

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**021876Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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

**Proprietary Name Review--Final**

Date: April 4, 2013

Reviewer: Manizheh Siahpoushan, PharmD  
Division of Medication Error Prevention and Analysis

Acting Team Leader: James Schlick, RPh, MBA  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Diclegis  
(Doxylamine Succinate and Pyridoxine Hydrochloride) Delayed-release  
Tablets, 10 mg/10 mg

Application Type/Number: NDA 021876

Applicant/Sponsor: Duchesnay Inc.

OSE RCM #: 2013-837

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

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## 1 INTRODUCTION

This re-assessment of the proposed proprietary name, Diclegis, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Diclegis, acceptable in OSE Review 2012-1809 dated September 20, 2012.

## 2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2012-1809. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded three new names (b) (4) Duavee\*\*\*, and Galzin), thought to look similar to Diclegis and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Diclegis and lead to medication errors. This analysis determined that the name similarity between Diclegis and the identified names was unlikely to result in medication error for the reasons presented in Appendices A and B.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 4, 2013. The Office of Prescription Drug Promotion OPDP had no concerns regarding the proposed name from a promotional perspective.

## 3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Diclegis, did not identify any vulnerabilities that would result in medication errors with any additional names. Thus, DMEPA has no objection to the proprietary name, Diclegis, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Office of Reproductive and Urologic Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Marcus Cato, OSE project manager, at 301-796-3903.

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## 4 REFERENCES

1. OSE Review # 2012-1809 Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride) Proprietary Name Review, Siahpoushan, M. September 20, 2012.
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)  
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)  
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**  
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

<b>Proprietary Name</b>	<b>Active Ingredient</b>	<b>Similarity to Diclegis</b>	<b>Failure Preventions</b>
Duavee ***	Bazedoxifene Acetate and Conjugated Estrogens	Look	The name pair has sufficient orthographic differences.

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**Appendix B:** 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.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b></p> <p><b>Dosage Form:</b>  <b>Delayed-release Tablets</b></p> <p><b>Strength: 10 mg/10 mg</b></p> <p><b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.			<p style="text-align: right;">(b) (4)</p>

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No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b></p> <p><b>Dosage Form:</b>  <b>Delayed-release Tablets</b></p> <p><b>Strength: 10 mg/10 mg</b></p> <p><b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
2.	<p>Galzin  (Zinc Acetate) Capsules  25 mg, 50 mg</p> <p>Usual Dose:  25 mg to 50 mg orally three times daily.</p>	<p><b>Orthographic:</b>  Both names share similar shapes, similar scripted beginning letters ('D' vs. 'G'), upstroke 'l' in similar positions of each name (fourth vs. third position) preceded by similar scripted letters ('c' vs. 'a'), and similar scripted ending letter strings ('-gis' vs. '-zin' when the letter 'z' is scripted as a downstroke).</p> <p><b>Route of Administration:</b>  Oral</p> <p><b>Dosage Form:</b>  Solid oral dosage form</p> <p><b>Possible Overlap in the Frequency of Administration:</b>  Three times daily</p> <p><b>Possible Partial Overlap in the Usual Dose:</b>  One (tablet vs. capsule)</p>	<p><b>Orthographic:</b>  The extra letter 'e' following the upstroke 'l' in Diclegis provides a longer appearance for this name and can help differentiate Diclegis and Galzin when scripted.</p> <p><b>Strength:</b>  Single strength (10 mg/10 mg) vs. multiple strengths (25 mg and 50 mg) with no overlap between strengths.</p>

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/s/  
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MANIZHEH SIAHPOUSHAN  
04/04/2013

JAMES H SCHLICK  
04/04/2013

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

**Proprietary Name Review**

Date: September 20, 2012

Reviewer(s): Manizheh Siahpoushan, PharmD  
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Diclegis  
(Doxylamine Succinate and Pyridoxine Hydrochloride)  
Delayed-release Tablets, 10 mg/10 mg

Application Type/Number: NDA 021876

Applicant/Sponsor: Duchesnay Inc.

OSE RCM #: 2012-1809

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\*\*This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.\*\*

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Diclegis, 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 BACKGROUND AND REGULATORY HISTORY

This 505 (b)(2) Application was resubmitted to the FDA by Duchesnay Inc., on June 8, 2012 [REDACTED] (b) (4) The Reference Listed Drug (RLD) is Bendectin. The US manufacturer of Bendectin ceased manufacturing Bendectin in 1983 and it has remained absent from the US market since that time. On August 9, 1999, FDA issued a notice of a determination under 21 CFR 314.161 that Bendectin (Doxylamine Succinate, Pyridoxine Hydrochloride) was not withdrawn from sale for safety or effectiveness reasons. Duchesnay Inc. has marketed a version of this drug product, called Diclectin, in Canada since 1975.

The proposed proprietary name, Diclegis (Doxylamine succinate, Pyridoxine Hydrochloride) Delayed-release Tablets for NDA 021876 was submitted to the FDA on August 3, 2012. The name, Diclegis, is the fifth proposed proprietary name for this product.



Additionally, the Applicant submitted insert labeling on June 8, 2012 and container labels on August 13, 2012 which will be reviewed under a separate cover in OSE Review #2012-1368.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the August 3, 2012 proprietary name submission.

- Active Ingredient: Doxylamine Succinate and Pyridoxine Hydrochloride

- Indication of Use: Pregnancy related nausea and vomiting
- Route of Administration: Oral
- Dosage Form: Delayed-release Tablets
- Strength: 10 mg/10 mg
- Dose and Frequency: The usual dosage for this product is 2 to 4 tablets. The frequency of administration is once to three times daily until symptoms of nausea and vomiting resolve, typically by week 16; thus the dosing interval is every day for at least 16 weeks. The maximum daily dose is 40 mg/40 mg.
- How Supplied: Bottle of 100 tablets
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)
- Container and Closure Systems: The packaging components in direct contact with the product help ensure its stability. The container closure system includes a 75-mL opaque bottle, a 38-mm child-resistant cap, and a silica gel desiccant canister. The cap component contains an induction inner seal consisting of a
 

(b) (4)
  
(b) (4)
- Pronunciation: dye-CLEE-gis

## 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 Reproductive and Urology Products 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 July 21, 2012 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, Diclegis, was not derived from any one particular concept. 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

Twenty-nine practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Thirteen out of twenty-nine practitioners interpreted the name correctly as Diclegis (six inpatient, six voice, and one outpatient). Three participants from the inpatient and six from the outpatient prescription studies misinterpreted the letter ‘g’ as the letter ‘y’ and one participant from the inpatient prescription study misinterpreted the letter ‘g’ as the letter ‘z’. One participant from the inpatient prescription study misinterpreted the name as “Dickeyis”. Most of the other misinterpretations occurred with the voice prescription studies. 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, August 19, 2012 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not forward any comments or 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, Diclegis. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Diclegis identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD). Table 1 also includes the names identified by (b) (4) not identified by DMEPA, and require further evaluation.

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and (b) (4))**

Look Similar					
Name	Source	Name	Source	Name	Source
Diazepam	(b) (4)	Dicloxacillin	(b) (4)	Pegasys	(b) (4)
Diectin	EPD	Diltzac	EPD	Dacogen	EPD
Diclazuril	EPD	Didronel	EPD	Divigel	EPD
Diuril	EPD	Ditropan XL	EPD	Diclofenac	EPD
Duexis	EPD	Decadron	EPD	Delazinc	EPD
Delsym	EPD	DentaGel	EPD	Octagam	EPD

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and (b) (4), Continued**

<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Baclofen	EPD	Dutoprol	EPD	Adagen	PR
Salagen	PR	Solage	PR	Dologesic	PR
Palgic	PR	Dolgic	PR	Aubagio	PR
<b>Look and Sound Similar</b>					
Cyclogyl	(b) (4)	Cycloset	(b) (4)	Taclonex	(b) (4)
Diclegis	EPD				

Our analysis of the 31 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 31 names will not pose a risk for confusion as described in Appendix D through E.

**2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines**

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on September 17, 2012. At that time we also requested additional information or concerns that could inform our review. The Division of Reproductive and Urologic Products did not state any additional concerns with the proposed proprietary name, Diclegis.

**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 Marcus Cato, OSE project manager, at 301-796-3903.

**3.1 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Diclegis, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your August 3, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

## 4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

**10. *Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://www.naturaldatabase.com))***

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

**11. *Access Medicine ([www.accessmedicine.com](http://www.accessmedicine.com))***

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

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

USAN Stems List contains all the recognized USAN stems.

**13. *Red Book ([www.thomsonhc.com/home/dispatch](http://www.thomsonhc.com/home/dispatch))***

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

**14. *Lexi-Comp ([www.lexi.com](http://www.lexi.com))***

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

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

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

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

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

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

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

**18. Rx List ([www.rxlist.com](http://www.rxlist.com))**

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

**19. Dogpile ([www.dogpile.com](http://www.dogpile.com))**

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

**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.<sup>1</sup>

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

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

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

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>2</sup>

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

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

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

<b>Type of Similarity</b>	<b>Considerations when Searching the Databases</b>		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

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

safety of the proposed proprietary name or product based on professional experience with medication errors.

### **1. Database and Information Sources**

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

### **2. Expert Panel Discussion**

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

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

### **3. FDA Prescription Simulation Studies**

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

#### **4. Comments from Other Review Disciplines**

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

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

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

#### **5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Appendix B:** Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Diclegis	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘D’	‘B’, ‘O’, ‘T’	‘B’, ‘T’
Lower case ‘d’	‘a’, ‘cl’, ‘ci’, ‘ol’	‘b’, ‘t’
Lower case ‘i’	‘e’, ‘l’	‘y’, ‘ee’
‘ic’	‘a’, ‘o’, (if the letters ‘a’ and ‘o’ are not fully closed), ‘u’	
Lower case ‘c’	‘a’, ‘e’, ‘i’, ‘l’	‘z’, ‘k’, ‘s’
Lower case ‘cl’	‘a’, ‘d’	
Lower case ‘l’	‘b’, ‘e’, ‘s’, ‘A’, ‘P’, ‘i’	
Lower case ‘e’	‘l’, ‘a’, ‘o’, ‘u’, ‘p’, ‘i’	Any vowel
Lower case ‘g’	‘q’, ‘j’, ‘s’, ‘z’, ‘y’	‘k’, ‘j’
Lower case ‘s’	‘G’, ‘5’, ‘n’, ‘g’	‘x’

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

**Figure 1. Diclegis Study (Conducted on 7/20/12)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u>  <i>Diclegis 2 tabs po at bedtime</i></p>	<p>Diclegis                      Tid as directed                      #90</p>
<p><u>Outpatient Prescription:</u>  <i>Diclegis</i>  <i>Tid as directed</i>  <i>#90</i></p>	

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

86 People Received Study  
 29 People Responded

**Study Name: Diclegis**

Total	10	11	8	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
DICKEYIS	0	0	1	1
DICLEGIS	6	6	1	13
DICLEGIT	0	1	0	1
DICLEYIS	3	0	6	9
DICLEZIS	1	0	0	1
DICLIDIX	0	1	0	1
DICLIGES	0	1	0	1
DICLIGIS	0	1	0	1
DIPLEGIS	0	1	0	1

**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 Diclegis	Failure preventions
1.	(b) (4)	Doxylamine Succinate and Pyridoxine Hydrochloride	(b) (4)	The first proposed name for this product which was found unacceptable by DMEPA in OSE Review #2011-4112, dated March 20, 2012 because it contained (b) (4)
2.	Diclazuril	Established name for Clinacox and Protazil	Look	Not a human drug; OTC type A medicated article animal drug for prevention of coccidiosis in chickens and turkeys.
3.	Diuril	Chlorthiazide Suspension	Look	The name pair has sufficient orthographic and / or phonetic differences.
4.	Decadron	Dexamethasone	Look	The name pair has sufficient orthographic and /or phonetic differences.
5.	Diclegis	Doxylamine Succinate and Pyridoxine Hydrochloride	Look and sound	Proposed proprietary name trademarked by Duchesnay Inc. and the subject of this review.
6.	Cyclogyl	Cyclopentolate Hydrochloride	Look and sound (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
7.	Cycloset	Bromocriptine Mesylate	Look and sound (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
8.	Diazepam	Diazepam	Look (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.
9.	Dicloxacillin	Dicloxacillin	Look (b) (4)	The name pair has sufficient orthographic and /or phonetic differences.

**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.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b></p> <p><b>Dosage Form:</b>  <b>Delayed-release Tablets</b></p> <p><b>Strength: 10 mg/10 mg</b></p> <p><b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	<p>Dacogen (Decitabine) Injection 50 mg/vial</p> <p>Usual Dose:                      Treatment option 1:                      Administer at a dose of 15 mg/m<sup>2</sup> by continuous intravenous infusion over 3 hours repeated every 8 hours for 3 days. Repeat cycle every 6 weeks for a minimum of four cycles.                      Treatment option 2:                      Administer at a dose of 20 mg/ m<sup>2</sup> by continuous intravenous infusion over 1 hour repeated daily for 5 days. Repeat cycle every 4 weeks for a minimum of four cycles.</p>	<p>Orthographic:                      Both names share the beginning letter 'D', letter 'c' in the third position of each name, similarly positioned downstroke 'g' (sixth vs. fifth position) followed by similar scripted ending letter strings ('-is' vs '-en').</p> <p>Strength:                      Single strength</p>	<p>Orthographic:                      The upstroke 'l' in Diclegis provides a different shape for this name and can help differentiate Diclegis and Dacogen when scripted.</p> <p>Usual Dose:                      2 tablets or one tablet vs. 15 mg/ m<sup>2</sup> or 20 mg/ m<sup>2</sup></p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b></p> <p><b>Dosage Form:</b>  <b>Delayed-release Tablets</b></p> <p><b>Strength: 10 mg/10 mg</b></p> <p><b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
2.	<p>Divigel  (Estradiol) Gel, 0.1%  0.25 mg, 0.5 mg, 1 mg</p> <p>Usual Dose:  Apply 0.25 mg to 1 mg topically once daily to the skin of either the right or left upper thigh.</p>	<p>Orthographic:  Both names share the beginning letter string ‘Di-‘ and the downstroke ‘g’ in similar positions of each name (sixth vs. fifth position) followed by similar scripted vowels (‘i’ vs. ‘e’).</p> <p>Possible Overlap in the Usual Dose:  One (tablet vs. application) or both products may be prescribed ‘as directed’.</p>	<p>Orthographic:  The position of upstroke ‘l’ in each name is different (fourth vs. seventh) which provides a different shape for each name and can help differentiate Diclegis and Divigel when scripted.</p> <p>Additionally, a prescriber would have to indicate the desired amount of Estradiol gel (i.e. 0.25 mg, 0.5 mg, or 1 mg) either as the strength or dosage on a prescription.</p>
3.	<p>Diltzac  (Diltiazem Hydrochloride)  Extended-release Capsules  120 mg, 180 mg, 240 mg,  300 mg, 360 mg</p> <p>Usual Dose:  120 mg to 360 mg (or one capsule) orally once daily.</p>	<p>Orthographic:  Both names share the beginning letter string ‘Di-‘ letter ‘l’ in similar positions of each name (fourth vs. third), and similar scripted downstrokes (‘g’ vs. ‘z’) in similar positions (sixth vs. fifth position).</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Solid oral</p> <p>Possible Overlap in the usual Dose:  One (tablet vs. capsule)</p>	<p>Orthographic:  The cross stroke ‘t’ in Diltzac provides a different shape for this name and can help differentiate Diclegis and Diltzac when scripted.</p> <p>Strength:  Single strength (10 mg/10 mg) vs. multiple strengths (120 mg, 180 mg, 240 mg, 300 mg, and 360 mg)</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b></p> <p><b>Dosage Form:</b>  <b>Delayed-release Tablets</b></p> <p><b>Strength: 10 mg/10 mg</b></p> <p><b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p> <p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
4.	<p>Ditropan XL  (Oxybutynin Chloride)  Extended-release Tablets  5 mg, 10 mg, 15 mg</p> <p>Usual Dose:  5 mg to 15 mg (or one tablet) orally once daily.</p>	<p>Orthographic:  Both names consist of 8 letters, share the beginning letter string 'Di-', a downstroke in the sixth position of each name ('g' vs. 'p'), similar scripted vowels in the fifth position of each name ('e' vs. 'o'), and similar scripted ending letters ('s' vs. 'n').</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Partial Overlap in the Strength:  10 mg</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The letter 'c' positioned between the upstrokes 'D' and 'l' in Diclegis, and the letter 'r' positioned between the upstroke 't' and downstroke 'p' in Ditropan XL provide different shapes for each name and can help differentiate Diclegis and Ditropan XL when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
5.	<p>Diclofenac Sodium (established name for Voltaren)            Delayed-release Tablets            50 mg and 75 mg</p> <p>Usual Dose:            150 mg to 200 mg orally daily in divided doses.</p>	<p>Orthographic:            Both names share the beginning letter string 'Dicl-' followed by similar scripted vowels ('e' vs. 'o'), and similar scripted letter strings in the same position of each name ('-is' vs. '-en-').</p> <p>Route of Administration:            Oral</p> <p>Dosage Form:            Tablets</p> <p>Possible Overlap in the Usual Dose:            One tablet</p>	<p>Orthographic:            The extra ending letter string '-ac' in Diclofenac provides a different shape and a longer length for this name and can help differentiate Diclegis and Diclofenac when scripted.</p> <p>Strength:            Single strength (10 mg/10 mg ) vs. multiple strength (50 mg and 75 mg)</p>
6.	<p>Delazinc (Mineral Oil and Pertrolatum) Ointment, 25%</p> <p>Usual Dose:            Apply to the affected area(s) three or more times daily as needed.</p>	<p>Orthographic:            Both names share the beginning letter 'D' followed by similar scripted vowels ('i' vs. 'e'), upstroke 'l' in similar positions of each name (fourth vs. third) followed by similar scripted letter strings ('-egis' vs. '-azin-').</p> <p>Strength:            Single strength</p> <p>Partial Overlap in the Usual Dose:            One (tablet vs. application) or both products may be prescribed 'as directed'.</p>	<p>Orthographic:            The letter 'c' in Diclegis provides a longer appearance for the letter grouping between the upstrokes 'D' and 'l' for this name vs. Delazinc, and the extra ending letter 'c' in Delazinc provides a longer appearance for this name and can help differentiate Diclegis and Delazinc when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
7.	<p>Delsym  (Dextromethorphan Hydrobromide) Extended-release Oral Suspension  30 mg/5 mL</p> <p>Usual Dose:  2.5 mg to 20 mg (or half to four teaspoonfuls) every four hours or 7.5 mg to 30 mg orally every 6 to 8 hours.</p>	<p>Orthographic:  Both names share the beginning letter 'D' followed by similar scripted vowels ('i' vs. 'e'), upstroke 'l' in similar positions of each name (fourth vs. third position), and a similar positioned downstroke ('g' vs. 'y').</p> <p>Route of Administration:  Oral</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Usual Dose:  One (tablet vs. teaspoonful) or 10 (mL vs. mg)</p>	<p>Orthographic:  The letter 'c' in Diclegis provides a longer appearance for the letter grouping between the upstrokes 'D' and 'l' for this name vs. Delsym, and the ending letter 'm' in Delsym does not appear similar to the ending letter string '-is' in Diclegis, and can help differentiate Diclegis and Delsym when scripted.</p>
8.	<p>Dentagel  (Sodium Fluoride) Gel, 1.1%</p> <p>Usual Dose:  Apply to the affected area once daily.</p>	<p>Orthographic:  Both names consist of 8 letters, share the beginning letter 'D' followed by similar scripted vowels ('i' vs. 'e'), a fourth position upstroke ('l' vs. 't') followed by similar scripted letter strings ('-egi-' vs. '-age-').</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Usual Dose:  One (tablet vs. application) or both products may be prescribed 'as directed'.</p>	<p>Orthographic:  The two skinny letter 'i's in Diclegis provide a shorter appearance for this name. Additionally, the ending upstroke 'l' in Dentagel provides a different shape, and the letter 'n' in this name (vs. letter 'c' in Diclegis) provides a longer appearance for Dentagel which can help differentiate Diclegis and Dentagel when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
9.	<p>Octagam  (Immune Globulin) Solution  5%</p> <p>Usual Dose:  300 mg/kg to 600 mg/kg intravenously every three to four weeks.</p>	<p>Orthographic:  Both names share similar scripted beginning letters ('D' vs. 'O'), similar positioned letter 'c' (third vs. second) followed by an upstroke ('l' vs. 't') and similar scripted letter strings ('-eg-' vs. '-ag-').</p> <p>Strength:  Single strength</p>	<p>Orthographic:  The skinny letter 'i' in Diclegis and the ending letter 'm' in Octagam provide a different shapes and lengths for each name and can help differentiate Diclegis and Octagam when scripted.</p> <p>Frequency of Administration:  Once, twice, or three times daily vs. every 3 to 4 weeks.</p> <p>Usual Dose:  Two tablets (or one tablet) vs. 300 mg/kg or 600 mg/kg</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
10.	<p>Baclofen  (established name for Lioresal) Tablets  10 mg and 20 mg</p> <p>Usual Dose:  The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 to 80 mg daily). The following dosage titration schedule is suggested:  5 mg 3 times daily for 3 days  10 mg 3 times daily for 3 days  15 mg 3 times daily for 3 days  20 mg 3 times daily for 3 days</p>	<p>Orthographic:  Both names consist of 8 letters, share similar scripted beginning letters ('D' vs. 'B'), letter string '-cl-' in the same position of each name followed by similar scripted vowels ('e' vs. 'o'), and similar scripted ending letter strings ('-is' vs. '-en').</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Numerical Overlap in the Strength:  10 mg</p> <p>Possible Overlap in the Frequency of Administration:</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The skinny letter 'i' and the downstroke 'g' in Diclegis (vs. the round vowel 'a' and the cross stroke 'f' in Baclofen) provide a different shape and a shorter appearance for this name and can help differentiate Diclegis and Baclofen when scripted. Additionally, we could not identify any writing samples which could demonstrate an orthographic similarity between Diclegis and Baclofen when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
11.	<p>Adagen  (Pegademase Bovine)  Injection, 250 units/mL</p> <p>Usual Dose:  Recommended for use in infants from birth or in children of any age at the time of diagnosis. Administered every 7 days intramuscularly. The dose should be individualized. The recommended dosing schedule is 10 units/kg for the first dose, 15 units/kg for the second dose, and 20 units/kg for the third dose. The usual maintenance dose is 20 units/kg per week.</p>	<p>Orthographic:  Both names share similar scripted letter strings in the same position of each name ('clegis' vs. 'dagen').</p> <p>Strength:  Single strength</p> <p>Possible Numerical Overlap in the Usual Dose:  10 mg vs. 10 units/kg</p>	<p>Orthographic:  The second position skinny letter 'i' in Diclegis (vs. no letters between the beginning letter 'A' and the upstroke 'd' in Adagen) provides a longer appearance and a different shape for this name and can help differentiate Diclegis and Adagen when scripted.</p> <p>Frequency of Administration:  Once, twice, or three times daily vs. every 7 days (or weekly)</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
12.	<p>Salagen  (Pilocarpine Hydrochloride)  Tablets, 5 mg and 7.5 mg</p> <p>Usual Dose:  5 mg to 10 mg orally three times daily if needed.</p>	<p>Orthographic:  Both names share similar position upstroke 'l' (fourth vs. third) followed by similar scripted ending letter strings ('-egis' vs. '-agen').</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Possible Overlap in Strength:  10 mg is achievable in Salagen</p> <p>Possible Overlap in the Frequency of Administration:  3 times daily</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The letter string 'Dic-' in Diclegis appears different than the letter string 'Sa-' in Salagen and can help differentiate Diclegis and Salagen when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
13.	<p>Solage            (Mequinol and Tretinoin)            Topical Solution            2%/0.01%</p> <p>Usual Dose:            Apply to the affected area(s)            twice daily.</p> <p>(This product is discontinued; however, the Application is not withdrawn.)</p>	<p>Orthographic:            Both names share similar scripted beginning letters ('D' vs. 'S' if the letter 'S' is scripted in lower case) followed by similar scripted letter and letter string ('-ic-' vs. 'o' if the letter 'o' is not fully closed), similar position upstroke 'l' (fourth vs. third position) followed by similar scripted letter strings ('-egi-' vs. '-age').</p> <p>Strength:            Single strength</p> <p>Possible Overlap in the Frequency of Administration:            Twice daily</p> <p>Possible Overlap in the Usual Dose:            One (tablet vs. application) or both products may be prescribed 'as directed'.</p>	<p>Orthographic:            The name Diclegis contains eight letters compared to only six letters in Solage. Additionally, the extra ending letter 's' in Diclegis provides a longer appearance for this name and can help differentiate Diclegis and Solage when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
14.	<p>Dologesic  (Acetaminophen and Phenyltoloxamine Citrate)  Delayed-release Tablets  500 mg/30 mg</p> <p>Usual Dose:  One half to two tablets orally every 4 to 6 hours.</p>	<p>Orthographic:  Both names share the beginning letter 'D' followed by similar scripted letter and letter string ('-ic-' vs. 'o' if the letter 'o' is not fully closed), similar position upstroke 'l' (fourth vs. third position) followed by similar scripted letter strings ('-egis-' vs. '-oges-').</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The ending letter string '-ic' in Dologesic provides a longer appearance for this name and can help differentiate Diclegis and Dologesic when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
15.	<p>Palgic  (Carbinoxamine Maleate)  Tablets, 4 mg</p> <p>Usual Dose:  One half to two tablets orally  3 to 4 times daily.</p>	<p>Orthographic:  Both names share similar scripted beginning letters ('D' vs. 'P') followed by similar scripted letter and letter string ('-ic-' vs. 'a' if the letter 'a' is not fully closed), similar position upstroke 'l' (fourth vs. third position), and the letter string '-gi-'.</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Frequency of Administration:  3 times daily</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The name Diclegis contains eight letters compared to only six letters in Palgic. Additionally, the extra letter 'e' in Diclegis provides a longer appearance for this name and can help differentiate Diclegis and Palgic when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
16.	<p>Dolgic (Acetaminophen and Butalbital) Tablets  650 mg/50 mg</p> <p>Usual Dose:  One tablet orally every four hours as needed.</p>	<p>Orthographic:  Both names share the beginning letter 'D', followed by similar scripted letter and letter string ('-ic-' vs. 'o' if the letter 'o' is not fully closed), similar position upstroke 'l' (fourth vs. third position), and the letter string '-gi-'.</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The name Diclegis contains eight letters compared to only six letters in Dolgic. Additionally, the extra letter 'e' in Diclegis provides a longer appearance for this name and can help differentiate Diclegis and Dolgic when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
17.	<p>Didronel  (Etidronate Sodium)  Tablets, 200 mg 400 mg</p> <p>Usual Dose:  Taken as a single, oral dose (5 mg/kg to 20 mg/kg per day). Tablet should be swallowed with a full glass of water (6 to 8 oz). Patients should not lie down after taking the medication. Do not take food, vitamins with minerals or antacids within 2 hours of dosing.</p>	<p>Orthographic:  Both names consist of 8 letters, share the beginning letter string 'Di-' followed by similar scripted letter and letter string ('-cl-' vs. 'd'), and similar scripted vowels in the same position of each name ('e' vs. 'o' in the fifth position and 'i' vs. 'e' in the seventh position of each name).</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The downstroke 'g' in Diclegis and the ending upstroke 'l' in Didronel provide different shapes for each name and can help differentiate Diclegis and Didronel when scripted.</p> <p>Strength:  Single strength (10 mg/ 10 mg) vs. multiple strengths (200 mg and 400 mg)</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
18.	<p>Duexis  (Ibuprofen and Famotidine)  Tablets, 800 mg/26.6 mg</p> <p>Usual Dose:  One tablet orally 3 times daily.</p>	<p>Orthographic:  Both names share similar scripted beginning letter strings ('Dic-' vs. 'Du-') and the ending letter string '-is'.</p> <p>Route of Administration:  Oral</p> <p>Dosage form:  Tablets</p> <p>Strength:  Single strength</p> <p>Possible Overlap in the Frequency of Administration:  3 times daily</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The upstroke 'l' and the downstroke 'g' in Diclegis (vs. no upstrokes and the cross stroke 'x' in Duexis, respectively) provide a different shape for this name and can help differentiate Diclegis and Duexis when scripted.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
19.	<p>Dutoprol  (Metoprolol Succinate and Hydrochlorothiazide) Tablets  25 mg/12.5 mg,  50 mg/12.5 mg,  100 mg/12.5mg</p> <p>Usual Dose:  Dose is individualized, titrated orally up to 200 mg/12.5 mg per day.</p>	<p>Orthographic:  Both names consist of 8 letters, share the beginning letter ‘D’ followed by similar scripted letter and letter string (‘-ic-’ vs. ‘u’), similar position upstrokes (‘l’ vs. ‘t’) followed by similar scripted vowels (‘e’ vs. ‘o’) and a downstroke (‘g’ vs. ‘p’), and similar scripted letters in similar positions (‘s’ vs. the seventh position letter ‘o’).</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Possible Overlap in the Frequency of Administration:  Once</p> <p>Possible Overlap in the Usual Dose:  One tablet</p>	<p>Orthographic:  The ending upstroke letter ‘l’ in Dutoprol provides a different shape for this name and can help differentiate Diclegis and Dutoprol when scripted.</p> <p>Strength:  Single strength (10 mg/10 mg) vs. multiple strengths (25 mg/12.5 mg, 50 mg/12.5 mg, and 100 mg/12.5 mg)</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
20.	<p>Taclonex (Calcipotriene/Betamethasone Dipropionate) Ointment 0.05%/0.064%  Taclonex Scalp (Calcipotriene/Betamethasone Dipropionate) Spray 0.05%/0.064%</p> <p>Usual Dose:  Apply to the affected area(s) once daily for up to 2 or 4 weeks or until clear.</p>	<p>Orthographic/Phonetic:  Both names consist of 8 letters, share similar scripted letters ('D' vs. 'T'), same position letter string '-cl-' followed by similar scripted vowels ('e' vs. 'o'), and similar scripted ending letter scripts ('-is' vs. '-ex'). Phonetically, both names share three syllables, share the sound 'cl', and similar sounding ending syllables ('ex' vs. 'is') when spoken.</p> <p>Strength:  Single strength</p> <p>Prtil Overlap in the Frequency of Administration:  Once</p> <p>Partial Overlap in the Usual Dose:  One (tablet vs. application)</p>	<p>Orthographic/Phonetic:  The downstroke 'g' in Diclegis provides a different shape for this name and can help differentiate Diclegis and Taclonex when scripted. Phonetically, the beginning sounds 'Di' and 'Ta' sound different. Additionally, the sound 'g' in Diclegis provides a different sound for this name and can help differentiate Diclegis and Taclonex when spoken.</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
21.	<p>Pegasys (Peginterferon Alfa-2a) Injection  180 mcg/mL,  135 mcg/0.5 mL,  180 mcg/0.5 mL</p> <p>Usual Dose:  Adults: 180 mcg per week and the duration of treatment depends on indication, genotype, and whether it is administered with Copegus.  Pediatrics: 180 mcg/1.73 m<sup>2</sup> × BSA per week, in combination with Copegus, and the duration of treatment depends on genotype</p>	<p>Orthographic:  Both names share similar scripted beginning letter strings ('Di-' vs. 'Pe-'), ending letter 's', and sixth position downstrokes ('g' vs. 'y').</p>	<p>Orthographic:  The letter string '-cle-' in Diclegis does not appear similar to the letter string '-gas-' in Pegasys and can help differentiate Diclegis and Pegasys when scripted.</p> <p>Strength:  Single strength (10 mg/10 mg) vs. multiple strengths (180 mcg/mL, 135 mcg/0.5 mL, and 180 mcg/0.5 mL)</p> <p>Usual Dose:  Two tablets (or one tablet) vs. 135 mcg or 180 mcg</p>

No.	<p><b>Proposed name:</b>  <b>Diclegis (Doxylamine Succinate and Pyridoxine Hydrochloride)</b>  <b>Dosage Form:</b>  <b>Delayed-release Tablets</b>  <b>Strength: 10 mg/10 mg</b>  <b>Usual Dose: 2 tablets at bedtime to control nausea and vomiting occurring in the morning, additionally, one tablet in the morning and one tablet in mid-afternoon to control symptoms throughout the day.</b></p>	<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>  <b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
22.	<p>Aubagio  (Teriflunomide) Tablets  7 mg, 14 mg</p> <p>Usual Dose:  One tablet by mouth once daily.</p>	<p>Orthographic:  Both names share a similar suffix when scripted ('-egis' vs. '-agio'), an upstroke in similar positions of each name (fourth vs. third), beginning letters that may appear similar when scripted ('D' vs. 'A' when 'A' is scripted in lower case, followed by a letter and letter string that may appear similar when scripted ('-ic-' vs. 'u').</p> <p>Route of Administration:  Oral</p> <p>Dosage Form:  Tablets</p> <p>Possible Overlap in Dose and Frequency of Administration:  One tablet once daily</p>	<p>Orthographic:  The suffix '-legis' appears shorter than the suffix '-bagio' due to the round attachment in the upstroke 'b' vs. no attachment in the upstroke 'l'.</p> <p>Strength:  Single strength (10 mg/10 mg) vs. multiple strengths (7 mg, 14 mg)</p>



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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MANIZHEH SIAHPOUSHAN  
09/20/2012

ZACHARY A OLESZCZUK  
09/20/2012

CAROL A HOLQUIST  
09/20/2012