

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203340Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: June 26, 2012

Reviewer: Jung Lee, RPh
Division of Medication Error Prevention and Analysis

Acting Team Leader: Jamie Wilkins Parker, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Nymalize (Nimodipine) Oral Solution, 60 mg/20 mL

Application Type/Number: NDA 203340

Applicant: Arbor Pharmaceuticals, Inc

OSE RCM #: 2012-1309

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Nymalize is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Nymalize, acceptable in OSE Review #2011-4340 dated February 10, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2011-4340. We note that none of the proposed product characteristics of Nymalize were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded no new names thought to look or sound similar to Nymalize and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 12, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on June 15, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Laurie Kelley, OSE project manager, at 301-796-5068.

4 REFERENCES

1. *Lee, J; OSE Review 2011-4340, Proprietary Name Review of Nymalize; February 10, 2012.*
2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JUNG E LEE
06/26/2012

JAMIE C WILKINS PARKER
06/28/2012

**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: February 7, 2012

Reviewer: Jung Lee, RPh
Division of Medication Error Prevention and Analysis

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

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

Drug Name and Strength: Nymalize (Nimodipine) Oral Solution,
60 mg/20 mL

Application Type/Number: NDA 203340

Applicant/Sponsor: Arbor Pharmaceuticals, Inc

OSE RCM #: 2011-4340

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Nymalize, 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

Nimodipine was first approved for US marketing on December 28, 1988 (Nimotop by Bayer Pharmaceuticals, NDA 018869). Generic nimodipine capsules were first approved by FDA on May 2, 2007. On July 8, 2011, Nimotop brand capsules were voluntarily withdrawn from the market by Bayer. Barr Pharmaceuticals' oral nimodipine liquid-filled gelatin capsule is now listed as the Reference Listed Drug (RLD) for this product.

In a postmarketing medication error review dated April 8, 2011 (OSE RCM # 2010-1047), DMEPA summarized 31 medication errors associated with nimodipine oral capsules. Postmarketing safety reports on oral nimodipine identified medication errors associated with the use of nimodipine capsules for nasogastric tube administration. In the professional insert labeling, dosing instructions are provided for situations where patients are unable to swallow. The instructions require that the liquid contents of the capsule be extracted into a syringe using a needle. As a result, patients were inadvertently given nimodipine intravenously instead of by mouth or through a nasogastric tube. The use of a needle-fitted syringe containing nimodipine in a health care setting is associated with a significant safety risk of erroneous intravenous administration.

In the postmarketing medication error review, DMEPA made the recommendation to Barr Pharmaceuticals, the manufacturer of the RLD for nimodipine capsules, to "create an oral solution or suspension with an oral dispensing device so that the capsules can be removed from the market." On November 18, 2011, a different Applicant, Arbor Pharmaceuticals submitted an NDA (203340) for Nymalize (Nimodipine) Oral Solution. Nymalize is a 505(b)(2) application. This NDA has been submitted by the Applicant to help resolve this safety risk.

On March 9, 2011 the active moiety of the drug, and not the formulation of the drug, was given orphan-drug designation for the treatment of "subarachnoid hemorrhage from ruptured intracranial berry aneurysms." The FDA granted the Applicant a designation of Fast Track for NDA 203340 on July 20, 2011.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 21, 2011 proprietary name submission.

- Active Ingredient: Nimodipine
- Indication of Use: A calcium channel blocker indicated in adults for subarachnoid hemorrhage
- Route of Administration: Oral
- Dosage Form: Oral Solution

- Strength: 60 mg/20 mL
- Dose and Frequency of Administration: 20 mL (60 mg) every 4 hours for 21 consecutive days
- How Supplied: 16 oz bottle and 20 mL unit-dose cup
- Storage: 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
- Container and Closure Systems:
 - 16 oz Bottle-- (b) (4), high density polyethylene (HDPE) bottles with white (b) (4) caps (b) (4) induction seal foil liners
 - 20 mL Unit-Dose Cup— (b) (4) HDPE unit-dose cups with (b) (4) lidding (foil stock heat sealing)

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 Neurology Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) SEARCH*

On February 2, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide the derivation of the proposed proprietary name, Nymalize. 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. In the Expert Panel Discussion (EPD), several participants noted that the proposed name, Nymalize, sounds very similar to the word "normalize." However, normalize is not a drug name; therefore, the risk of medication errors with the word "normalize" was not evaluated in this review.

2.2.3 *FDA Name Simulation Studies*

Thirty-nine practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Twenty practitioners interpreted the proposed name, Nymalize, correctly. Out

of these 20 participants, 8 were from the inpatient study, 2 from the voice study and 10 from the outpatient study. Of the 11 inpatient participants, 8 correctly identified the name as Nymalize while the other 3 misinterpreted the ‘y’ for ‘ig’ or ‘ij’. Only 2 voice study participants spelled the name correctly; although, the remaining 10 voice study participants did phonetically spell the name to sound similar to Nymalize. In the outpatient study, 10 out of 16 participants spelled Nymalize correctly with 5 participants spelling Nymalize with the letter ‘M’ instead of the letter ‘N’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, December 6, 2011 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Nymalize. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Nymalize identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by (b) (4) but were not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable) (n=36)

Look Similar		Look Similar		Look Similar	
Name	Source	Name	Source	Name	Source
Dyazide	(b) (4)	Myozyme	FDA/Primary Reviewer	Nymaliza	FDA
Minirin	FDA	Mysoline	FDA (b) (4)	Nystatin	FDA
Minitec	FDA	Nimbex	FDA	Nystex	FDA
Minizide	FDA	Nimodipine	FDA	Nystop	FDA
Mintezol	FDA	Nimotop	FDA	Symadine	FDA
Myadec	FDA	Normal Saline	(b) (4)	Symbyax	FDA
Mycelex	FDA	Nucynta	FDA	Synalar	FDA
Mylicon	(b) (4)	Numoisyn	FDA	Vyvanse	FDA
Mynatal	FDA	Nydravid	Primary Reviewer	Zyclara	FDA

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable) (n=36)

Look Similar		Look Similar		Look Similar	
Myobloc	FDA	Nylidrin	FDA	Zymaxid	FDA
Myoflex	FDA				
Sound Similar		Sound Similar		Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Namenda	(b) (4)	Nimesulide	FDA	Normozide	FDA/Primary Reviewer
Look and Sound Similar		Look and Sound Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Nasalide	FDA	Normodyne	FDA (b) (4)		

Our analysis of the 36 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 36 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Neurology Products via e-mail on January 6, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products on January 18, 2012, they stated no additional concerns with the proposed proprietary name, Nymalize.

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 Laurie Kelley, OSE project manager, at 301-796-5068.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Nymalize, and have concluded that this name is acceptable. If any of the proposed product characteristics as stated in your November 21, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. This proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

17. **Walgreens (www.walgreens.com)**

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

18. **Rx List (www.rxlist.com)**

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

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

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

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

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

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

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.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 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 Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Nymalize	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'N'	M, R, V, Y, W	'DN', 'GN', 'KN', 'MN', 'PN'
Lower case 'n'	h, m, r, s, u, v, x	'dn', 'gn', 'kn', 'mn', 'pn'
Lower case 'y'	f, p, u, v, x, Z	'e', 'i', 'u'
Lower case 'm'	n, mm, rn, v, vi, w, wi, onc, z	
Lower case 'a'	el, ci, cl, d, o, u	Any Vowel
Lower case 'l'	b, e, l, s, A, P	
Lower case 'i'	e	
Lower case 'z'	c, e, g, n, m, q, r, s, v	'c', 's', 'x'
Lower case 'e'	a, I, l, p	Any Vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Nymalize Study (Conducted on December 6, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Nymalize 20 mL po every 4 hours</i></p>	<p>Nymalize</p> <p>Take 4 tspful by mouth every 4 hours</p> <p>#16 oz</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Nymalize</i></p> <p><i>4 tsp po q4h</i></p> <p><i>#16 oz</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study				
39 People Responded				
Study Name: Nymalize				
Total	11	12	16	39
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
MYMALIZE	0	0	5	5
NIGMALIZE	2	0	0	2
NIJMALIZE	1	0	0	1
NIMALIZE	0	1	0	1
NIMELIZE	0	1	0	1
NIMOLIZE	0	1	0	1
NIMOLYZE	0	1	0	1
NIMYLYSE	0	1	0	1
NYMALISE	0	1	0	1
NYMALIZE	8	2	10	20
NYMOLISE	0	1	0	1
NYMOLIZE	0	2	0	2
NYMYLIZE	0	1	0	1
NYSUALIZE	0	0	1	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described. (n=21)

No.	Proprietary Name	Active Ingredient	Similarity to Nymalize	Failure preventions
1	Dyazide	Triamterene/ Hydrochlorothiazide	Look Alike	Lacks convincing orthographic similarity
2	Minirin	Desmopressin Acetate	Look Alike	Canadian brand name for desmopressin
3	Minitec	Technetium TC-99M Sodium Perchnetate Generator	Look Alike	NDA 017339 withdrawn 2/15/2007 with no available generics
4	Minizide	Prazosin HCl & polythiazide	Look Alike	NDA 017986 withdrawn 6/5/2008 with no available generics
5	Mintezol	Thiabendazole	Look Alike	Lacks convincing orthographic similarity
6	Myadec	Multivitamin and minerals	Look Alike	Lacks convincing orthographic similarity
7	Mylicon	Simethicone	Look Alike	Lacks convincing orthographic similarity
8	Myobloc	Rimaboltulinumtoxinb	Look Alike	Lacks convincing orthographic similarity
9	Myoflex	Trolamine salicylate	Look Alike	Lacks convincing orthographic similarity
10	Namenda	Memantine HCl	Sound Alike	Lacks convincing orthographic similarity
11	Nimbex	Cisatracurium Besylate	Look Alike	Lacks convincing orthographic similarity
12	Nimesulide	Nimesulide	Sound Alike	A sulfonanilide compound available in Europe
13	Nimodipine	Nimodipine	Look Alike	Lacks convincing orthographic similarity
14	Nimotop	Nimodipine	Look Alike	Lacks convincing orthographic similarity
15	Normal Saline	Sodium Chloride	Look Alike	Lacks convincing orthographic similarity
16	Normozide	Hydrochlorothiazide/ labetalol HCl	Sound Alike	NDA 019046 withdrawn on 11/16/1993 with no available generics
17	Nucynta	Tapentadol HCl	Look Alike	Lacks convincing orthographic similarity
18	Nymaliza		Look Alike	Name registered to Arbor Pharmaceuticals but has not been submitted as an alternate name for Nymalize (b) (4)
19	Nystex	Nystatin	Look Alike	ANDA 062519 withdrawn on 11/1/2005 (b) (4)
20	Nystop	Nystatin	Look Alike	Lacks convincing orthographic similarity
21	Vyvanse	Lisdexamfetamine dimesylate	Look Alike	Lacks convincing orthographic similarity

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. (n=15)

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
1	<p>Mycelex (Clotrimazole) Cream</p> <p>Strength: 1%</p> <p>Usual Dose: Apply to affected areas twice a day</p>	<p>Orthographic Similarity:</p> <p>Both names contain a downstroke in the 2nd position and one upstroke in the middle.</p> <p>Strength: Both products are available in a single strength.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Mycelex contains a cross-stroke in the last position while Nymalize contains a downstroke in the suffix. When scripted, the letters ‘celex’ in Mycelex do not look similar to ‘malize’ in Nymalize.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. The dose for Mycelex would need to be specified as apply to affected area vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>
2	<p>Mynatal (Prenatal Vitamins) Capsules</p> <p>Usual Dose: Take 1 capsule once daily</p>	<p>Orthographic Similarity:</p> <p>When scripted, ‘Myna’ may appear orthographically similar to ‘Nyma’.</p> <p>Route of Administration: Both are given orally.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Mynatal contains a cross-stroke ‘t’ and an additional upstroke ‘l’ while Nymalize contains an additional downstroke giving both names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. The dose for Mynatal would need to be specified as one tablet vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p> <p><u>Frequency:</u> Once daily vs. every 4 hours</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
3	<p>Myozyme (alglucosidase alfa) Injection Solution</p> <p>Strength: 50 mg</p> <p>Usual Dose: 20 mg/kg body weight administered every 2 weeks as an IV infusion administered over 4 hours</p>	<p>Orthographic Similarity:</p> <p>When scripted, ‘My’ may appear orthographically similar to ‘Ny’. Both names also contain 2 downstrokes.</p> <p>Strength: Both products are available in a single strength.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize contains an additional upstroke ‘l’ in the middle of the name while Myozyme contains 2 downstrokes ‘zy’ next to each other in the middle of the name and no additional upstrokes giving both names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. Myozyme is dosed based on the patient’s body weight; therefore, a dose would need to be specified when prescribed vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful. In order to achieve the same 60 mg dose as Nymalize, the patient would have to weigh 3 kg. The likelihood of a patient weighing 3 kg or less is unlikely in the usual practice setting.</p>
4	<p>Mysoline (Primidone) Tablets</p> <p>Strengths: 50 mg, 250 mg</p> <p>Usual Dose: 100 mg to 250 mg up to 4 times a day</p>	<p>Orthographic Similarity:</p> <p>When scripted, ‘My’ may appear orthographically similar to ‘Ny’. Both names also contain an upstroke ‘l’ in the 5th position.</p> <p>Route of Administration: Both are given orally.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize may contain an additional downstroke ‘z’ in the 7th position which is absent in Mysoline giving the names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. Mysoline would be dosed as 2 to 5 tablets of the 50 mg strength or 1 tablet of the 250 mg strength vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
5	<p>Nasalide (Flunisolide) Nasal Solution</p> <p>Strength: 0.25 mg/actuation</p> <p>Usual Dose: 1 to 2 sprays in each nostril 2 to 3 times per day</p>	<p>Orthographic and Phonetic Similarities:</p> <p>Both names begin with the letter ‘N’, contain an upstroke ‘l’ in the 5th position and end in the letter ‘e’. Both names contain 3 syllables. When spoken, the 1st and 3rd syllables could sound similar.</p> <p>Strength: Both products are available in a single strength.</p>	<p>Orthographic and phonetic differences in the name and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic and Phonetic Differences:</p> <p>Nymalize may contain 2 downstrokes while Nasalide contains no downstrokes. Also, Nasalide contains an additional upstroke in the 7th position which is absent in Nymalize.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. Nasalide is dosed as 1 to 2 sprays vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>
6	<p>Normodyne (Labetalol HCl) Tablets and Injection Solution</p> <p>Strengths:</p> <p><u>Tablet:</u> 100 mg, 200 mg, 300 mg</p> <p><u>Injection:</u> 5 mg/mL</p> <p>Usual Dose:</p> <p><u>Tablet:</u> 1 to 2 tablets twice daily</p> <p><u>Injection:</u> 4 mL (20 mg) to 16 mL (80 mg) IV once, repeat if necessary</p>	<p>Orthographic and Phonetic Similarities:</p> <p>Both names begin with the letter ‘N’ and contain an upstroke and downstroke in the suffix. Both names contain 3 syllables. The 1st syllable begins with the letter ‘N’ and the 2nd syllable begins with the letter ‘m’.</p>	<p>Name was withdrawn on 6/16/2006. Generics are currently available.</p> <p>Orthographic and phonetic differences in the name and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic and Phonetic Differences:</p> <p>Nymalize contains a downstroke in the 2nd position, whereas Normodyne does not giving the names a different shape. When spoken, the 1st and 3rd syllables sound distinctly different.</p> <p>Differentiating Product Characteristics:</p> <p><u>Frequency:</u> Oral Normodyne is given twice daily and IV Normodyne is given as a single IV dose. Nymalize is given every 4 hours.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
7	<p>Numoisyn (Saliva Substitute) Spray Solution and Lozenges</p> <p>Usual Dose:</p> <p><u>Spray:</u> Spray for ½ second or less as needed for dryness</p> <p><u>Lozenges:</u> Dissolve slowly in mouth when needed for dryness</p>	<p>Orthographic Similarity:</p> <p>Both names begin with the letter ‘N’, contain the letter ‘m’ in the 3rd position and contain a downstroke in the 7th position.</p> <p>Route of Administration: Both are given orally.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize contains a downstroke ‘y’ in the 2nd position and an upstroke ‘l’ in the 5th position while Numoisyn does not giving the names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. Numoisyn is dosed as 1/2 second spray or 1 lozenge vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>
8	<p>Nydrazid (Isoniazid) Injection Solution</p> <p>Strength: 100 mg/mL</p> <p>Usual Dose:</p> <p><u>Tb Prophylaxis Adults >30 kg:</u> 300 mg IM in a single dose</p> <p><u>Tb Treatment:</u> 5 mg/kg IM in a single daily dose or 15 mg/kg IM given 2 or 3 times per week</p>	<p>Orthographic Similarity:</p> <p>Both names begin with the letters ‘Ny’ and contain a downstroke in the suffix.</p> <p>Strength: Both products are available in a single strength.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nydrazid contains an upstroke ‘d’ in the 3rd and 8th position while Nymalize contains an upstroke ‘l’ in the 5th position giving the names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Frequency:</u> Single dose vs. every 4 hours</p> <p><u>Dosage:</u> No dose overlap. Nydrazid is dosed as 300 mg IM for adults >30 kg for Tb prophylaxis or by patient’s weight for Tb treatment vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
9	<p>Nylidrin (Nylidrin HCl) Tablets</p> <p>Strengths: 6 mg, 12 mg</p> <p>Usual Dose: 3 mg to 12 mg 3 to 4 times a day</p>	<p>Orthographic Similarity:</p> <p>Both names begin with the letters ‘Ny’ and contain an upstroke ‘l’ in the infix.</p> <p>Route of Administration: Both are given orally.</p> <p>Numeric Similarity in Strength: 6 mg vs. 60 mg</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nylidrin contains an upstroke ‘l’ in the 3rd position, an additional upstroke ‘d’ in the 5th position and no additional downstrokes while Nymalize may contain a downstroke ‘z’ in the 7th position giving the names a different shape.</p> <p>Differentiating Product Characteristics:</p> <p><u>Frequency:</u> 3 to 4 times a day vs. every 4 hours</p>
10	<p>Nystatin (Nystatin) Suspension, Ointment, Cream, Tablets</p> <p>Strengths:</p> <p>100,000 u/mL, 100,000 u/gm</p> <p>Usual Dose:</p> <p><u>Suspension:</u> 1 mL to 6 mL (100,000 units to 600,000 units) 4 times a day</p> <p><u>Tablet:</u> 5 to 10 tablets every 8 hours</p> <p><u>Topical:</u> Apply 2 to 3 times a day</p> <p><u>Vaginal Tablet:</u> Insert 1 tablet daily at bedtime for 2 weeks</p>	<p>Orthographic Similarity:</p> <p>Both names begin with the letters ‘Ny’ and contain an upstroke in the middle of the name.</p> <p>Numeric Similarity in Strength: 6 mL or 6 tablets vs. 60 mg</p>	<p>Orthographic differences minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nystatin contains an additional upstroke ‘t’ in the 6th position and no downstrokes in the suffix while Nymalize may contain a downstroke ‘z’ in the 7th position and no additional upstrokes giving the names a different shape.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
11	<p>Symbyax (Olanzapine/ fluoxetine) Capsules</p> <p>Strengths: 3 mg/25 mg, 6 mg/50 mg, 12 mg/25 mg, 12 mg/50 mg</p> <p>Usual Dose: Between 6 mg to 18 mg Olanzapine and 25 mg to 50 mg fluoxetine once daily</p>	<p>Orthographic Similarity: Both names contain 2 downstrokes and one upstroke and share the letters ‘ym’ in the same position.</p> <p>Route of Administration: Both are given orally.</p> <p>Numeric Similarity in Strength: 6 mL or 6 tablets vs. 60 mg</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference: Symbyax contains a downstroke ‘y’ in the 5th position and a cross-stroke ‘x’ at the end of the name giving the names a different appearance.</p> <p>Differentiating Product Characteristics: <u>Frequency:</u> Once daily vs. every 4 hours</p>
12	<p>Symadine (Amantadine) Capsules</p> <p>Strength: 100 mg</p> <p>Usual Dose: 200 mg as a single daily dose or 100 mg twice daily</p>	<p>Orthographic Similarity: When scripted in lower case, the first letter ‘s’ may look like the first letter ‘n’ making the first half of the name look similar.</p> <p>Route of Administration: Both are given orally.</p> <p>Strength: Both products are available in a single strength.</p>	<p>ANDA 071000 withdrawn 10/27/1997. SDI (b) (4)</p> <p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference: Symadine contains the upstroke ‘d’ while Nymalize contains the upstroke ‘l’ and may contain a downstroke ‘z’.</p> <p>Differentiating Product Characteristics: <u>Dosage:</u> No dose overlap. Symadine is dosed as 1 or 2 capsules vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
13	<p>Synalar (Fluocinolone acetonide) Cream, Ointment, Solution</p> <p>Strengths: 0.01%, 0.025%</p> <p>Usual Dose: Apply thin film to affected area 3 times a day</p>	<p>Orthographic Similarity:</p> <p>Both names contain a downstroke ‘y’ in the 2nd position and an upstroke ‘l’ in the middle of their names.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize may contain a downstroke ‘z’ in the suffix which is absent in Synalar giving the names a different shape. When scripted, the letters ‘ar’ in Synalar appear shorter and different from ‘ize’ in Nymalize.</p> <p>Differentiating Product Characteristics:</p> <p><u>Strength:</u> No strength overlap. Synalar is available in multiple strengths vs. a single strength for Nymalize. When prescribed a strength would need to be specified for Synalar.</p> <p><u>Dosage:</u> No dose overlap. The dose for Synalar would need to be specified as apply to affected area vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>
14	<p>Zyclara (Imiquimod) Cream</p> <p>Strength: 3.75%</p> <p>Usual Dose: Apply to affected area before bedtime and leave on for 8 hours, then remove with mild soap and water</p>	<p>Orthographic Similarity:</p> <p>Both names contain a downstroke ‘y’ in the 2nd position and an upstroke ‘l’ in the middle of their names.</p> <p>Strength: Both products are available in a single strength.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize may contain an additional downstroke ‘z’ in the 7th position which is absent in Zyclara. Also, the letters ‘ma’ in Nymalize appear longer than the letter ‘c’ in Zyclara giving the names a different appearance.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage and Frequency:</u> Apply to affected area before bedtime and leave on for 8 hours, then wash off vs. 20 mL (60 mg) or 4 teaspoonsful every 4 hours.</p>

No.	Proposed name: Nymalize	Strength(s): 60 mg/ 20 mL	Usual dose: 20 mL (60 mg) every 4 hour for 21 consecutive days
	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
15	<p>Zymaxid (Gatifloxacin) Ophthalmic Solution</p> <p>Strength: 0.50%</p> <p>Usual Dose: Instill 1 drop to affected eye(s) every 2 hours while awake on day 1, then 1 drop up to 4 times a day while awake.</p>	<p>Orthographic Similarity:</p> <p>Both names share the same letters ‘ym’ in the same position and contain an upstroke in the suffix.</p> <p>Strength: Both products are only available as a single strength.</p>	<p>Orthographic differences and differences in product characteristics minimize the potential for medication error in the usual practice setting.</p> <p>Orthographic Difference:</p> <p>Nymalize contains an upstroke ‘l’ in the middle and an additional downstroke ‘z’ in suffix of the name, whereas Zymaxid contains the upstroke ‘d’ at the end of the name and no additional downstrokes.</p> <p>Differentiating Product Characteristics:</p> <p><u>Dosage:</u> No dose overlap. The dose for Zymaxid would need to be specified as 1 drop vs. Nymalize which is dosed as 20 mL (60 mg) or 4 teaspoonsful.</p>

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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02/07/2012

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