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RESEARCH**

APPLICATION NUMBER:

203202Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date: October 23, 2013

Reviewer: Loretta Holmes, BSN, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Northera (Droxidopa) Capsules
100 mg, 200 mg, and 300 mg

Application Type/Number: NDA 203202

Applicant: Chelsea Therapeutics, Inc.

OSE RCM #: 2013-2119

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Northera, 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. We previously reviewed this name in OSE Review 2008-1244, dated December 1, 2008 and OSE Review 2011-3917, dated December 28, 2011 and found the name acceptable.

1.1 PRODUCT INFORMATION

The following product information was provided in the August 13, 2013 proprietary name submission.

Table 1. XX Product Characteristics	
Active Ingredient	Droxidopa
Indication of Use	Northera is indicated for the treatment of symptomatic neurogenic orthostatic hypotension in adult patients with primary autonomic failure (Parkinson's Disease, Multiple System Atrophy and Pure Autonomic Failure), Dopamine Beta Hydroxylase Deficiency and Non-Diabetic Autonomic Neuropathy
Route of Administration	Oral
Dosage Form	Capsules
Strengths	100 mg, 200 mg, and 300 mg
Dose and Frequency	The recommended starting dose of Northera is 100 mg, taken orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum dose of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
How Supplied	Commercial: 90-count bottles Professional Sample: 21-count bottles
Storage	Store at room temperature, 20°C to 25°C (68°F to 77°F); excursions permitted to 15 °C to 30 °C (59 °F to 86 °F).
Container and Closure System	HDPE bottles (b) (4)
Intended Pronunciation of the Proposed Proprietary	Not provided
Derivation of the Proposed Proprietary Name	Not provided

2 RESULTS

The following sections provide 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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiovascular and Renal Products (DCRP) 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

There is no USAN stem present in the proposed proprietary name.¹

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide the drug name derivation or intended meaning in their submission of the proposed name. The proprietary name is comprised of a single word that does not contain any components such as a modifier, route of administration, dosage form, etc.

2.2.3 FDA Name Simulation Studies

Sixty-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with currently marketed products nor did they appear or sound similar to any currently marketed products or products pending in the pipeline. Two participants in the written outpatient study interpreted the letter "o" as the letter "a". We have considered the variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, September 25, 2013 e-mail, the Division of Cardiovascular and Renal Products (DCRP) 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

The potential letter and letter string variations listed in Appendix B were used to search for names with possible orthographic and phonetic similarity to the proposed proprietary name, Northera (see Table 1).

¹ USAN stem list searched September 20, 2013.

The name Northera has been previously reviewed. The product characteristics have not changed since our most recent review. 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. Our evaluation has not altered our previous conclusion regarding the previously identified names; therefore, they are not included in Table 1, below.

Our analysis of the 17 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 17 names will not pose a risk for confusion as described in Appendices D through E.

Table 1: Collective List of Potentially Similar Names from EPD					
Look Similar (n=17)					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	EPD Panel	Amethia	EPD Panel	Vertavis	EPD Panel
(b) (4)	EPD Panel	Materna	EPD Panel	Nestabs Rx	EPD Panel
Navelbine	EPD Panel	Marlissa	EPD Panel	Matulane	EPD Panel
Ranitidine	EPD Panel	Valtrex	EPD Panel	(b) (4)	EPD Panel
Mestinon	EPD Panel	Neulasta	EPD Panel	Verluma	EPD Panel
(b) (4)	Primary Safety Evaluator	Meritene	Primary Safety Evaluator		

2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products via e-mail on October 15, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products on October 18, 2013, they stated no additional concerns with the proposed proprietary name, Northera.

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 Cheryle Milburn, OSE Project Manager, at 301-796-2084.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 13, 2013 submission are altered, the name must be resubmitted for review.

4 REFERENCES

1. Micromedex Integrated Index (<http://csi.micromedex.com>)
Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.
2. ***Phonetic and Orthographic Computer Analysis (POCA)***
POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.
3. Drug Facts and Comparisons, online version, St. Louis, MO
(<http://factsandcomparisons.com>)
Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.
4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***
DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.
5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***
This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.
6. Drugs@FDA (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.
7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)
USPTO provides information regarding patent and trademarks.
8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)
Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***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.
10. ***Access Medicine*** (www.accessmedicine.com)
Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.
11. ***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.
12. ***Red Book*** (www.thomsonhc.com/home/dispatch)
Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.
13. ***Lexi-Comp*** (www.lexi.com)
Lexi-Comp is a web-based searchable version of the Drug Information Handbook.
14. ***Medical Abbreviations*** (www.medilexicon.com)
Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.
15. ***CVS/Pharmacy*** (www.CVS.com)
This database contains commonly used over the counter products not usually identified in other databases.
16. ***Walgreens*** (www.walgreens.com)
This database contains commonly used over the counter products not usually identified in other databases.
17. ***Rx List*** (www.rxlist.com)
RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.
18. ***Dogpile*** (www.dogpile.com)
Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

19. 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.²

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

² National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

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).

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ 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

⁴ 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

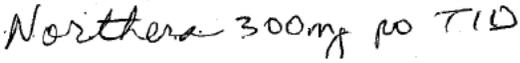
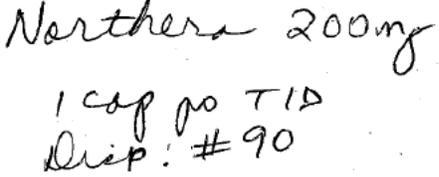
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Northera	Scripted May Appear as	Spoken May Be Interpreted as
N	M, V, U, W	DN, GN, KN, MN, PN
n	m, u, x, r, h, s	dn, gn, kn, mn, pn
o	a, c, e, u	Any vowel
r	s, n, e, v	
t	b, f, l, r, x, A	c, d, f, s
h	k, b, n, r, L	
e	a, c, i, l, o, p	Any vowel
r	s, n, e, v	
a	el, ci, cl, d, e, o, u	Any vowel
Letter Strings		
er	u	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Northera Study (Conducted on August 2, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Inpatient Medication Order:</u> 	Northera 200 mg 1 capsule po TID Disp. #30
<u>Outpatient Prescription:</u> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

				192 People Received Study
				68 People Responded
Study Name: Northera				
Total	27	18	23	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
MERCERA	0	1	0	1
NARTHERA	2	0	0	2
NORFERA	0	1	0	1
NORSERA	0	1	0	1
NORTHARA	0	1	0	1
NORTHERA	25	14	22	61
NOTHERA	0	0	1	1

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

No.	Drug Name	Active Ingredient	Similarity to Northera	Failure preventions
1.	Ranitidine	Ranitidine	Look	The pair have sufficient orthographic differences.
2.	Mestinon	Pyridostigmine Bromide	Look	The pair have sufficient orthographic differences.
3.	Amethia	Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol Tablets	Look	The pair have sufficient orthographic differences.
4.	Marlissa	Levonorgestrel and Ethinyl Estradiol	Look	The pair have sufficient orthographic differences.
5.	Valtrex	Valacyclovir	Look	The pair have sufficient orthographic differences.
6.	Neulasta	Pegfilgrastim	Look	The pair have sufficient orthographic differences.
7.	Nestabs Rx	Multiple ingredient multivitamin with minerals	Look	The pair have sufficient orthographic differences.
8.	Matulane	Procarbazine Hydrochloride	Look	The pair have sufficient orthographic differences.
9.	Vertavis	Veratrum Viride Root	Look	This product was withdrawn FR effective 11/05/1992. There are no generics available. Additionally, full product characteristic information is not available in our usual drug information databases.
10.	(b) (4)	Crofelemer	Look	The NDA for this product was approved under the name Fulyzaq.
11.	Meritene	“Nutritional supplement”	Look	Unable to find full product characteristic information in our usual drug information databases.

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

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.

	<u>Proposed name:</u> Northera (droxidopa) Capsules	<u>Strengths:</u> 100 mg, 200 mg, and 300 mg	<u>Usual Dose:</u> The starting dose is 100 mg orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
12.	(b) (4)		

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	<u>Proposed name:</u> Northera (droxidopa) Capsules	<u>Strengths:</u> 100 mg, 200 mg, and 300 mg	<u>Usual Dose:</u> The starting dose is 100 mg orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
13.	<div style="text-align: right;">(b) (4)</div>		

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

	<u>Proposed name:</u> Northera (droxidopa) Capsules	<u>Strengths:</u> 100 mg, 200 mg, and 300 mg	<u>Usual Dose:</u> The starting dose is 100 mg orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
14.	Navelbine (vinorelbine tartrate) Injection <u>Strength:</u> 10 mg/mL (1 mL and 5 mL vials) <u>Dosage:</u> <i>Single agent:</i> 30 mg/m ² intravenously once weekly <i>In combination with Cisplatin:</i> 25 mg/m ² or 30 mg/m ² <i>Dose modifications:</i> Reduce dose down to as low as 25% of the starting dose	<u>Orthographic:</u> The beginning letter strings “Nor” vs. “Nav” and ending letter strings “hera” vs. “bine” look similar when written. <u>Dose:</u> There is numerical similarity between the doses of the products (500 mg vs. 50 mg).	<u>Orthographic:</u> Northera contains the letter “t” which has a cross-stroke which helps to differentiate the names. Navelbine contains the letter “e” before the upstroke letters which helps to lengthen the middle portion of the name as compared to Northera. <u>Frequency of administration:</u> Three times per day vs. once weekly

	<u>Proposed name:</u> Northera (droxidopa) Capsules	<u>Strengths:</u> 100 mg, 200 mg, and 300 mg	<u>Usual Dose:</u> The starting dose is 100 mg orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
15.	<p>Materna (Ascorbic Acid (Vitamin C) 120mg, Biotin 30mcg, Calcium Carbonate 250mg, Chromic Chloride 25mcg, Cupric Oxide 2mg, Cyanocobalamin (Vitamin B12) 12mcg, Ferrous Fumarate 27mg, Folic Acid (Vitamin B9) 1mg, Magnesium Oxide 50mg, Manganese Sulfate 5mg, Molybdenum 25mcg, Niacinamide 20mg, Pantothenic Acid (Vitamin B5) 10mg, Potassium Iodide 0.15mg, Pyridoxine (Vitamin B6) 10mg, Riboflavin (Vitamin B2) 3.4mg, Selenium 20mcg, Thiamine Mononitrate (Vitamin B1) 3mg, Vitamin A 5000IU, Vitamin D 400IU, Vitamin E 30IU, Zinc Oxide 25mg) Tablet</p> <p><u>Strength:</u> Multiple ingredient product but the ingredient strengths would not be written on a prescription</p> <p><u>Dosage:</u> One tablet orally once daily</p>	<p><u>Orthographic:</u> The beginning letters “No” vs. “Ma” look similar when written. Both names contain the infix letters “t” and “er” and end with the letter “a”.</p> <p><u>Route of administration:</u> Both products are administered orally.</p>	<p><u>Orthographic:</u> Northera contains the additional upstroke letter “h” and the third position letter “r” which help to differentiate the names.</p> <p><u>Strength:</u> 100 mg, 200 mg, 300 mg (multiple strengths) vs. strength would not be specified on a prescription</p> <p>Northera is available in three strengths so the strength would have to be specified on a prescription whereas a strength would not be specified on a prescription for Materna.</p>

	<u>Proposed name:</u> Northera (droxidopa) Capsules	<u>Strengths:</u> 100 mg, 200 mg, and 300 mg	<u>Usual Dose:</u> The starting dose is 100 mg orally three times daily. The dose may be increased in increments of 100 mg three times daily every 24 to 48 hours up to a maximum of 600 mg three times daily (i.e., a maximum total daily dose of 1800 mg).
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
16.	Verluma (nofetumomab merpentan) Injection <u>Strength:</u> 10 mg/mL (1 mL vial) <u>Dosage:</u> 5 mg to 10 mg intravenously once	<u>Orthographic:</u> The beginning letter strings “Nor” vs. “Ver” look similar when the cross stroke on the letter “t” is not prominent. Both names end with the letter “a”. <u>Dose:</u> There is numerical similarity between the doses of the products (100 mg vs. 10 mg)	<u>Orthographic:</u> Northera contains the cross-stroke letter “t” and the additional upstroke letter “h” which helps to differentiate the names. The infix letters “er” vs. “um” look different when written. <u>Context of use:</u> Verluma is a radioactive product used as an imaging agent. The context of use, routes of distribution and method of dispensing differ between radioactive imaging agents and nonradioactive prescription products.
17.	(b) (4)		

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/s/

LORETTA HOLMES
10/23/2013

IRENE Z CHAN
10/23/2013

**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: December 28, 2011

Reviewer(s): Ray Ford, RPh, Safety Evaluator
Division of Medication Error Prevention and Analysis

Acting Division Director: Irene Z Chan, PharmD, BCPS
Division of Medication Error Prevention and Analysis

Drug Name(s): Northera (Droxidopa) Capsules
100 mg, 200 mg, and 300 mg

Application Type/Number: NDA 203202

Applicant/sponsor: Chelsea Therapeutics, Inc.

OSE RCM #: 2011-3917

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Northera, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Northera was evaluated by the Division of Medication Error Prevention and Analysis (DMEPA) during the IND phase (IND 077248) in OSE review # 2008-1244 dated December 1, 2008. DMEPA found the name conditionally acceptable. The applicant submitted an amendment on January 3, 2012 in accordance with Guidance for Industry Submission for the Evaluation of Proprietary Names. This amendment meets the requirements put forth in the above guidance for the Evaluation of Proprietary Names.

1.2 PRODUCT INFORMATION

The following product information is provided in the October 07, 2011 proprietary name submission.

- Established Name: Droxidopa
- Indication of Use: Northera is indicated for the treatment of neurogenic symptomatic orthostatic hypotension in patients with primary autonomic failure, including multiple system atrophy (Shy-Drager syndrome), pure autonomic failure, Parkinson's disease (cerebrovascular parkinsonism), dopamine- β -hydroxylase deficiency and nondiabetic autonomic neuropathy (amyloid and autoimmune).
- Route of administration: Oral
- Dosage form: Capsules
- Strength: 100 mg, 200 mg, and 300 mg
- Dose: The recommended dose is 300 mg to 900 mg per day in three divided doses (minimum dose 300 mg/day, 100 mg three times daily; usual dose is 900 mg/day, 300 mg three times daily). The maximum recommended dose in a 24-hour period is 1,800 mg (600 mg three times per day).
- How Supplied: 21 count professional sample bottles and 90 count retail bottles
- Storage: Northera is to be stored at 25° Celsius (77° Fahrenheit); excursions to 15° Celsius to 30° Celsius (59° Fahrenheit to 86 ° Fahrenheit) are permitted [see USP Controlled Room Temperature]
- Container and Closure systems: high density polyethylene bottles

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's promotional assessment of the proposed name. The Applicant submitted an external proprietary name promotional assessment; however, this was the same promotional assessment that was previously submitted when we reviewed the name Northera in OSE review # 2008-1244 dated December 1, 2008. The findings of the external proprietary name promotional assessment were the same as the findings of OPDP's promotional assessment.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

On November 8, 2011, the United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation of the name in the name submission. 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.

2.2.5 FDA Name Simulation Studies

Forty practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Thirty-five practitioners interpreted the proposed name, Northera, correctly. All 14 voice prescriptions were interpreted as Northera. In the outpatient written study, 9 out of 10 participants correctly identified Northera. In the inpatient written study, 2 of the 16 participants misinterpreted the "n" as an "h." See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

1.2.5 Comments from Other Review Disciplines

In response to the OSE, November 7, 2011 e-mail, the Division of Cardiovascular and Renal Products (DCRP) forwarded one comment relating to the proposed name at the initial phase of the proprietary name review: "*Might this sound too much like Ortho Evra, the birth control pill?*" We previously reviewed the name Ortho Evra orthographically and phonetically in OSE review # 2008-1244 dated December 1, 2008. The product characteristics for Northera have not changed since our last review; therefore, we will not re-review the name Ortho Evra.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Northera. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Northera, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. The Applicant submitted an external proprietary name safety assessment conducted by (b) (4) however, this was the same safety assessment that was previously submitted when we reviewed the name Northera in OSE review # 2008-1244 dated December 1, 2008. Since the product characteristics for Northera have not changed since our last review, we will not re-review previously identified names of concerns; therefore, such names have not been included in Table 1.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Heather	FDA	Norcuron	FDA	Strattera	FDA
Kelnor	FDA	Norfloxacin	FDA	Valturna	FDA
Martinic	FDA	Norgesic	FDA	Verdeso	FDA
Methadone	FDA	Norinyl	FDA	Vistaril	FDA
Morphine	FDA	Norlutate	FDA	Vitrase	FDA
Natachew	FDA	Norlutin	FDA	Voltaren	FDA
Natracor	FDA	Normiflo	FDA	Westhroid	FDA
Natroba	FDA	Nortin (international name)	FDA	Zithromax	FDA
Natrova	FDA	Nuvelo	FDA	Zorbtive	FDA
Noratuss	FDA	Restora	FDA	Zortress	FDA
Sound Similar					
Mircera	FDA	Provera	FDA		
Look and Sound Similar					
Nephron FA	FDA	Nordette	FDA	Nortala	FDA

Our analysis of the 35 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 35 names do not pose a risk for confusion as described in Appendices D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products via e-mail on December 15, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products on December 21, 2011, they stated no additional concerns with the proposed proprietary name, Northera.

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 Nina Ton, OSE project manager, at 301-796-1648.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Northera, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 07, 2011 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 the 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)

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

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

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

13. Red Book Pharmacy's Fundamental Reference

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

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

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

15. Medical Abbreviations Book

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

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

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

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

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

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

¹ 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.² The product characteristics considered for this review appears in Appendix B1 of this review.

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

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

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

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

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

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

1. Database and Information Sources

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

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

characteristics listed in Appendix B1 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, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘N’	M, V, U, W	DN, GN, KN, MN, PN
Lowercase ‘n’	m, u, x, r, h, s	dn, gn, kn, mn, pn
Lowercase ‘o’	a, c, e, u	dn, gn, kn, mn, pn
Lowercase ‘r’	s, n, e, ,v	N/A
Lowercase ‘t’	r, f, x, A	d
Lowercase ‘h’	k, b, n, L	N/A
Lowercase ‘e’	a, i, l, o, u, p	Any vowel
Lowercase ‘r’	s, n, e, ,v	N/A
Lowercase ‘a’	el, ci, cl, d, o, u	Any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Northera Study (Conducted on 10/20/2011)

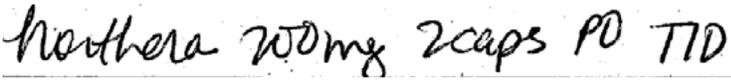
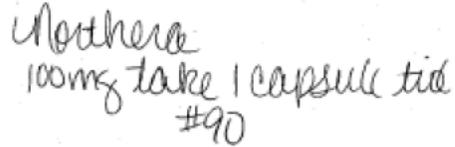
Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p>	<p>Northera 200 mg take 2 capsule orally three times daily</p>
<p><u>Outpatient Prescription:</u> </p>	

Figure 2. Northera Prescription Simulation Studies (Conducted 11/16/2011)

FDA Prescription Simulation Responses (n=40).

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
HORTHERA	1	0	0	1
HORTHERA (NORTHERA?)	1	0	0	1
NORHERA	0	0	1	1
NORTHERA	12	14	9	35
NOTHERA	1	0	0	1
NSITHERA	1	0	0	1

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

	Proprietary Name	Similarity to Northera	Active Ingredient	Failure preventions
1	Natrova	Look Alike	Spinosad	The proposed proprietary name Natrova was found unacceptable in OSE Review 2009-407 The name Natrova was replaced with Natroba and found acceptable in OSE Review 2010-1633.
2	Nuvelo	Look Alike	Alfimiprase	Lack of orthographic similarity
3	Noratuss	Look Alike	Dextromethorphan, guaifenesin, pseudoephedrin	Lack of orthographic similarity
4	Norlutate	Look Alike	Norethindrone 0.35 mg	Canadian oral contraceptive marketed outside of United States.
5	Normiflo	Look Alike	Ardeparin Sodium	There are no generic equivalents available. The application has been withdrawn FR Effective 02/11/2002.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
6	<p>Heather (Norethindrone)</p> <p><u>Dosage form</u> Tablets</p> <p><u>Strength</u> 0.35 mg</p> <p><u>Usual dosage</u> One tablet daily</p>	<p>Orthographic similarity ‘N’ and ‘H’ appear similar when scripted</p> <p>Both drugs have ‘th’ as the fourth and fifth letter</p> <p>Both names have similar length</p> <p>Both names end in similar letters ‘ther’</p> <p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both have solid oral dosage forms</p> <p><u>Route of administration</u> Both are given orally</p>	<p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Heather is available as a single strength and may not be written. There is no overlap in strength</p> <p><u>Frequency of administration</u> Three times daily vs. once daily</p>
7	<p>Kelnor (Norethindrone 0.35 mg)</p> <p><u>Dosage form</u> Tablets</p> <p><u>Strength</u> 0.35 mg</p> <p><u>Usual dosage</u> One tablet daily</p>	<p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both have solid dosage forms</p> <p><u>Route of administration</u> Both are given orally</p> <p><u>Dosage</u> Both can be written on a prescription as 1 tablet or capsule</p>	<p>Orthographic differences ‘Nor’ in Nothera and ‘Kel’ lack orthographic similarity when scripted.</p> <p>Northera contains two up-strokes in the fourth and fifth position vs. Kelnor has an up-stroke in third position</p> <p>Northera contains a cross-stroke in the fourth position vs. Kelnor does not contain a cross- stroke</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily	
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)	
		<p>Differing product characteristics</p> <p><u>Frequency of administration</u> Northera is taken three times daily vs. Kelnor is taken daily</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Kelnor is available as a single strength and may not be written. There is no overlap in strength</p>	
8	<p>Martinic (Multivitamin contains Vitamin C, Vitamin B12, Folic Acid, Ferrous Fumarate, Liver Stomach Concentrate)</p> <p><u>Dosage form</u> Capsules</p> <p><u>Strength</u> Combined in capsule: Vitamin C- 75 mg, Vitamin B12- 15 micrograms, Folic Acid 0.5 mg, Ferrous Fumarate 110 mg, Liver Stomach Concentrate 240 mg</p> <p><u>Usual dosage</u> One capsule twice daily</p>	<p>Orthographic similarity ‘Nor’ in Northera appears similar to ‘Mar’ in Martinic when scripted</p> <p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both medications are available as capsules</p> <p><u>Route of administration</u> Oral</p>	<p>Orthographic differences Northera contains three up strokes vs. Martinic contains two up stroke</p> <p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Martinic is available as a single strength and may not be written. There is no overlap in strength.</p> <p><u>Frequency of administration</u> Northera is taken three times daily vs. Martinic is taken twice daily</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<p>9</p> <p>Methadone is the established name</p> <p><u>Dosage form</u> Tablet, injection, solution, suspension</p> <p><u>Strength</u> 5 mg, 10 mg, injection (10 mg/mL), solution (1 mg/mL, 2 mg/mL, 10 mg/mL), 40 mg tablet for suspension</p> <p><u>Usual dosage</u> Titrated up to the dose that provides adequate pain control every 8 hours; for opioid dependence, methadone is administered on a daily basis; for drug detoxification administration is based on symptoms</p>	<p>Orthographic similarity Both start with similar appearing letters ‘No’ and ‘Me’</p> <p>Northera has a ‘th’ in a similar position as in Methadone</p> <p>Overlapping Product Characteristics <u>Strength</u> 100 mg vs 10 mg numerical overlap</p> <p><u>Dosage form</u> Tablets</p> <p><u>Route of administration</u> Oral</p> <p><u>Frequency of administration</u> Both drugs can be given several times daily</p>	<p>Orthographic differences Northera has three up strokes vs. Methadone has four up strokes which appears different when scripted</p> <p>Northera has a shorter length than Methadone when scripted</p> <p>Northera ends with ‘era’ which appears different from ‘done’ in methadone when scripted</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
10 Morphine is the established name <u>Dosage form</u> Tablet, capsule, solution, suppository, injection <u>Strength</u> Kadian®: (10 mg, 20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg); Solution, oral, as sulfate [concentrate]: 100 mg/5 mL; MS Contin®: 15 mg, 30 mg, 60 mg, 100 mg, 200 mg; Extended Release, oral, as sulfate: 15 mg, 30 mg, 60 mg, 100 mg, 200 mg, sustained Release, oral, as sulfate: Oramorph® SR: 15 mg, 30 mg, 60 mg, 100 mg <u>Usual dosage</u> 10 mg to 30 mg every 4 hours or as needed depending on dosage form	Orthographic similarity Northera begins with ‘nor’ vs. Morphine ‘mor’ which appear similar when scripted Northera and Morphine contain an upstroke in the fifth position Northera ends with ‘era’ vs. Morphine ‘ine’ which appear similar when scripted Overlapping Product Characteristics <u>Frequency of administration</u> Both drugs can be given three times daily <u>Dosage form</u> Capsules <u>Route of administration</u> Oral <u>Strength</u> Both drugs have a 100 mg and 200 mg strength available	Orthographic differences Northera contains two up strokes in the third and fourth position vs. Morphine has a down stroke and then an up stroke in the third and fourth position which appear different when scripted Differing Product Characteristics Morphine is a controlled class II medication that requires additional security measures and written prescription requirements be used since this is a medication with high abuse potential.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
11	<p>Natachew (Prenatal vitamins)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> Contains: Vitamin A 1,000 units , vitamin D 3 -11 International Units, Vitamin C 120 mg, Folic Acid 1 mg, Thiamine 2 mg, Riboflavin 3 mg, Niacinamide 20 mg, Vitamin B 6, 10 mg, Vitamin B 12 12 mcg, ferrous fumarate 29 mg</p> <p><u>Usual dosage</u> One tablet daily</p>	<p>Orthographic similarity Northera and Natachew begin with ‘N’</p> <p>Both names have many letter that appear similar when scripted (a, e, o)</p> <p>Both names have a similar length when scripted</p> <p>Overlapping Product Characteristics <u>Dosage form</u> Solid oral dosage forms</p> <p><u>Route of administration</u> Oral</p>	<p>Orthographic differences Northera contains two up strokes adjacent to one another in the middle of the name vs. Natachew has two up stokes separated by two letters which appear different when scripted</p> <p>Differing product characteristics <u>Frequency of administration</u> Northera is given three times daily vs. Natachew is given once daily</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Natachew is available as a single strength and may not be written. There is no overlap in strength.</p>
12	<p>Natreacor (Nesiritide)</p> <p><u>Dosage form</u> Injection: powder for reconstitution: 1.5 mg per vial</p> <p><u>Strength</u> 1.5 mg per vial</p> <p><u>Usual dosage</u> Acute decompensated</p>	<p>Orthographic similarity ‘Nor’ and ‘Nat’ appear similar when scripted</p> <p>Both names contain an up-stroke in a similar position \</p> <p>Both names are similar in length</p>	<p>Orthographic differences Northera contains two up strokes adjacent to each other vs. Natreacor has only one up stroke making it appear different when scripted</p> <p>Differing product characteristics <u>Frequency of administration</u> Three times daily vs. bolus then infusion times one</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

<p>PROPOSED NAME: Northera (Droxidopa) Capsules</p>	<p>STRENGTH: 100 mg, 200 mg, and 300 mg</p>	<p>USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily</p>
<p>FAILURE MODE: Name Confusion</p>	<p>CAUSES: (Potential reasons for name confusion that could lead to medication error)</p>	<p>PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)</p>
<p>heart failure: Intravenous: Initial: 2 mcg/kg (bolus optional); followed by continuous infusion at 0.01 mcg/kg/minute.</p>		<p><u>Dosing</u> 100 mg, 200 mg, 300 mg vs. 2 mcg/kg or 0.01 mcg/kg/minute in a controlled setting for heart failure</p>
<p>13 Natroba (Spinosad)</p> <p><u>Dosage form</u> Topical suspension</p> <p><u>Strength</u> 1 %</p> <p><u>Usual dosage</u> Shake bottle well. Apply sufficient NATROBA Topical Suspension to cover dry scalp, then apply to dry hair. Depending on hair length, apply up to 120 mL (one bottle) to adequately cover scalp and hair. Leave on for 10 minutes, then rinse NATROBA Topical Suspension with warm water. If live lice are seen 7 days after the first treatment, a second treatment should be applied.</p>	<p>Orthographic similarity Both names have an up-stroke in similar position</p> <p>Both names have many letter that appear similar when scripted (a, o)</p> <p>Both names are similar in length</p>	<p>Orthographic differences Northera has two up-strokes that are adjacent to each other vs. Natroba has two letters in between the two up-strokes</p> <p>Differing product characteristics <u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Natroba is available as a single strength and may not be written. There is no overlap in strength.</p> <p><u>Frequency of administration</u> Three times daily vs. once</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<p>14</p> <p>Nephron FA (multivitamin with folic acid)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> Vitamin C 40 mg, Thiamin 1.5 mg,, Ribloflavin 1.7 mg, Nicain 20 mg, Vitamin B6 10 mg, Folate 1,000 micrograms, Vitamin B12 6 micrograms, Biotin 800 micrograms, Pantothenic Acid 10 mg, Iron 66 mg</p> <p><u>Usual dosage</u> One tablet daily without food</p>	<p>Orthographic similarity Both names begin with ‘N’ and are of similar length</p> <p>Phonetic similarity Both names start with and ‘N’ sound when spoken</p> <p>Northera ‘th’ may sound similar to ‘ph’ when spoken</p> <p>Overlapping Product Characteristics <u>Dosage form</u> Both are solid dosage forms</p> <p><u>Route of administration</u> Both are taken orally</p>	<p>Orthographic differences Northera has two up-strokes that are adjacent to each other and does not have a modifier vs. Nephron FA has an up stroke and down stroke adjacent with no letter in between</p> <p>Phonetic differences Northera has three syllables vs. Nephron FA has two syllables and a modifier with two syllables</p> <p>Northera ‘ther’ sounds different than ‘phron’ in Nephron FA when spoken</p> <p>Northera is pronounced beginning with a nasal alveolar /n/ followed by a back open-mid / / then post-aveolar approximant /r/ in the first syllable. Nephron FA is pronounced beginning with a nasal alveolar /n/ followed by an front open-mid /ε/ then a labio-dental fricative /f/ in the first syllable. These two syllables sound different when spoken.</p> <p>Differing product characteristics <u>Frequency of administration</u> Three times daily vs. once daily</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Nephron FA is available as a single strength and may not be written. There is no overlap in strength.</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
15	<p>Norcuron (Vecuronium)</p> <p><u>Dosage form</u> Injection</p> <p><u>Strength</u> Vials 10 mg and 20 mg for reconstitution</p> <p><u>Usual dosage</u> 80 mcg/kg to 100 mcg/kg for intubation</p>	<p>Orthographic similarity Both names start with 'Nor'</p> <p>Both names have similar length</p> <p>Both names have many letter that appear similar when scripted (o, e, u)</p> <p>Overlapping product characteristics Strength The strength of each drug will be written on a prescription</p>	<p>Orthographic differences Northera has two up-strokes in the middle of the name vs. Norcuron has none making it appear different when scripted</p> <p>Differing product characteristics <u>Frequency of administration</u> Three times daily vs. as needed prior to procedure</p> <p><u>Dose</u> 100 mg, 200 mg, 300 mg vs 80 micrograms to 100 mcg/kg dosing range; no dose overlap</p>
16	<p>Nordette (Ethinyl Estradiol and Levonorgestrel)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> Ethinyl estradiol 0.03 mg and levonorgestrel 0.15 mg</p> <p><u>Usual dosage</u> 1 tablet daily for 21 or 28 days</p>	<p>Orthographic similarity -Both names start with 'Nor'</p> <p>-Both names have similar length</p> <p>Both names have many letter that appear similar when scripted (o, e)</p> <p>Phonetic similarity Both names being with the 'Nor' sound when spoken</p>	<p>Orthographic differences Northera has two up strokes in the middle of the name vs. Nordette has one up stroke, one letter, and then two up strokes that appear different when scripted</p> <p>Phonetic differences The second syllable in Northera begins with a dental affricative /θ/ then front open-mid /ε/ followed by a post-alveolar approximant /r/ vs. the second syllable in Nordette which starts with an alveolar plosive /d/ then front open-mid /ε/ followed by an alveolar plosive /t/ which sound different when spoken.</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
	<p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Tablets</p> <p><u>Route of administration</u> Oral</p>	<p>Northera contains three syllables vs. Nordette has two syllables</p> <p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Nordette is available as a single strength and may not be written. There is no overlap in strength.</p> <p><u>Frequency of administration</u> Three times daily vs. daily</p>
<p>17 Norfloxacin is the established name</p> <p><u>Dosage form</u> Tablet, ophthalmic solution</p> <p><u>Strength</u> 400 mg, 0.3 %</p> <p><u>Usual dosage</u> One tablet is taken every 12 hours for various durations; Solution-one drop four times daily for up to 7 days</p>	<p>Orthographic similarityBoth names start with ‘Nor’</p> <p>Both names have many letter that appear similar when scripted (o, a)</p> <p>Both name contain two up-strokes in the same position</p> <p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both drugs are available as solid dosage forms</p> <p><u>Frequency of administration</u></p>	<p>Orthographic differences</p> <p>Northera does not contain a down stroke vs. Norfloxacin does contain a down stroke</p> <p>Northera appears shorter (8 letters) than Norfloxacin (11 letters) when scripted</p> <p>Northera has an ‘a’ suffix vs. ‘acin’ in Norfloxacin which appears different when scripted</p> <p>Differing product characteristics</p> <p><u>Frequency of administration</u> Northera must specify three times daily on a prescription vs. Norfloxacin twice daily (tablet) or four times daily (solution)</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Norfloxacin is available as a</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
	Both drugs can be administered several times daily <u>Route of administration</u> Oral	single strength tablet and solution which may not be written. .There is no overlap in strength.
18 <p>Norgesic (Orphenadrine, Aspirin, and Caffeine)</p> <p><u>Dosage form</u> Tablets</p> <p><u>Strength</u> Norgesic Forte: (Orphenadrine 25 mg, Aspirin 385 mg, and Caffeine 30 mg) Compound-DS: Orphenadrine 50 mg, Aspirin 770 mg, and Caffeine 60 mg);</p> <p><u>Usual dosage</u> For muscular pain/spasms: 1-2 tablets 3-4 times/day</p>	<p>Orthographic similarity Both names begin with ‘Nor’</p> <p>Both names have similar length</p> <p>Both names have many letter that appear similar when scripted (o, c, e, i, a)</p> <p>Overlapping Product Characteristics <u>Dosage form</u> Both are available as solid dosage forms <u>Route of administration</u> Oral</p> <p><u>Frequency of administration</u> Both can be given three times daily</p>	<p>Orthographic differences Northera contains two up strokes in the middle of the name vs. Norgesic contains one down stroke making them appear different when scripted.</p> <p>Differing product characteristics <u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Norgesic is available as a single strength and may not be written. There is no overlap in strength.</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
19 Norinyl (Ethinyl Estradiol and Norethindrone) <u>Dosage form</u> Tablets <u>Strength</u> Ethinyl estradiol 0.035 mg and norethindrone 1 mg <u>Usual dosage</u> One tablet daily	Orthographic similarity Both names begin with ‘Nor’ Both names have similar length Both names have many letters that appear similar when scripted (a, e, i) Overlapping Product Characteristics <u>Dosage form</u> Both are solid dosage forms <u>Route of administration</u> Both are taken orally	Orthographic differences Northera contains 3 up strokes vs. Norinyl contains two up strokes. The position of the up stroke is different. Norinyl contains a down stroke which is absent in Northera. Differing product characteristics <u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Norinyl is available as a single strength and may not be written. There is no overlap in strength. <u>Frequency of administration</u> Three times daily vs. once daily
20 Norlutin (Norethindrone) <u>Dosage form</u> Tablet <u>Strength</u> 5 mg	Orthographic similarity Both names begin with ‘Nor’ Both names have at least one upstroke in the fourth position Both names have similar	Orthographic differences Northera has two up stokes in the middle of the name vs. Norlutin has one up stroke, one letter, then one up stroke making the names appear different when scripted. Differing product characteristics <u>Strength</u> Northera is available in multiple strengths

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
	<u>Usual dosage</u> One tablet daily	length Overlapping Product Characteristics <u>Dosage form</u> Both are tablets <u>Route of administration</u> Both are taken orally	which must be specified on a prescription to be dispensed vs. Norlutin is available as a single strength and may not be written. There is no overlap in strength. <u>Frequency of administration</u> Three times daily vs. daily
21	Nortala (Nitroglycerin 0.4%) <u>Dosage form</u> Ointment <u>Strength</u> 0.4 % <u>Route of administration</u> Intra-anally <u>Usual dosage</u> One application intra- anally every 12 hours	Orthographic similarity Both names begin with 'Nor' Both names have similar length Both names have many letters that appear similar when scripted (a, e) Both names end in 'a' Phonetic similarities Both names begin with the 'Nor' prefix sound	Orthographic differences Northera has two up stokes together vs. Nortala has one up stroke separated by a letter and then another up stroke which appear different when scripted Phonetic differences The second syllable in Northera begins with a dental affricative /θ/ then front open-mid /ɛ/ followed by a post-alveolar approximant /ɹ/ vs. the second syllable in Nortala which begins with an alveolar plosive /t/ followed by back near open /ɑ/ Differing product characteristics <u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Nortala is available as a single strength and may not be written. There is no overlap in strength.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
22	<p>Nortin (international name)</p> <p>Tablet, oral: Diane-35: Cyproterone 2 mg and ethinyl estradiol 0.035 mg (21-tablet pack)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> Cyproterone 2 mg and ethinyl estradiol 0.035 mg</p> <p><u>Route of administration</u> Oral</p> <p><u>Usual dosage</u> One tablet daily for 21 days then off for 7 days</p>	<p>Orthographic similarity Both names begin with ‘Nor’</p> <p>Both names have many letter that appear similar when scripted</p> <p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both are tablets</p> <p><u>Route of administration</u> Both are taken orally</p>	<p>Orthographic differences Northera appears longer with 8 letters vs. Nortin 6 letters when scripted</p> <p>Northera has two up strokes in the middle of the name vs. one up stroke in Nortin which appear different when scripted</p> <p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Nortin is available as a single strength and may not be written. There is no overlap in strength..</p> <p><u>Frequency of administration</u> Three times daily vs. once daily</p>
23	<p>Restora (Lactobacillus casei K 99 enhanced with omega-3)</p> <p><u>Dosage form</u> Capsules</p>	<p>Orthographic similarity ‘n’ and ‘r’ appear similar when scripted</p> <p>Both names have similar length</p>	<p>Orthographic differences Northera has two up strokes in the middle of the name vs. Restora has one up stroke</p> <p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<u>Route of administration</u> Oral <u>Strength</u> Omega 3 fish oil 400 mg, Lactobacillus casei (KE-99) 4 billion colony forming units <u>Usual dosage</u> One capsule daily	Both names have many letters that appear similar when scripted (e, o) Both names end in ‘a’ Overlapping Product Characteristics <u>Dosage form</u> Both come as capsules <u>Route of administration</u> Both are given orally	which must be specified on a prescription to be dispensed vs. Restora is available as a single strength and may not be written. There is no overlap in strength. <u>Frequency of administration</u> Three times daily vs. once daily
24 Strattera (Atomoxetine) <u>Dosage form</u> Capsules <u>Strength</u> 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg <u>Route of administration</u> Oral <u>Usual dosage</u> One capsule daily	Orthographic similarity ‘n’ and ‘s’ appear similar when scripted Both names share letters strings ‘t’ and ‘era’ in similar locations Both names have similar length Overlapping Product Characteristics <u>Dosage form</u> Capsules <u>Strength</u> Both drugs have a 100 mg strength <u>Route of administration</u> Oral	Orthographic differences The prefix ‘Str’ contains an up stroke and appears different from the prefix ‘Nor’ when scripted. Differing product characteristics <u>Frequency of administration</u> Three times daily vs. daily

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
25	<p>Valturna (Aliskiren and Valsartan)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> Aliskiren 150 mg and Valsartan 160 mg</p> <p><u>Route of administration</u> Oral</p> <p><u>Usual dosage</u> One tablet daily</p>	<p>Orthographic similarity ‘N’ and ‘V’ appear similar when scripted</p> <p>Both name contain a ‘t’ in the same position</p> <p>Both names have similar length</p> <p>Both names have many letters that appear similar when scripted (a, e, u)</p> <p>Both names end in ‘a’</p> <p>Overlapping Product Characteristics <u>Dosage form</u> Tablet</p> <p><u>Route of administration</u> Oral</p>	<p>Differing product characteristics <u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Valturna is available as a single strength and may not be written. There is no overlap in strength.</p> <p><u>Frequency of administration</u> Three times daily vs. daily</p>
26	<p>Verdeso <u>Dosage form</u> Foam</p> <p><u>Strength</u> Foam 0.05%</p> <p><u>Route of administration</u> Topical</p>	<p>Orthographic similarity ‘N’ and ‘V’ appear similar when scripted</p> <p>Both name contain a up stroke in the same position</p> <p>Both names have many letters that appear similar when scripted (a, e, o)</p>	<p>Orthographic differences Northera contain two up strokes in the middle of the name vs. Vistaril has one in the middle and one at the end of name which appear different when scripted</p> <p>Differing Product Characteristics <u>Strength</u> Northera is available in multiple strengths</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
		which must be specified on a prescription to be dispensed vs. Verdosol is available as a single strength and may not be written. There is no overlap in strength <u>Frequency of administration</u> Three times daily vs. twice daily <u>Dosage form</u> Tablets vs. Foam
27	Vistaril (Hydroxyzine) <u>Dosage form</u> Tablets, capsules <u>Strength</u> Capsules: 25 mg, 50 mg, 100 mg, Tablets: 10 mg, 25 mg, 50 mg, injection: (25 mg/ml, 50 mg/ml) <u>Route of administration</u> Oral, injection <u>Usual dosage</u> 50 mg to 100 mg as needed or four times daily	Orthographic similarity ‘N’ and ‘V’ appear similar when scripted Both name contain a ‘t’ in the same position Both names have many letters that appear similar when scripted (a, e, i) Overlapping Product Characteristics <u>Strength</u> Both available as 100 mg <u>Frequency of administration</u> Both products can be administered three times daily <u>Dosage form</u> Both are available as capsules

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
	<u>Route of administration</u> Oral	
28 <p>Vitrise (Hyaluronidase)</p> <p><u>Dosage form</u> Injection</p> <p><u>Strength</u> 200 units/mL</p> <p><u>Route of administration</u> Subcutaneously</p> <p><u>Usual dosage</u> Add 15 units to each 100 mL of intravenous fluid to be administered subcutaneously or 150 units followed by subcutaneous isotonic fluid administration ≥1000 mL</p>	<p>Orthographic similarity ‘N’ and ‘V’ appear similar when scripted</p> <p>Both name contain a ‘t’ in a similar position</p> <p>Both names have similar length</p> <p>Both names have many letters that appear similar when scripted (a, e, i, o)</p> <p><u>Frequency of administration</u> Both products may be administered several times daily</p> <p><u>Route of administration</u> Both can be adminstered by a single route which may be omitted on the prescription</p>	<p>Orthographic differences Northera contains two up strokes in the middle of the name vs. Vitrise contains only one up stroke</p> <p>Differing product characteristics <u>Strength/Dose</u> Northera strength must be specified on a prescription to dispense vs. the units of vitrase for the dose must be specified for injection into specific areas. There is no overlap.</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
29	<p>Voltaren (Diclofenac)</p> <p><u>Dosage form</u> Tablets, Capsules, Gel</p> <p><u>Strength</u> 25 mg, 50 mg, 75 mg, 100 mg</p> <p><u>Route of administration</u> Oral</p> <p><u>Usual dosage</u> One tablet or capsule three times daily or every 8 hours</p>	<p>Orthographic similarity ‘N’ and ‘V’ appear similar when scripted</p> <p>Both name contain an up- stroke ‘t’ in a similar position</p> <p>Both contain two up- strokes in a similar position</p> <p>Overlapping Product Characteristics</p> <p><u>Strength</u> Both drugs have a 100 mg strength</p> <p><u>Dosage form</u> Both have solid dosage forms</p> <p><u>Frequency of administration</u> Both are given three times daily</p> <p><u>Route of administration</u> Oral</p>	<p>Orthographic differences The ‘r’ in the third position in Northera lengthens the distance between the first letter ‘N’ and the upstroke ‘t’ when compared to Voltaren. Additionally, the ‘n’ at the end of Voltaren lengthens the suffix of the name in comparison to Northera.</p>
30	<p>Westhroid (Thyroid Desiccated)</p> <p><u>Dosage form</u> Tablets</p>	<p>Orthographic similarity N’ and ‘W’ appear similar when scripted</p> <p>Both name contain an up- stroke ‘th’ in a similar</p>	<p>Differing product characteristics</p> <p><u>Strength</u> Northera is available in multiple strengths which must be specified on a prescription to be dispensed vs. Westhroid is available in multiple strengths that must be specified.</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<p><u>Strength</u> 16.25 mg, 32.5 mg, 48.75 mg, 60 mg, 65 mg, 97.5 mg, 130 mg, 162.5 mg, 180 mg, 260 mg, 325 mg</p> <p><u>Route of administration</u> Oral</p> <p><u>Usual dosage</u> One tablet daily</p>	<p>position</p> <p>Both names have similar length</p> <p>Both names have many letters that appear similar when scripted (e, i, o)</p> <p>Overlapping Product Characteristics</p> <p><u>Dosage form</u> Both are solid dosage forms</p> <p><u>Route of administration</u> Oral</p>	<p>There is no overlap in strength.</p> <p><u>Frequency of administration</u> Three times daily vs. once daily</p>
<p>31 Zithromax (Azithromycin)</p> <p><u>Dosage form</u> Tablet, suspension</p> <p><u>Strength</u> Tablet: 250 mg, 500 mg, 600 mg Suspension: 100 mg/ 5 ml, 200 mg/5 ml, 1 gram packets</p>	<p>Orthographic similarity ‘N’ and ‘Z’ appear similar when scripted</p> <p>Both name contain an upstroke ‘th’ in a similar position</p> <p>Both names have similar length</p> <p>Both names have many letters that appear similar</p>	<p>Orthographic differences The suffix ‘-max’ in zithromax contains a cross stroke in the ‘x’ and appears different from the suffix ‘-era’ in Northera. Additionally, the letters ‘ro’ in zithromax lengthen the distance from the upstroke to the end of the name in comparison to Northera.</p> <p>Differing product characteristics <u>Frequency of administration</u> Three times daily vs. once daily</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<u>Route of administration</u> Oral <u>Usual dosing frequency</u> 500 mg day one then 250 mg daily for 4 days, 1 gram once, or 10 mg/kg once then 5 mg/kg once daily for 4 days	when scripted (e, i, o) Overlapping Product Characteristics <u>Dosage form</u> Both are available as solid dosage forms <u>Route of administration</u> Oral <u>Strength</u> Numerical overlap 100 mg vs. 10 mg	
32 Zorbtive (Somatropin) <u>Dosage form</u> Injection <u>Strength</u> 8.8 mg <u>Route of administration</u> subcutaneously <u>Usual dosage</u> 0.1 mg/kg subcutaneously daily to a maximum of 8 mg daily for 4 weeks.	Orthographic similarity - Nor' and 'Zor' appear similar when scripted Both name contain two upstrokes in a similar position Both names have similar length Both names have many letters that appear similar when scripted (e, i, o)	Differing product characteristics <u>Strength</u> Northera is available in multiple strengths vs. Zorbitive is single strength and there is no strength overlap <u>Dose</u> One capsule vs 0.1 mg/kg (maximum dose is 8 mg); no dose overlap <u>Frequency of administration</u> Three times daily vs. once daily for 4 weeks.

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules		STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion		CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
33	<p>Zortress (Everolimus)</p> <p><u>Dosage form</u> Tablet</p> <p><u>Strength</u> 0.25 mg, 0.5 mg, 0.75 mg</p> <p><u>Route of administration</u> Oral</p> <p><u>Usual dosage</u> Starting oral dose of 0.75 mg twice daily</p>	<p>Orthographic similarity ‘Nor’ and ‘Zor’ appear similar when scripted</p> <p>Both name contain one up- strokes in a similar position</p> <p>Both names have similar length</p> <p>Both names have many letters that appear similar when scripted (a, e, o)</p> <p>Overlapping Product Characteristics <u>Frequency of administration</u> Both products can be administered several times daily</p> <p><u>Route of administration</u> Oral</p> <p><u>Dosage form</u> Both drugs are available as solid dosage forms</p>	<p>Orthographic differences Northera has two up strokes in the middle of the name vs. Zortress has only one up strokes which appear different when scripted.</p> <p>Differing product characteristics <u>Strength</u> Both products are available in multiple strengths which must be specified on a prescription to be dispensed. There are no overlaps in strength.</p>
34	<p>Provera (Medroxyprogesterone)</p> <p><u>Dosage form</u> Tablets</p>	<p>Phonetic similarity Both names contain two syllables</p> <p>Both names end in the</p>	<p>Phonetic differences The alveolar nasal /n/ in Northera sounds different from the bilabial plosive /p/ in Provera</p>

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

PROPOSED NAME: Northera (Droxidopa) Capsules	STRENGTH: 100 mg, 200 mg, and 300 mg	USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily
FAILURE MODE: Name Confusion	CAUSES: (Potential reasons for name confusion that could lead to medication error)	PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)
<u>Strength</u> 2.5 mg, 5 mg, 10 mg <u>Route of administration</u> Oral <u>Usual dosage</u> One tablet daily	same suffix ‘era’ ‘th’ in Northera produces a alveolar plosive and glottal fricative sound similar to the ‘v’ in Provera labio-dental affricative in the frontal region of the mouth Overlapping Product Characteristics <u>Dosage form</u> Both are available as solid dosage forms <u>Route of administration</u> Oral <u>Strength</u> Numerical overlap 100 mg vs. 10 mg	Differing product characteristics <u>Frequency of administration</u> Three times daily vs. once daily
35 Mircera (methoxy polyethylene glycol-epoetin beta) <u>Dosage form</u> Single use vial or prefilled syringe <u>Strength</u> 50 micrograms, 75 micrograms, 100 micrograms, 150 micrograms,	Phonetic similarity Both names contain two syllables Both names end in the same suffix ‘era’ ‘N’ in Northera produces a alveolar nasal sound similar to the ‘M’ in Micera bilabial nasal sound <u>Strength</u>	Phonetic differences The second syllable in Northera begins with a dental affricative /θ/ vs. the second syllable in Mircera which begins with alveolar fricative /s/ Differing product characteristics <u>Route of administration</u> Oral vs. subcutaneous or intravenous <u>Frequency of administration</u> Three times daily vs. once monthly

Appendix E: Potentially confusing names with orthographic, phonetic or multiple differentiating product characteristics that decrease the risk of medication errors.

<p>PROPOSED NAME: Northera (Droxidopa) Capsules</p>	<p>STRENGTH: 100 mg, 200 mg, and 300 mg</p>	<p>USUAL DOSE: 100 mg three times daily with a maximum dose of 600 mg three time daily</p>
<p>FAILURE MODE: Name Confusion</p>	<p>CAUSES: (Potential reasons for name confusion that could lead to medication error)</p>	<p>PREVENTION OF FAILURE MODE (Reasons why the risk of medication error is minimized)</p>
<p>200 micrograms, 250 micrograms</p> <p><u>Route of administration</u> intravenous or subcutaneous</p> <p><u>Usual dosage</u> Starting dose is 0.6 micrograms/kg every two weeks</p>	<p>Northera is measured in ‘mg’ vs. Mircera is measure in ‘micrograms’ and these may look similar</p>	

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/s/

FOREST R FORD
01/04/2012

CAROL A HOLQUIST on behalf of IRENE Z CHAN
01/04/2012
for Irene Chan

CAROL A HOLQUIST
01/04/2012