

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22518Orig1s000

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**

Date: June 2, 2010

To: Badrul Chowdhury, MD, Director
Division of Pulmonary, Allergy, and Rheumatology Products

Through: Todd Bridges, RPh, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Deveonne Hamilton-Stokes RN, BSN, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)
Inhalation Aerosol
100 mcg/5 mcg and 200 mcg/5 mcg

Application Type/Number: NDA 022518 (IND 70,283)

Applicant: Schering-Plough

OSE RCM #: 2009-1498

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Dulera, 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, Dulera, acceptable in OSE Review #2009-502 dated August 4, 2009. DDMAC reviewed the proposed name on March 26, 2009 and October 19, 2009 and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Dulera during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search 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. We used the same search criteria used in OSE Review #2009-502 for the proposed proprietary name, Dulera. (b) (4) Dulera will only be available in strengths of 100 mcg/5 mcg and 200 mcg/5 mcg. This change in the number of available strengths still makes Dulera a multiple strength product. Thus, we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA)¹ of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded five new names, Differin, Zyclara, Asclera***, (b) (4) and (b) (4), thought to look and/or sound similar to Dulera and represent a potential source of drug name confusion. These names were evaluated using FMEA. The findings of the FMEA indicate that the proposed name, Dulera, is not likely to result in name confusion with any of the names for the reasons presented in Appendix A through C.

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 27, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Dulera, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Dulera, 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 Division of Pulmonary, Allergy, and Rheumatology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

We are willing to meet with the Division for further discussion, if needed. If you have questions or need clarifications, please contact Carolyn Volpe, OSE Project Manager, at 301-796-5204.

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¹ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

4 REFERENCES

4.1 REVIEW

1. OSE review # 2009-502 Proprietary Name Review of Dulera, August 4, 2009; Deveonne Hamilton-Stokes

4.2 DATABASES

1. *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.

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

USAN Stems List contains all the recognized USAN stems.

3. *CDER Proposed Names List*

Compiled list of proposed proprietary names submitted to the Division of Medication Error and Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA

Appendix A: Proposed proprietary names

Proprietary Name	Similarity to Dulera	Additional Information
(b) (4)		

Appendix B: Product with no overlap in dose or strength

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Dosage Form/ Strength	Usual Dose (if applicable)
Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)	N/A	Inhalation aerosol (metered dose inhaler) 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)
Asclera*** (Polidocanol)	Look and Sound	Intravenous injection: 0.5% and 1% per 2 mL ampules	0.1 to 0.3 mL of 0.5% per injection for spider veins and 0.1 to 0.3 mL of 1% per injection for reticular veins. Maximum daily dose per treatment day is 0.4 mL/kg body weight for 0.5% solution and 0.2 mL/kg body weight for 1% solution.
Zyclara (Imiquimod)	Look and Sound	Topical cream: 3.75%	Apply a thin film once daily before bedtime to the skin of the affected area for two 2-week treatment cycles separated by a 2-week no-treatment period. Cream should be left on the skin for approximately 8 hours, after which time the cream should be removed by washing the area with mild soap and water.
Differin (Adapalene)	Look	Topical lotion: 0.1 % Topical cream: 0.1% Topical gel: 0.1% and 0.3%	Apply a thin film to the entire face and other affected areas of the skin once daily.

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Appendix C: Products with numerically similar strength and achievable dose or overlap in strength but multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Product Name	Strength	Usual Dose	Other Differentiating Product Characteristics
<p>Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)</p>	<p>N/A</p>	<p>MDI: 100 mcg/5 mcg, 200 mcg/5 mcg</p>	<p>2 inhalations every 12 hours (morning and evening)</p>	<p>N/A</p>

(b) (4)

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22518	ORIG-1	SCHERING CORP	MOMETASONE FUROATE/FORMOTEROL FUMARATE

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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**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: August 4, 2009

To: Badrul Chowdhury, MD, Director
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From: Deveonne Hamilton-Stokes RN, BSN, Safety Evaluator
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Subject: Proprietary Name Review

Drug Name(s): Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)
Inhalation Aerosol
(b) (4) 100 mcg/5 mcg and 200 mcg/5 mcg

Application Type/Number: NDA 22-518 (IND 70,283)

Applicant: Schering-Plough

OSE RCM #: 2009-502

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EXECUTIVE SUMMARY

Dulera is the proposed proprietary name for Mometasone Furoate and Formoterol Fumarate Dihydrate Inhalation Aerosol. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Dulera conditionally acceptable for this product. The proposed proprietary name must be re-reviewed upon submission of the NDA and 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Schering-Plough dated March 13, 2009, for an assessment of the proposed proprietary name, Dulera, regarding potential name confusion with other proprietary or established drug names in the usual practice settings.

1.2 REGULATORY HISTORY

Schering-Plough initially submitted the (b) (4) (Loratadine and Motelukast Sodium tablets) (b) (4)

1.3 PRODUCT INFORMATION

Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate) is a combination product indicated for the (b) (4) treatment of asthma in adults and children 12 years of age and older. The usual recommended dose is 2 inhalations (b) (4), 100 mcg/5 mcg or 200 mcg/5 mcg per inhalations) twice daily (12 hours apart). Dulera will be available as (b) (4) 100 mcg/5 mcg and 200 mcg/5 mcg metered dose inhalers and supplied as (b) (4) 120 inhalations per canister.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Dulera.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘D’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

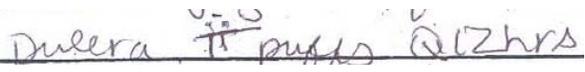
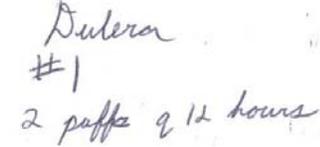
To identify drug names that may look similar to Dulera, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (two, capital letter ‘D’ and lowercase ‘l’), down strokes (none), cross strokes (none), and dotted (none). Additionally, several letters in Dulera may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Dulera.

When searching to identify potential names that may sound similar to Dulera, the DMEPA staff search for names with similar number of syllables (three), stresses (DO-ler-a or do-LER-a), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as ‘Du-’ may sound like ‘Do-’ or ‘Da-’ and ‘-lera’ may sound like ‘-lara’ or ‘-laira’ (See Appendix B). The Applicant’s intended pronunciation (doo-ler-a) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescriptions were communicated during the FDA prescription studies.

Figure 1. Dulera Rx Study (conducted on April 17, 2009)

HANDWRITTEN MEDICATION ORDER AND OUTPATIENT PRESCRIPTION	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	“ Dulera 2 puffs every 12 hours”
<p><u>Outpatient Prescription:</u></p> 	

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

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

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 21 names as having some similarity to the name Dulera.

Fifteen of the names were thought to look like Dulera. These include: Duloxetine, Pylera, Dolene, Dolana, Clolar, Dolaren, Dulcolax, (b) (4) Debrase, Debrox, Clobex, Exubera, Covera, Sular and Soliris. Two of the names (Lutera and Femara) were thought to sound like Dulera. The remaining names thought to look and sound similar to Dulera are: Alera, Alora, (b) (4) ** and Stelara***.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of May 12, 2009.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Dulera.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 22 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. About 81% of the participants (n=18) interpreted the name correctly as "Dulera", with correct interpretation occurring more frequently in the written studies. The remainder of the respondents (n=4) misinterpreted the drug name. In the verbal prescription study the vowel 'e' was misinterpreted as 'a'. Additionally, in the written prescription studies, the letter 'r' was misinterpreted as the letter 'x' and the letter 'a' was misinterpreted as the letter

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

3.4 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Applicant, DSI identified and evaluated a total of fifty-one names thought to have some potential for confusion with the name Dulera. Of the fifty-one names identified by DSI, DMEPA had identified fourteen of the names (Alera, Covera-HS, Dolene, Dolorac, Dulcolax, Duloxetine, Exubera, Lutera, Pylera, Relera, Sular, Dilacor XR, Dilantin and Fludara) during the database searches. The remaining thirty-seven names (Advera, Cholera, Dallery, Demulen, Desyrel, Diuril, Doldram, Dolmar, Doloral, Duplex, Hepsera, Humira, Myleran, Nulev, Provera, Suphera, U-keria, Ultram, Allegra, Allerx, Byetta, Cylert, Dantrium, Depo-Provera, Diovan, Dolobid, Duet, Duetact, Duoneb, Hylira, Kaletra, Lyrica, Mircena, Myleran, Strattera, Synera, and Xolair) were evaluated during the Safety Evaluator Assessment.

3.5 COMMENTS FROM THE DIVISION

In response to the OSE, March 30, 2009 e-mail, DPAP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

DMEPA notified the Division of Pulmonary and Allergy Products via e-mail that we had no objections to the proposed proprietary name, Dulera, on June 2, 2009. Per e-mail correspondence from the Division of Pulmonary and Allergy Products on June 15, 2009, they indicated they had no concerns with the proposed proprietary name, Dulera.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified 15 additional names which were thought to look or sound similar to Dulera and represent a potential source of drug name confusion.

The names identified to have look-alike similarities are: Dilacor, Bois Douleur, Leukeran, Dolorac, Del-Vi-A, Dilaudid, and Dilantin. The names thought to have sound-alike similarities include: Aldara and Fludara. The remaining names, Relera, Dolorex, Dolorex Forte, Delaro, Doloro, and Dilor/Dilor G were identified to have look-alike and sound-alike similarities. Thus, we evaluated a total of 73 names.

4 DISCUSSION

Neither DDMAC or the review Division had concerns with the proposed name.

DMEPA identified and evaluated 73 names for their potential similarity to the proposed name, Dulera. Twenty-nine names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix D).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 44 names and lead to medication errors. This analysis determined that the name similarity between Dulera was unlikely to result in medication errors with any of the 44 products for the reasons presented in Appendices E through K.

Our evaluation did not note any other aspects in the name that would render it unacceptable.

5 CONCLUSIONS AND RECOMMENDATIONS

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

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation. For questions or clarifications, please contact Sean Bradley, OSE Project Manager, at 301-796-1332.

5.1 COMMENTS TO THE APPLICANT

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

Dulera will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

6 REFERENCES

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

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

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

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

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

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

4. ***AMF Decision Support System [DSS]***

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

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

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

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

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

7. ***Electronic online version of the FDA Orange Book*** (<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

15. Lexi-Comp (www.lexi.com)

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.³

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases

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

the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁵ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the 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.

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

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

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

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

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the

proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

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

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names 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.

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

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or

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

suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the 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 Sponsor. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or 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. . (See Section 4 for limitations of the process).

Appendix B: Potential orthographic or phonetic misinterpretations of the letters in Dulera

Letters in Name, Dulera	Scripted may appear as	Spoken may be interpreted as
Capital 'D'	O, S, R, A, P	V
lower case 'd'	cl	v
lower case 'u'	a or o	any vowel
lower case 'l'	h, m, r, s, t, u, v, or x	'l' or 'm'
lower case 'e'	a, i, or u	any vowel
lower case 'r'	c	-
lower case 'a'	c, ci, ce, o, or u	any vowel

Appendix C:

CDER Prescription Study Responses

Outpatient Prescription	Voice Prescription	Inpatient Medication Order
Dulera	Dulera	Dulera
Dulera	Dulara	Dulera
Duleron	Dulara	Dulera
Dulera		Dulexa
Dulera		

Appendix D: Names without convincing look-alike and/or sound-alike similarities to Dulera.

Proprietary Name	Similarity to Dulera	Proprietary Name	Similarity to Dulera
Dulcolax	Look	Allegra	DSI
Dilantin	Look	Allerx	DSI
Dilaudid	Look	Byetta	DSI
Dallergy	DSI	Cylert	DSI
Demulen	DSI	Dantrium	DSI
Desyrel	DSI	Depo-Provera	DSI
Diuril	DSI	Diovan	DSI
Duplex	DSI	Duet	DSI
Hepsera	DSI	Duetact	DSI
Humira	DSI	Duoneb	DSI
Ultram	DSI	Hylira	DSI
Myleran	DSI	Kaletra	DSI
Lyricea	DSI	Mircera	DSI
Myleran	DSI	Strattera	DSI
Xolair	DSI		

Appendix E: Identified foreign product name

Proprietary Name	Similarity to Dulera	Country
Dolana (Tramadol)	Look	Indonesia
Dolaren (Diclofenac)	Look	Mexico
Doloral	DSI	India

Appendix F: Proprietary names not approved by the Agency

Proprietary Name	Similarity to Dulera	Status
(b) (4)		

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

Appendix G: Products with limited or no additional information found in DMEPA References 1-16 (See Section 6 of this review)

Proprietary Name	Similarity to Dulera	Additional Information
Dolorex (Acetaminophen/Salicylamide/ Phenyltoloxamine)	Look/Sound	None
Delaro	Look/Sound	USPTO- Listed as Dead Trademarks for: Chemical Preparation for the treatment of seeds and fertilizer and Educational Services
Doloro	Look/Sound	USPTO-Listed as Dead Trademark for an analgesic preparation
Bois Douleur	Look	Natural medicine states it is a small evergreen tree in which the roots, bark and fruits are used to treat various conditions. Tree is found in the Pacific Islands, Asia, Australia and India
Doldram (Salicylamide)	DSI	None

Appendix H: Names with orthographic or phonetic similarity to Dulera that are discontinued and have no generic equivalents available

Proprietary Name	Similarity to Dulera
Cholera (Cholera vaccine)	DSI

Appendix I: Products with no numerical overlap in strength or dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)	N/A	Inhalation aerosol (metered dose inhaler) <small>(b) (4)</small> 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)
Pylera (Bismuth Subcitrate Potassium; Metronidazole; Tetracycline)	Look	Capsule : 140 mg/125 mg/ 125 mg	3 capsules taken 4 times a day, after meals and at bedtime for 10 days. One omeprazole 20 mg capsule should be taken twice a day with Pylera after the morning and evening meal for 10 days
Debrase (Debridase)	Look	Topical Gel: 2 g, 5 g	Apply to wound surface
Debrox	Look	Otic drops: none	Instill 5 to 10 drops twice daily for up to 4 days
Clobex (Clobetasol Propionate)	Look	Topical Shampoo: 0.05% Topical Spray 0.05%	Apply to scalp once a day in a thin film to the affected areas; leave in place for 15 minutes, then add water, lather and rinse Spray directly onto the affected skin areas twice daily and rub in gently and completely
Exubera (Insulin Recombinant Human)	Look	Inhalation Powder: 1 mg, 3 mg	Individualized and determined based on the physician's advice in accordance with the needs of the patient
Dolene (Propoxyphene Hydrochloride)	Look	Capsule: 65 mg	65 mg every 4 hours
Covera-HS (Verapamil Hydrochloride)	Look	Tablet: 180 mg, 240 mg	Initiate therapy at 180 mg and dose may be titrated up to 480 mg once daily at bedtime
Lutera (Ethinyl estradiol/Levonorgestrel)	Sound	Tablet: 20 mcg/0.1 mg	One white tablet daily for 21 consecutive days, followed by one peach inert tablet daily for seven consecutive days

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)	N/A	Inhalation aerosol (metered dose inhaler) <small>(b) (4)</small> 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)
<small>(b) (4)</small>			
Alera (Hydroquinone)	Look/Sound	Topical emulsion: 4%	Apply to the affected area twice daily
Stelara*** (Ustekinumab)	Look/Sound	Solution for injection autoinjector : 45 mg, 90 mg	45 mg or 90 mg subcutaneously followed by an additional dose 4 weeks after the first dose, then every 12 weeks thereafter.
Dolorac (Capsaicin)	Look	Topical lotion/cream	Apply to affected area up to four times daily
Aldara (Imiuiomod)	Sound	Topical cream: 5%	Apply to the affected area two, three or five times per week (depending on condition being treated) for up to 16 weeks
Dilacor XR (Diltiazem Hydrochloride)	Look	Capsule: 120 mg, 180 mg, 240 mg	180 mg to 480 mg once daily
Leukeran (Chlorambucil)	Look	Tablet: 2 mg	0.1 mg/kg to 0.2 mg/kg of body weight daily for three to six weeks (typically amounts to 4 mg to 10 mg per day for the average patient)
Relera (Chlorpheniramine/ Phenylephrine)	Look/Sound	Caplets: 8 mg/20 mg	One caplet 2 to 3 times per day
Del-Vi-A (Vitamin A Palmitate) Discontinued, but generics available	Look	Capsule: 50,000 units	Individualized to patient
Alora (Estradiol)	Look/ Sound	Topical Patch: 0.05 mg, 0.075 mg, 0.1 mg, 0.025 mg	Apply 0.05 mg to 0.025 mg twice weekly
Femara (Letrozole)	Sound	Tablet: 2.5 mg	One tablet once a day

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)	N/A	Inhalation aerosol (metered dose inhaler) <small>(b) (4)</small> 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)
Advera (Nutritional supplement)	DSI	Oral Liquid: none	Based upon individual needs
Dolmar (Butalbital, Acetaminophen, Caffeine)	DSI	Capsules, Tablets: none	Take 1 or 2 capsules or tablets every 4 hours as needed
Nulev (Hyoscyamine Sulfate)	DSI	Chewable Tablet: 0.125 mg	1 to 2 tablets every 4 hours as needed
U-Kera (Urea)	DSI	Topical Cream: 40%	Apply preparation to the affected areas twice a day
Synera (Lidocaine, Tetracaine)	DSI	Topical Patch: 70 mg/70 mg	Apply to intact skin for 20-30 minutes

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

Appendix J: Products with numerically similar strength or achievable dose with differentiating product characteristics

Product name with potential for confusion	Similarity to Product Name	Strength	Usual Dose	Other Differentiating Product Characteristics
Dulera (Mometasone Furoate and Formoterol Fumarate Dihydrate)	N/A	MDI: (b) (4) 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)	N/A
Soliris (Eculizumab)	Look	Injection: 300 mg vial	600 mg every 7 days for the first 4 weeks, followed by 900 mg for the fifth dose 7 days later, then 900 mg every 14 days thereafter	Dosage forms: Inhalation aerosol (metered dose inhaler) vs. Injection Frequency of administration: Every 12 hours vs. 7 days to 14 days Route of administration: Oral inhalation vs. Intravenous Usual dose: 2 puffs vs. 600 mg or 900 mg Additionally, the dose of Dulera will usually be written in puffs or inhalations whereas Soliris will be written for as mg to be injected.
Fludara (Fludarabine)	Sound	Injection: 50 mg vial	25 mg/m ² administered intravenously over a period of approximately 30 minutes daily for five consecutive days. Each 5 day course of treatment should commence every 28 days	Dosage forms: Inhalation aerosol (metered dose inhaler) vs. Injection Frequency of administration: Every 12 hours vs. 5 consecutive days every 28 days Route of administration: Oral inhalation vs. Intravenous Usual dose: 2 puffs vs. 25 mg/m ²
Provera (Medroxyprogesterone acetate)	DSI	Tablets: 2.5 mg, 5 mg, 10 mg	5 mg or 10 mg given daily by mouth for 5 days to 10 days	Dosage forms: Inhalation aerosol (metered dose inhaler) vs. Tablet Frequency of administration: Every 12 hours vs. daily Usual dose: 2 puffs vs. 5 mg or 10 mg given daily for 5 days to 10 days

Product name with potential for confusion	Similarity to Product Name	Strength	Usual Dose	Other Differentiating Product Characteristics
Dulera (Mometasone furoate and formoterol fumarate dihydrate)	NA	MDI: (b) (4) 100 mcg/5 mcg, 200 mcg/5 mcg	2 inhalations every 12 hours (morning and evening)	NA
Suphera (Sulfacetamide Sodium and Sulfur)	DSI	Topical Cream: 10%/5%	Apply a thin film to the affected areas 1 to 3 times a day	Dosage forms: Inhalation aerosol (metered dose inhaler) vs. Cream Route of administration: Oral inhalation vs. Topical Instructions for use: Inhale vs. Apply Additionally, a strength must be specified for Dulera because it is available in multiple strengths. Furthermore, Suphera may be written without the product strength since it is a single strength product.
Clolar (clofarabine)	Look	Injection: 20 mg/20 mL	52 mg/m ² as an intravenous infusion over 2 hours daily for 5 consecutive days of a 28 day cycle. Repeat every 2 to 6 weeks	Dosage forms: Inhalation aerosol (metered dose inhaler) vs. Injection Frequency of administration: Every 12 hours vs. 5 consecutive days every 28 days; Repeat every 2 weeks Route of administration: Oral inhalation vs. Intravenous Usual dose: 2 puffs vs. 52 mg/m ²

Appendix K: Potential confusing name with numerical overlap in strength or dose

Failure Mode: Name Confusion	Causes (could be multiple)	Rationale
<p>Dulera (Mometasone furoate/formoterol fumarate dihydrate)</p> <p>MDI: (b) (4) (b) (4) 100/5 mcg, 200/5 mcg</p>		<p>Usual Dose: 2 puffs every 12 hours (morning and evening)</p>
<p>Sular (Nisoldipine extended-release tablets)</p> <p>8.5 mg, 17 mg, 25.5 mg, 34 mg</p> <p>17 mg to 34 mg once daily</p>	<p>Orthographic similarity: both names share similar letters in similar positions “uler” vs. “ular” and capital letter “D” may look like capital letter “S” when scripted.</p> <p>Numerical overlap in strength (25/5 vs. 25.5)</p>	<p>Differentiating product characteristics will help reduce the risk of medication errors.</p> <p>Rationale: Both products are available in multiple strengths. Even if the 25/5 was misinterpreted as 25.5, Sular is available as a tablet with a usual dose of one tablet per day. Dulera is a metered dose inhaler and the usual dose is 2 puffs every 12 hours. These directions will be included in an order for Dulera or it can be written as “use as directed”. However, Sular is less likely to be written as “use as directed”. Therefore the directions for use will help distinguish these products.</p>
<p>Duloxetine Hydrochloride (established name for Cymbalta)</p> <p>Capsule: 20 mg, 30 mg, 60 mg</p> <p>Range depending on condition being treated, from 20 mg twice daily to 60 mg once daily</p>	<p>Orthographic similarity: both names begin with “Dul”</p> <p>Attainable strength and dose of 50 mg vs. 50 mcg</p>	<p>Orthographic as well as product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>Rationale: Orthographic differences stem from the fact that the “Dulera contains 6 letters and Duloxetine contains 10 letters and the endings of the names appear different (“-era” vs. “oxetine”. Additionally, the products differ in dosage form (tablet vs. inhalation aerosol). Additionally, an order for Dulera may have directions such as “2 puffs or inhalations” or may be ordered as “use as directed”.</p>
<p>Dilor, Dilor 400 (Dyphylline)</p> <p>Discontinued, but generics available</p> <p>Tablet: 200 mg, 400 mg</p> <p>15 mg/kg up to 4 times a day (about six hours apart)</p>	<p>Orthographic similarity: both names contain the letters “D”, “l” and “r” in the same positions. Additionally, the vowels “i” and “o” can look similar to “u” and “a” when scripted.</p> <p>Share overlapping strength of 200 mg</p>	<p>Differentiating product characteristics will help reduce the risk of medication errors.</p> <p>Rationale: Dilor/Dilor 400 is available as a tablet with a usual dose of up to 15 mg/kg every 6 hours. In contrast, Dulera is a metered dose inhaler and the usual dose is 2 puffs every 12 hours. These directions will be included in an order for Dulera or it can be written as “use as directed”. However, Dilor/Dilor 400 is less likely to be written as “use as directed”. Therefore the directions for use will help distinguish these products.</p>

Failure Mode: Name Confusion	Causes (could be multiple)	Rationale
<p>Dulera (Mometasone furoate/formoterol fumarate dihydrate)</p> <p>MDI: (b) (4), (b) (4) 100/5 mcg, 200/5 mcg</p>		<p>Usual Dose: 2 puffs every 12 hours (morning and evening)</p>
<p>Dolorex Forte (Acetaminophen/Hydrocodone)</p> <p>Tablets: 500 mg/5mg</p> <p>1 to 2 tablets every 4 to 6 hours as needed for pain</p>	<p>Orthographic Similarity: Orthographic similarity: both names contain the letters “D”, “I” and “r” in the same positions. Additionally, the vowels “o” and “o” can look similar to “u” and “a” when scripted.</p> <p>Share a numerically similar strength (50 mcg/5 mcg vs. 500 mg/5 mg)</p> <p>Share a numerical dosing similarity (2 tablets vs. 2 puffs)</p>	<p>Orthographic as well as product characteristic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>Rationale: The ending letter “x” and the modifier forte in Dolorex Forte help to provide distinction. Additionally, an order for Dulera will typically include “puffs” or it can be written as “use as directed”. However, Dolorex Forte is less likely to be written as “use as directed” and will likely include information such as prn, for pain, etc. Therefore the directions for use will help distinguish these products.</p>
<p>Dolobid (Diflunisal)</p> <p>Discontinued but generics available</p> <p>Tablets: 500 mg</p> <p>500 mg – 1000 mg every 8 to 12 hours</p>	<p>Orthographic Similarity: Orthographic similarity: both names contain the letters “D” and “I” in the same positions. Additionally, the vowels “o” and “o” can look similar to “u” and “a” when scripted.</p> <p>Share a numerically similar strength (50 mcg/5 mcg vs. 500 mg)</p> <p>Share overlapping frequency of administration (12 hours)</p>	<p>Orthographic differences minimize the likelihood of medication error in the usual practice setting.</p> <p>Rationale: Although there are similarities in the context of use for these products orthographic differences stem from the fact that the Dolobid contains 2 additional upstrokes (b and d) at the end of it’s name, in comparison to Dulera and the endings “bid” and “ra” do not appear similar.</p>

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