daily or 1600 mg by mouth daily in divided doses
- How Supplied: Bottles of 180 capsules
- Storage: Room temperature

- Container and Closure System: Child-resistant cap

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The January 10, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Delzicol, is partly derived from the Asacol proprietary name since the products have comparable pharmacokinetic profiles and are bioequivalent and partly derived from the dibutyl phthalate free capsule formulation. .

2.2.4 FDA Name Simulation Studies

Sixty-six practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. The most frequently misinterpreted aspects of the name were mistaking the first letter 'D' for 'R', the letter 'e' for 'i', the letter 'z' for 'n', 'r', or 's', and the letter 'i' for 'a'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, January 11, 2013 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Delzicol. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Delzicol identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

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

Look Similar to Delzicol					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Dibenil	FDA	Delsym	FDA	Desferal	FDA
Desyrel	FDA	Durezol	FDA	Palgic	FDA
Didronel	FDA	Dificid	FDA	Divigel	FDA
Probucol	FDA	Balneol	FDA	Balziva	FDA
Dilaudid	FDA	(b) (4)	FDA	Diflunisal	
Delazinc	FDA	Diltzac	FDA	Relenza	FDA
Relafen	FDA	Delacort	FDA	Delcort	FDA
Deladiol	FDA	Relagard	FDA	Visicol	FDA
Felbetol	FDA	Dilacor XR	FDA	Balziva	FDA
Sound Similar to Delzicol					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Dilacor	FDA	(b) (4)	FDA		
Look and Sound Similar to Delzicol					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Detrol	FDA	Drisdol	FDA	Danazol	FDA
Delzicol	FDA				

Our analysis of the thirty three names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined thirty-three names will not pose a risk for confusion as described in Appendices D and E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Error Products (DGIEP) via e-mail on January 15, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Error Products

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(DGIEP) on January 23, 2013, they stated no additional concerns with the proposed proprietary name, Delzicol.

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 Phong (Pete) Do, OSE Project Manager, at 301-796-4795.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Delzicol, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your January 18, 2013 submission are altered, the name must be resubmitted for review.

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.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

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.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.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).

² 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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> 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/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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

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

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in the Name	Scripted May Appear as	Spoken May Be Interpreted as
Delzicol		
Capital 'D'	O, T, B, P, R	B, T
Lower case 'd'	Cl, ci	B, t
Lower case 'e'	a, i, l, o, u, p	a
Lower case 'l'	b, e, s, A, P, i	
Lower case 'z'	c, e, g, n, m, q, r, s, v	c, s, x
Lower case 'i'	L, a	
Lower case 'c'	a, e, I, l	k
Lower case 'o'	a, c, e, u	oh
Letter strings in the Name 'Delzicol'	Scripted May Appear as	Spoken May Be Interpreted as
col	cal	call, cawl, caul

Appendix C: Prescription Simulation Samples and Results

Figure 1. Delzicol Study (Conducted on January 10, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Delzicol 800mg po three times daily</i></p>	<p>“Delzicol – Take 1 capsule orally three times daily; dispense quantity #180”</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Delzicol</i></p> <p><i>One capsule orally three times daily #180</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

190 People Received Study

66 People Responded

Study Name: Delzicol

INPATIENT	STRENGTH	VOICE	STRENGTH	OUTPATIENT	STRENGTH
DELINCOL	800 mg	DELSACHOL		DELRICOL	1
DELINOCOL	800 mg	DELSECOL		DELRICOL	none
DELNICOL	800 mg	DELSICOL		DELRICOL	
DELNICOL	800 mg	DELSICOL		DELRICOL	
DELNICOL	800mg	DELTACOL	1 capsule	DELRICOL	
DELZICOL	800 mg	DELZACALL		DELSICOL	
DELZICOL	800mg	DELZACHOL		DELSICOL	none given
DELZICOL	800 mg	DELZACOL		DELSICOL	
DELZICOL	800mg	DELZACOL	none	DELSICOL?	
DELZICOL	800mg	DELZACOL		DELVICOL	one cap
DELZICOL	800 mg	DELZACOL	None given	DILRICOL	
DELZICOL	800mg	DELZACOL		DILRICOL	
DELZICOL	800 mg	DELZCAL	none given	DILRICOL	?
DELZICOL	800 mg	DELZICOL	1 capsule	DILRICOL	
DELZICOL	800 mg	DELZICOL		DILRICOL	
DELZICOL	800mg	DELZICOL	none	DILRICOL	?
DELZICOL	800 mg	DELZICOL	None	DILRICOL	
RELZICOL	800 mg	DELZICOL		DILRICOL	
RELZICOL	800mg	DELZICOL		DILRICOL	
		DELZICOL		DILRICOL	
		DELZICOL		DILRIROL	
		DELZICOL		DILSICOL	one po
		DELZYCOL		DILVICOL	
		DESACOL			

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Delzicol	Failure preventions
1.	(b) (4)	(b) (4)	Sound Alike	(b) (4)
2.	Dilacor	Digoxin	Sound Alike	Dilacor is the proprietary name for Digoxin in Great Britain (source: Lexicomp)
3.	Balneol	Topical cleanser	Look Alike	Balneol is not a drug and therefore is not anticipated to be confused with the proposed name, Delzicol.
4.	Probucol	Probucol is the active ingredient for the proprietary name, Lorelco (250 mg and 500 mg strengths)	Look Alike	Probucol was voluntarily removed from the U.S. market in 1995 due primarily to safety concerns (Source: Micromedex); NDA 017535 was withdrawn by the FDA Commissioner June 4, 2004. There are no therapeutic equivalents/generic products in the marketplace
5.	(b) (4)	(b) (4)	Look Alike	(b) (4) was an alternative proprietary name to (b) (4) *** which was found to be unacceptable due to its similarity to (b) (4) An alternative name, (b) (4), was submitted for our review and also found to be unacceptable due to its similarity to the marketed name, (b) (4) Therefore, the name, (b) (4) is no longer an active name for consideration and

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

				is not anticipated to be confused with Delzicol..
6.	(b) (4)	Unknown	Sound Alike	(b) (4)
7.	Delzicol	Mesalamine	Look Alike and Sound Alike	Delzicol is the trademark of Warner Chilcott, the Applicant for this name review. (Source: USPTO)

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.

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Danazol Capsule 50 mg, 100 mg, 200 mg <u>Usual dose:</u> 100 mg to 400 mg in 2 divided doses	Orthographic similarity stems from sharing the same first and last 2 letters in their names ('D' and 'ol') and both names share the letter 'z' in similar positions.	The proposed name, Delzicol, includes an up stroke ('l') near the middle of its name which gives it a different shape from that of the marketed name, Danazol. Additionally, the letter string 'lzi' (in Delzicol) in the third through fifth positions is orthographically different from 'naz' (in Danazol) when written because of the up stroke 'l' (Delzicol) and because the letter 'n' (Danazol) is a wider letter. This difference would be more pronounced if the 'z' were written as a down stroke. Danazol is available in multiple strengths and this information is needed prior to dispensing/administering the medication as needed.
2.	Delsym (Dextromethorphan) Extended-release Oral Liquid (Over the counter) 30 mg/5 mL <u>Usual dose:</u> 60 mg (2 teaspoonsful) every 12 hours	Orthographic similarity stems from sharing the first three letters ('Del') in their names.	The marketed name, Delsym, includes a down stroke ('y') in the fifth position and the proposed name, Delzicol, includes an up stroke ('l') in the last position which gives these names different shapes from one another. One differing product characteristic is the dose (60 mg or 2 teaspoonsful vs. 2 capsules or 800 mg).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Desferal (Deferoxamine) Injection 2 grams, 500 mg <i>Usual dose:</i> 1 gram, then 500 mg intramuscularly every 4 hours for 2 doses	Orthographic similarity stems from sharing the same first 2 letters ('De') and last letter ('l'). Additionally, both names have an up stroke appearing in similar locations within their names ('f' vs. 'l') giving them similar shapes.	Differing product characteristics include the dose (1 gram, then 500 mg vs. 2 capsules or 800 mg) and the frequency of administration (every 4 hours for 2 doses vs. three times daily).
4.	Desyrel (Trazodone) Tablet 50 mg, 100 mg, 150 mg, 200 mg <i>Usual dose:</i> 400 mg to 600 mg in divided doses	Orthographic similarity stems from sharing the same first 2 letters ('De') and last letter ('l').	Delzicol includes an up stroke ('l') in the third position within its name giving them different shapes when scripted. Desyrel is available in multiple strengths and this information is needed prior to dispensing/administering the medication as needed. The strengths do not overlap

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
5.	Detrol (Tolterodine) Tablet 1 mg, 2 mg Detrol LA (Tolterodine) Extended Release Capsule 2 mg, 4 mg <u>Usual dose:</u> 2 mg twice daily or 4 mg once daily	Orthographic similarity stems from sharing the same first 2 letters ('De') and last letter ('l').	The marketed name, Detrol, includes a cross stroke ('t') in the third position and the proposed name, Delzicol appears longer in length when written (8 letters vs. 6 letters). One differing product characteristic is the strength (1 mg, 2 mg, 4 mg vs. 400 mg).
6.	Dibenil (Diphenhydramine Hydrochloride) Oral Elixir 12.5 mg/5 mL (Dibenil is no longer marketed but generic products exist) <u>Usual dose:</u> 25 mg to 50 mg every 4 hours to 6 hours	Orthographic similarity stems from sharing the same first ('D') and last ('l') letters and having an up stroke in the middle of their names ('b' vs. 'l'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	Differing product characteristics include the dose (25 mg to 50 mg or 10 mL to 20 mL vs. 2 capsules or 800 mg) and the frequency of administration (every 4 to 6 hours vs. three times daily).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
7.	Didronel (Etidronate) Tablet 200 mg, 400 mg <u>Usual dose:</u> 5 to 10 mg/kg/day, or 11 to 20 mg/kg/day from 2 weeks to 6 months' duration (depending upon diagnosis)	Orthographic similarity stems from sharing the same first and last letters ('D' and 'l'), having an up stroke in the third position ('d' vs. 'l') within their names, and the fact that both names are the same length (8 letters). Overlapping product characteristics include the strength (400 mg) and potentially the dose (e.g., 800 mg of Didronel for an 80 kg patient).	The letters in the fourth through sixth positions in the marketed name, Didronel and the proposed name, Delzicol, look different when scripted ('ron' vs. 'zic').

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Dificid (Fidaxomicin) Tablet 200 mg <u>Usual dose:</u> 200 mg twice daily for 10 days	Orthographic similarity stems from sharing the same first letter ('D') and having two up strokes in the same positions within their names ('f' and 'd' vs. two 'l's). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The letters in the fourth through sixth positions in the marketed name, Dificid ('ici') and the proposed name, Delzicol ('zic') are orthographically different when written. One differing product characteristic is the dose (1 tablet or 200 mg vs. 2 capsules or 800 mg)
9.	Divigel (Estradiol) Gel 0.1% <u>Usual dose:</u> Apply daily to the right or left upper thigh on alternating days	Orthographic similarity stems from sharing the same first and last letters ('D' and 'l'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The proposed name, Delzicol, includes a second up stroke ('l') in the third position. Additionally, the marketed name, Divigel includes a down stroke ('g') in the fifth position. These differences give this name pair different shapes. Differing product characteristics include the dose (apply to the thigh . . . vs. 2 capsules or 800 mg)

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Drisdol (Ergocalciferol) Capsule 50,000 units <u>Usual dose:</u> 50,000 to 200,000 units daily	Orthographic similarity stems from sharing the first and last letters of their names ('D' and 'I'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The marketed name, Drisdol has an up stroke ('d') in the fifth position whereas the ups troke in Delzicol appears in the third position within the name giving these names different shapes. Differing product characteristics include the dose (1 capsule or 50,000 units vs. 2 capsules or 800 mg) and the frequency of administration (once daily vs. three times daily).
11.	Durezol (Difluprednate) Ophthalmic Emulsion 0.05% <u>Usual dose:</u> One drop into the conjunctival sac of the affected eye(s) 4 times daily for 14 days followed by tapering as clinically indicated	Orthographic similarity stems from sharing the first and last letters of their names ('D' and 'I'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The proposed name, Delzicol, includes an up stroke ('l') in the third position which gives it a different shape from the marketed name, Durezol. One differing product characteristic is the dose (one drop vs. two capsules or 800 mg).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
12.	Delazinc (Zinc Oxide) Topical Ointment 25% <u>Usual dose:</u> Apply a thin layer to superficial non-infected, wounds and burns	Orthographic similarity stems from sharing the same first 3 letters ('Del'). Both products are single strength and therefore this information is not needed to dispense/administer as intended. One potentially overlapping product characteristic is the frequency of administration (three times daily).	The ending letter strings 'col' (Delzicol) vs. 'inc' (Delazinc) look different when scripted due to the presence of the ending upstroke ('l') in Delzicol. One differing product characteristic is the dose (apply a thin layer vs. 2 capsules or 800 mg).
13.	Diltzac (Diltiazem) Extended Release Capsule 120 mg, 180 mg, 240 mg, 300 mg, 360 mg <u>Usual dose:</u> 120 mg to 480 mg once daily	Orthographic similarity stems from sharing the same letters in the first and third positions ('D' and 'l').	The proposed name, Delzicol, and the marketed name, Diltzac have different shapes when written because of the presence of a cross stroke ('t') immediately following the first up stroke ('l') in Diltzac and the fact that Delzicol has a terminal up stroke ('l'). Diltzac is available in multiple strengths and this information is needed prior to dispensing/administering the medication as needed. The strengths do not overlap.

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
14.	Relenza (Zanamivir) Diskhaler 5 mg/blister <u>Usual dose:</u> 10 mg inhaled once daily for 10 to 28 days	Orthographic similarity stems from the similar appearance of their first letters ('R' vs. 'D') and the fact that both names share the same letters in their second and third positions ('el'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The proposed name, Delzicol, includes an up stroke ('l') at the end of its name giving it a different shape from the marketed name, Relenza. Additionally, if the letter 'z' is scripted as a down stroke, this letter appears in the fourth position in Delzicol and in the sixth position in Relenza further differentiating this name pair. Differing product characteristics include the dose (2 blisters or 10 mg vs. 2 capsules or 800 mg) and the frequency of administration (once daily vs. three times daily).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Relafen (Nabumetone) Tablet 500 mg, 750 mg <u>Usual dose:</u> 1,500 mg to 2000 mg as a single dose or twice daily.	Orthographic similarity stems from the similar appearance of their first letters ('R' vs. 'D') and the fact that both names share the same letters in their second and third positions ('el'). One potentially overlapping product characteristic is the dose (2 [tablets/capsules]).	The proposed name, Delzicol, includes an up stroke ('l') at the end of its name while the second up stroke ('f') in the marketed name, Relafen appears in the fifth position giving these names different shapes. Relafen is available in multiple strengths and this information is needed prior to dispensing/administering the medication as needed. The strengths do not overlap.

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Delacort (Hydrocortisone) Topical 1% (product is no longer marketed, but generic products exist) <i>Usual dose:</i> Apply to affected area(s) 3 to 4 times daily	Orthographic similarity stems from sharing the same first 3 letters ('Del'). Both products are single strength and therefore this information is not needed to dispense/administer as intended. One potentially overlapping product characteristic is the frequency of administration (three times daily).	The letter string 'aco' (in Delacort) is orthographically different from the letter string in the same position for Delzicol ('zic'). This difference would be more pronounced if the letter 'z' were scripted as a down stroke. One differing product characteristic is the dose (apply to affected area(s) vs. 2 capsules or 800 mg).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
17.	Delcort (Hydrocortisone) Cream 1% (product is no longer marketed, but generic products exist) <i>Usual dose:</i> Apply to affected area(s) 3 to 4 times daily	Orthographic similarity stems from sharing the same first 3 letters ('Del'). Both products are single strength and therefore this information is not needed to dispense/administer as intended. One potentially overlapping product characteristic is the frequency of administration (three times daily).	The letter string 'cor' (in Delcort) is orthographically different from the letter string in the same position for Delzicol ('zic'). This difference would be more pronounced if the letter 'z' were scripted as a down One differing product characteristic is the dose (apply to affected area(s) vs. 2 capsules or 800 mg).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
18.	Deladiol (Estradiol valerate) Injection 40 mg/mL (Deladiol is no longer marketed, but generic products exist) <i>Usual dose:</i> 10 mg to 30 mg intramuscularly every 1 week to 4 weeks (depending upon the diagnosis)	Orthographic similarity stems from sharing the same first 3 letters ('Del') and the last two letters ('ol'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The marketed name, Deladiol, has an added up stroke ('d') in the fifth position within its name giving it a different shape from the proposed name, Delzicol. Differing product characteristics include the dose (10 mg to 30 mg vs. 2 capsules or 800 mg) and the frequency of administration (every 1 to 4 weeks vs. three times daily).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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.	Relagard (Acetic Acid Glacial and Oxyquinoline Sulfate) Vaginal Gel 0.9%/0.025% (50 grams) Usual dose: Over the counter product to control vaginal acidity; to be used as directed by physician	Orthographic similarity stems from the similar appearance of their first letters ('R' vs. 'D') and the fact that both names share the same letters in their second and third positions ('el'). Additionally, both names end with an up stroke ('d' vs. 'l'). Both products are single strength and therefore this information is not needed to dispense/administer as intended	The letter string, 'agar' (Relagard) is orthographically different from the letters string, 'zico' (Delzicol) because of the down stroke ('g') in the fifth position of the marketed name, Relagard. Additionally, should the letter 'z' be scripted as a down stroke, it would appear in the fourth position.

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
20.	Visicol (Sodium Phosphate) Tablet Dibasic (0.398 grams), Monobasic (1.102 grams) <u>Usual dose:</u> The evening before the procedure, take 3 tablets with 240 mL of clear liquids every 15 minutes for a total of 20 tablets. On the day of the procedure, starting 3 to 5 hours before the procedure, take 3 tablets with 240 mL of clear liquids every 15 minutes for a total of 20 tablets	Orthographic similarity stems from sharing the last four letters ('icol') in their names. Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The letter string which appears prior to the shared letters 'icol' ('Vis' in Visicol and 'Delz' in Delzicol) do not look similar when written because of the presence of the up stroke ('l') in the proposed name, Delzicol. Differing product characteristics include the dose (3 tablets with 240 mL of clear liquids . . for a total of 20 tablets vs. 2 capsules or 800 mg) and the frequency of administration (every 15 minutes vs. three times daily).

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
21.	Felbetol (Felbamate) Tablet 400 mg, 600 mg <u>Usual dose:</u> 1200 mg per day in divided doses 3 or 4 times daily	Orthographic similarity stems from sharing the second and third letters ('e' and 'l') and the last two letters ('ol'). Overlapping product characteristics include the dose (2 tablets/capsules), the strength (400 mg) and the frequency of administration (three times daily).	The letter string 'bet' (in the marketed name, Felbetol) and 'zic' (in the proposed name, Delzicol) do not look similar when scripted because of the two up strokes in Felbetol ('b' and 't').
22.	Dilacor XR (diltiazem) Extended-release Capsule 180 mg, 240 mg <u>Usual dose:</u> 180 mg to 240 mg once daily	Orthographic similarity stems from sharing the first and third letters within their names ('D' and 'l') and the fact that the second letters are orthographically similar ('i' vs. 'e').	Differing product characteristics include the dose (1 capsule or 180 mg/240 mg vs. 2 capsules or 800 mg) and the frequency of administration (once daily vs. three times daily). Dilacor XR is available in multiple strengths and this information is needed prior to dispensing/administering the medication as needed. The strengths do not overlap and are not achievable.

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
23.	Balziva (Ethinyl Estradiol and Norethindrone) Tablet 35 mcg/0.5 mg <u>Usual dose:</u> One tablet orally daily	Orthographic similarity stems from sharing the third, fourth, and fifth letters ('lzi') and the fact that their first letter looks similar when written ('B' vs. 'D'). Both products are single strength and therefore this information is not needed to dispense/administer as intended.	The letter string 'va' (in the marketed name, Balziva) looks different from the letter string 'col' (in the proposed name Delzicol) when scripted because of the up stroke ('l'), which appears at the end of Delzicol. Differing product characteristics include the dose (1 tablet vs. 2 capsules or 800 mg)

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
24.	Palgic (Carbinoxamine Maleate) Tablet 4 mg <u>Usual dose:</u> 4 mg to 8 mg orally 3 to 4 times daily	<p>Orthographic similarity stems from sharing letters in the third, fifth, and sixth positions ('l', 'i', 'c') and the fact that the letters in the first and second positions look similar when scripted ('P' vs. 'D' and 'a' vs. 'e'). Additionally, the fourth letters may be orthographically similar if the letter 'z' is scripted as a down stroke ('g' vs. 'z').</p> <p>Both products are single strength and therefore this information is not needed to dispense/administer as intended.</p> <p>Potentially overlapping product characteristics include the dose (2 [tablets/capsules) and the frequency of administration (three times daily).</p>	<p>The last two letters in the proposed name, Delzicol ('ol') give this name a different shape from that of the marketed name, Palgic because of the terminal up stroke ('l') in Delzicol. Additionally, Delzicol appears longer in length than Palgic when written (8 letters vs. 6 letters).</p>

No.	Proposed name: Delzicol (Mesalamine) Dosage Form(s): Delayed Release Capsules Strength(s): 400 mg Usual Dose: 800 mg (2 capsules) three times daily or 1.6 grams (4 capsules) daily in divided doses	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
25.	<p>Dilaudid (Hydromorphone)</p> <p>Tablet: 2 mg, 4 mg, 8 mg</p> <p>Injection: 1 mg/mL, 2 mg/mL, 4 mg/mL</p> <p><u>Usual dose:</u></p> <p>2 mg to 4 mg orally every 4 to 6 hours as needed; OR 0.2 mg to 1 mg intravenously every 2 to 3 hours</p>	<p>Orthographic similarity stems from sharing the same first and third letters ('D' and 'l') and the fact that both names have an upstroke at the end of their names ('d' vs. 'l').</p>	<p>The letter string 'aud' (in the marketed name, Dilaudid) is orthographically different from the letter string 'zic' (in the proposed name Delzicol) when written because of the presence of the up stroke 'd'.</p> <p>The marketed name, Dilaudid is available in more than one strength and more than one dosage form, and therefore both of them are needed in order to dispense/administer the medication as intended.</p> <p>Differing product characteristics (for comparison with the oral form of Dilaudid) include the dose (2 mg, 4 mg, or 8 mg vs. 2 capsules or 800 mg) and the frequency of administration (every 4 to 6 hours vs. three times daily).</p>
26.	<p>Diflunisal (Oral) Tablet</p> <p>500 mg</p> <p><u>Usual dose:</u></p> <p>250 mg to 1000 mg daily in 2 divided doses</p>	<p>Orthographic similarity stems from sharing the same first and last letters ('D' and 'l').</p> <p>Both products are single strength and therefore this information is not needed to dispense/administer as intended.</p>	<p>The marketed name, Diflunisal, includes two consecutive up strokes ('fl') in the third and fourth positions. Additionally, Diflunisal appears longer in length than Delzicol when written (8 letters vs. 10 letters).</p> <p>One differing product characteristic is the dose (250 mg to 1000 mg vs. 2 capsules or 800 mg).</p>

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