CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125390Orig1s000

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:	July 25, 2013
Reviewer:	Reasol S. Agustin, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Myalept (Metreleptin) For Injection (b) (4)
Application Type/Number:	BLA 125390
Applicant/Sponsor:	Amylin Pharmaceutical, Inc.
OSE RCM #:	2013-1024

*** 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, Myalept (Metreleptin), from a safety and promotional perspective. This proposed name was previously evaluated and found acceptable (see OSE review #2012-903 on June 27, 2012). However, since the proprietary name was reviewed over a year ago, DMEPA is reviewing the name to ensure that Myalept continues to be acceptable. This application is a rolling Biologic License Application (BLA) and the final reviewable unit was submitted on March 27, 2013. Of note, product characteristics have not changed since the previous DMEPA name review. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the April 10, 2012 proprietary name submission.

- Active Ingredient: Metreleptin
- Indication of Use: Indicated for the treatment of diabetes mellitus and/or hypertriglyceridemia in pediatric and adult patients with inherited or acquired lipodystropy.
- Route of Administration: Subcutaneous Injection
- Dosage Form: Lyophilized powder
- Strength: (b) (4)
- Dose and Frequency:
    - 2.5 mg (0.5 mL) once daily (men)
    - 5 mg (1 mL) once daily (women)
    - 0.06 mg/kg (0.012 mL/kg) once daily (less than 40 kg)
- How Supplied: Multiple dose 5 mL vial
- Storage: Store under refrigeration 36° F to 46° F (2° C to 8° C) and protect from light
- Container and Closure Systems: Primary container closure is a 5 mL glass vial, rubber stopper, and aluminum seal with a plastic flip-off cap.

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and

Endocrinology Products (DMEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Myalept, has no intended meaning or derivation. This proprietary name is comprised of a single word that does not contain a modifier, route of administration, dosage form, etc.

2.2.3 FDA Name Simulation Studies

Sixty-five practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Fourteen of the 16 inpatient participants responded correctly and misinterpretation occurred with 2 participants misinterpreting the letter 'a' for 'la' and 'u' (i.e. My***A***lept misinterpreted as 'My***U***lept and My***LA***lept'). Five of the 25 voice participants responded correctly and the most common misinterpretation occurred with 14 participants misinterpreting the letter 'a' for 'o' (i.e. My***A***lept misinterpreted as 'My***O*** or Mi***O***'). Twenty-two of the 24 outpatient participants responded correctly and there was no common misinterpretation. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results of the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 4, 2012 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters used in the search for similar names to the proposed proprietary name, Myalept. Table 1 contains the names previously identified (OSE review #2012-903) and Table 2 contains additional names identified since the last review. Our analysis of the collective names determined all 44 names will not pose a risk for confusion as described in Appendix D and E.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study) in OSE Review #2012-903					
Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Cellcept	External	Maxalt	External	Micozall	EPD
Mirapex	External	Myadec	EPD	Myambutol	EPD
My-B-Tabs	EPD	Viracept	EPD	Mycept	EPD
Mycobutin	EPD	Mycolog-II	EPD	Myidyl	EPD
Mykacet	EPD	Mylanta	EPD	Myobloc	EPD
My-O-Den	EPD	Myofibex	EPD	Myoflex	EPD
Myophen	EPD	Myoscint	EPD	Myotrol	EPD
Myoview	EPD	Myoxin	EPD	Mysoline	EPD
Mytelase	EPD	Nydrazid	EPD	Nystatin	EPD
Nystat-Rx	EPD	Nystop	EPD	Nytcold	EPD
Nytyme	EPD	Myolite	EPD		
Sound Similar					
Genoptic	External				
Look and Sound Similar					
Myalept	EPD	Myoleptin CLA	EPD	Mycelex	EPD

Table 2: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)					
Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Nystex	EPD	Nyamyc	EPD	Mybec	EPD
Myelokit	EPD	Trileptal	EPD	Oleptro	EPD
Nystop	EPD	Vyndaqel	EPD		

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on June 13, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on June 13, 2013 they stated no additional concerns with the proposed proprietary name, Myalept.

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 Margarita Tossa, OSE project manager, at 301-796-4053

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the BLA. The results are subject to change. If any of the proposed product characteristics as stated in your April 10, 2012 submission are altered, the name must be resubmitted for review.

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

   USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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[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 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**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• 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	• 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	• 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 gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

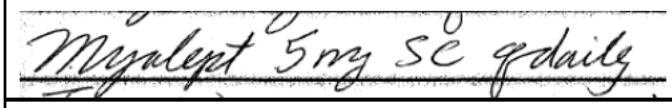
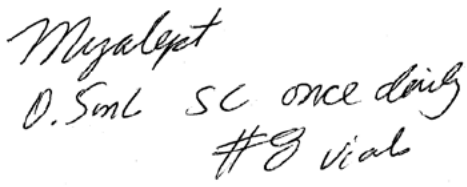
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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, Myalept	Scripted May Appear as	Spoken May Be Interpreted as
Upper case 'M'	J, Ss, U	
Lower case 'm'	nn, n, rn v, w, wi, vi, onc, z	
Lower case 'y'	f, p, u, v, x, Z, ij, iz	e, i, u
Lower case 'a'	c, ce, ci, cl, d, i, o, u, la	Any vowel
Lower case 'l'	A, b, e, i, P, s	El
Lower case 'e'	a, i, l, p	Any vowel
Lower case 'p'	g, j, l, q, yn, ys	b
Lower case 't'	A, f, r, x	D
Letter strings		
le	B	
my	Nuj	
al	D	
ep	ys	ec
Pt		x

Appendix C: Prescription Simulation Samples and Results

Figure 1. Myalept Study (Conducted on *May* 10, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Myalept Inject 0.5 mL subq once daily #8

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Myalept

191 People Received Study

65 People Responded

Study Name: Myalept

Total	24	25	16	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
MILALET 0.5ML SQ	0	1	0	1
MIOLEPT	0	1	0	1
MIOLET	0	1	0	1
MIZALEPT	1	0	0	1
MYALECT	0	1	0	1
MYALEPT	22	5	14	41
MYELECT	0	1	0	1
MYELEPT	0	2	0	2
MYLALEPT	0	0	1	1
MYLEJECT	1	0	0	1

MYLEX	0	1	0	1
MYOLECT	0	1	0	1
MYOLEPT	0	7	0	7
MYOLET	0	3	0	3
MYOLEX	0	1	0	1
MYULEPT	0	0	1	1

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

Proprietary Name		Active Ingredient	Similarity to Myalept	Failure preventions
1	**Myalept**	Metreleptin	Look and Sound alike	This name is the subject of this review.
2	**Mybec**	Multivitamin/Mineral	Look alike	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
3	**Myelo-kit**	Iohexol	Look alike	Name identified in Redbook. Unable to find product characteristics in commonly used drug databases.
4	**Trileptal**	Oxcarbazepine	Look like	The pair have sufficient orthographic differences
5	**Oleptro**	Trazodone HCl	Look alike	The pair have sufficient orthographic differences
6	**Vyndaqel**[***]	Tafamidis Meglumine	Look alike	The pair have sufficient orthographic differences

[***] This is proprietary and confidential information that should not be shared with 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.

	Proposed name: ***Myalept*** (Metreleptin) **Dosage form and Strength(s):** Lyophilized powder for subcutaneous injection: (b) (4) **Usual dose:** 2.5 mg (0.5 mL) once daily (men), or 5 mg (1 mL) once daily (women), or 0.06 mg/kg (0.012 mL/kg) once daily (less than 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1	**Nystex*** (Nystatin) **Dosage Form and Strength:** Oral suspension: 100000 units/mL; Oral tablet: 500000 units; Topical cream, ointment, powder: 100000 units/gm; Vaginal tablet: 100000 units **Usual dose:** 4 to 6 mL by mouth 4 times daily or 1 to 2 tablets by mouth 3 times daily; 1 tablet intravaginally daily for 2 weeks Apply liberally to affected areas topically 2 to 3 times daily. **Product is discontinued with generic available*	**Orthographic similarity:** The beginning letter strings 'Mya' and 'Nys' appear orthographically similar when scripted. In addition, both names contain the upstroke letters 'l' vs. 't' in the same positions giving them a similar shape when scripted. **Dose:** There is numerical similarity between the doses (i.e. 0.5 mL vs. 5 mL)	**Orthographic difference:** Myalept contains a downstroke 'p' and an additional upstroke 't' which is absent in Nystex, giving the names different shapes. In addition, the ending letter strings 'ept' and 'ex' appear orthographically different when scripted. **Dosage form and route of administration:** Myalept is available as a powder for reconstitution given subcutaneously vs. Nystex is available in multiple dosage forms (i.e. oral suspension, oral tablet, vaginal tablet, and topical cream ointment, and powder) which need to be specified for a complete prescription.

	Proposed name: ***Myalept*** (Metreleptin) **Dosage form and Strength(s):** Lyophilized powder for subcutaneous injection: (b) (4) **Usual dose:** 2.5 mg (0.5 mL) once daily (men), or 5 mg (1 mL) once daily (women), or 0.06 mg/kg (0.012 mL/kg) once daily (less than 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
2	**Nyamyc** (Nystatin) **Dosage Form and Strength:** Oral suspension: 100000 units/mL; oral tablet: 500000 units; Topical cream, ointment, powder: 100000 units/gm; vaginal tablet: 100000 units **Usual dose:** 4 to 6 mL by mouth 4 times daily or 1 to 2 tablets by mouth 3 times daily; 1 tablet intravaginally daily for 2 weeks Apply liberally to affected areas topically 2 to 3 times daily. **Product is discontinued with generic available*	**Orthographic similarity:** The beginning letter strings 'Mya' and 'Nya' appear orthographically similar when scripted. In addition, both names contain the downstroke letters 'p' vs. 'y' in similar positions giving them a similar shape when scripted. **Dose:** There is numerical similarity between the doses (i.e. 0.5 mL vs. 5 mL)	**Orthographic difference:** Myalept contains an upstroke 'l' and ends with an additional upstroke 't' which is absent in Nyamyc, giving the names different shapes. In addition, the ending letter strings 'lept' and 'myc' appear orthographically different when scripted. **Dosage form and route of administration:** Myalept is available as a powder for reconstitution given subcutaneously vs. Myalept is available in multiple dosage forms (i.e. oral suspension, oral tablet, vaginal tablet, and topical cream ointment, and powder) which need to be specified for a complete prescription.

	Proposed name: ***Myalept*** (Metreleptin) **Dosage form and Strength(s):** Lyophilized powder for subcutaneous injection: (b) (4) **Usual dose:** 2.5 mg (0.5 mL) once daily (men), or 5 mg (1 mL) once daily (women), or 0.06 mg/kg (0.012 mL/kg) once daily (less than 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3	**Nystop** (Nystatin) **Dosage Form and Strength**: External powder: 0.1 million unit/gm **Usual dose:** Apply to candidal lesions 2 or 3 times daily until lesions have healed. For fungal infection of the feet caused by *Candida* species, the powder should be dusted freely on the feet as well as in shoes and socks.	**Orthographic similarity:** The beginning letter strings 'Myalep' and 'Nystop' appear orthographically similar when scripted. Both names contains an upstroke 'l'/'t' and a downstroke 'p' in similar positions, giving the names similar shapes.	**Orthographic difference:** Myalept ends with an additional upstroke 't' which is absent in Nystop, giving the names different shapes. **Dose:** xx mL or xx mg vs. Apply

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/s/

REASOL AGUSTIN
07/25/2013

YELENA L MASLOV
07/26/2013

CAROL A HOLQUIST
07/26/2013

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:	June 27, 2012
Reviewer:	Kevin Wright, PharmD, Safety Evaluator Division of Medication Error and Prevention Analysis
Acting Team Leader:	Yelena Maslov, PharmD Division of Medication Error and Prevention Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error and Prevention Analysis
Drug Name and Strength:	Myalept (Metreleptin) For Injection (b) (4)
Application Type/Number:	BLA 125390
Applicant/Sponsor:	Amylin Pharmaceutical, Inc.
OSE RCM #:	2012-903

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

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2.2 Safety Assessment 1
3 CONCLUSIONS 4
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Myalept (Metreleptin), 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 PRODUCT INFORMATION

The following product information is provided in the April 10, 2012 proprietary name submission.

- Active Ingredient: Metreleptin
- Indication of Use: Indicated for the treatment of diabetes mellitus and/or hypertriglyceridemia in pediatric and adult patients with inherited or acquired lipodystropy.
- Route of Administration: Subcutaneous Injection
- Dosage Form: Lyophilized powder
- Strength: (b) (4)
- Dose and Frequency:
    - 2.5 mg (0.5 mL) once daily (men)
    - 5 mg (1 mL) once daily (women)
    - 0.06 mg/kg (0.012 mL/kg) once daily (less than 40 kg)
- How Supplied: Multiple dose 5 mL vial
- Storage: Store under refrigeration 36° F to 46° F (2° C to 8° C) and protect from light

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) 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 safety evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

The June 8, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Myalept, has no intended meaning or derivation. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Thirty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. In the written studies, 26 of 33 participants correctly interpreted the prescription. Common misinterpretations in the written studies include: 'Mia', 'Myo' for 'Mya' and 'let', 'lapet' for 'lept' respectively. In the voice study, participants commonly misinterpreted 'Myo' and 'Mia' for 'Mya'. 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, May 4, 2012 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) 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, Myalept. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Myalept identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by the Applicant, but not identified by DMEPA, and requiring further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study)					
Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Cellcept	External	Maxalt	External	Micozall	EPD
Mirapex	External	Myadec	EPD	Myambutol	EPD
My-B-Tabs	EPD	Mycelex	EPD	Mycept	EPD
Mycobutin	EPD	Mycolog-II	EPD	Myidyl	EPD
Mykacet	EPD	Mylanta	EPD	Myobloc	EPD
My-O-Den	EPD	Myofibex	EPD	Myoflex	EPD
Myophen	EPD	Myoscint	EPD	Myotrol	EPD
Myoview	EPD	Myoxin	EPD	Mysoline	EPD
Mytelase	EPD	Nydrazid	EPD	Nystatin	EPD
Nystat-Rx	EPD	Nystop	EPD	Nytcold	EPD
Nytyme	EPD	Viracept	EPD		
Sound Similar					
Genoptic	External				
Look and Sound Similar					
Myalept	EPD	Myoleptin CLA	EPD		

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 will not pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on June 21, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on June 21, 2012, they stated no additional concerns with the proposed proprietary name, Myalept.

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 Margarita Tossa, OSE project manager, at 301-796-4053.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Myalept (Metreleptin), and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your April 10, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the BLA. 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

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[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 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**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• 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	• 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	• 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 gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

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

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

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses 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, Myalept	Scripted May Appear as	Spoken May Be Interpreted as
Upper case 'M'	J, Ss, U	em, en
Lower case 'm'	nn, n, rn v, w, wi, vi, onc, z	em, en
Lower case 'y'	f, p, u, v, x, Z	e, i, u
Lower case 'a'	c, ce, ci, cl, d, i, o, u	Any vowel
Lower case 'l'	A, b, e, i, P, s	El
Lower case 'e'	a, i, l, p	Any vowel
Lower case 'p'	g, j, l, q, yn, ys	b
Lower case 't'	A, f, r, x	D

Appendix C: Prescription Simulation Samples and Results

Figure 1. Myalept Study (Conducted on 04/20/12)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Myalept 2.5mg sub-q once daily	Myalept Take 2.5 mg sub-q once daily
Outpatient Prescription: Myalept #15 Sig: Inject 2.5mL sub-q once daily	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

				84 People Received Study 33 People Responded
Study Name: Myalept				
Total	**12**	**12**	**9**	**33**
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
MIALEPT	0	1	0	1
MYALAX	0	1	0	1
MYALEPT	11	9	6	26
MYALET SUB	1	0	0	1
MYOLAPET	0	1	0	1
MYOLEPT	0	0	3	3

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

Proprietary Name	Active Ingredient	Similarity to Myalept	Failure preventions
Cellcept	Mycophenolate	Look	The pair have sufficient orthographic and/or phonetic differences.
Genoptic	Gentamicin	Sound	The pair have sufficient orthographic and/or phonetic differences.
Maxalt	Rizatriptan	Look	The pair have sufficient orthographic and/or phonetic differences.
Micozall	Miconazole nitrate	Look	The pair have sufficient orthographic and/or phonetic differences.
Mirapex	Pramipexole	Look	The pair have sufficient orthographic and/or phonetic differences.
Myadec	Multi-vitamin	Look	The pair have sufficient orthographic and/or phonetic differences.
Myalept	Metreleptin	Look and Sound	The proprietary name is the subject of this review
Mycept	Mycophenolic acid	Look & Sound	International product marketed in Philippines
Myofibex	Calcium/Magnesium/ Valerian/Ginkgo Biloba	Look	Name identified in Micromedex database. Unable to find product characteristics in commonly used drug databases
My-O-Den	Adensoine Phosphate	Look	The pair have sufficient orthographic and/or phonetic differences.
My-B-Tabs	adenosine/ cyanocobalamin/ folic acid	Look	The pair have sufficient orthographic and/or phonetic differences.
Myoscint	Imciramab Pentetate	Look	The pair have sufficient orthographic and/or phonetic differences.
Myoview	Technetium Tetrofosmin Kit	Look	The pair have sufficient orthographic and/or phonetic differences.

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

Proprietary Name	Active Ingredient	Similarity to Myalept	Failure preventions
Myoxin	Benzocaine/ Chloroxylenol/ Hydrocortisone Acetetate	Look	The pair have sufficient orthographic and/or phonetic differences.
Nystat-Rx	Nystatin	Look	Name identified in Red book database. Unable to find product characteristics in commonly used drug databases.
Nytcold	Acetaminophen/ Dextromorphan/ Doxylamine/ Pseudoephrine	Look	Name identified in Red book database. Unable to find product characteristics in commonly used drug databases.
Nytyme	Acetaminophen/ Dextromorphan/ Doxylamine/ Pseudoephrine	Look	Name identified in Red book database. Unable to find product characteristics in commonly used drug databases.
Viracept	Nelfinavir	Look	The pair have sufficient orthographic and/or phonetic differences.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myambutol Tablets (Ethambutol) Dosage form: Tablets Strength: 100 mg, 400 mg Usual dose: INH resistant TB Take 1.6 grams by mouth once daily Rifamycin resistant TB Take 2 grams by mouth once daily	Orthographic similarity to Myalept, Myalept and Myambutol share the prefix, 'mya'. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Frequency of Administration Both products are administered once daily. Strength Similarity in numerical strength, 10.0 mg vs. 100 mg	Orthographic differences When scripted the name Myambutol appears longer in length than Myalept. Additionally, the shape of Myalept is different than Myambutol. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myambutol is comprised of 4 upstrokes and 1 downstroke. Dose Myalept is administered as a single dose compared to Myambutol which requires 4-5 units for a dose. Route of administration Subcutaneous injection compared to oral administration.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mycelex Troches (Clotrimazole) Dosage form: Troches Strength: 10 mg Usual dose: Take 1 troche by mouth 5 times daily.	Orthographic similarity to Myalept When scripted the letter string 'Myale' may look similar to 'Mycele'. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Strength (b) (4) Dose Numerical overlap in dose, 1 mL vs. 1 troche	Orthographic differences When scripted the letter string, 'pt' may look different than 'x'. Additionally, the shape of Myalept is different than Myambutol. Mycelex is compromised of 3 upstrokes and 2 downstrokes. Whereas, Mycelex is comprised of 2 upstrokes and 1 downstroke. Frequency of Administration Myalept is administered once daily compared to oral administration up to 5 times daily.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mycobutin (Rifabutin) Dosage form: Capsule Strength: 150 mg Usual dose: Take 2 capsules by mouth once daily or Take 1 capsule by mouth twice daily.	Orthographic similarity to Myalept When scripted the letter string 'Myal' may look similar to 'Mycob'. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Dose Potential overlap in numerical overlap 1.50 mg (25 kg) compared to 150 mg. Frequency of Administration Both products can be administered once daily.	Orthographic differences The shape of Myalept is different than Mycobutin. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Mycobutin is comprised of 3 upstrokes and 1 downstroke. Route of administration Subcutaneous injection compared to oral administration. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mycolog II Cream, Ointment (Nystatin and Triamcinolone) Dosage form: Cream and Ointment Strength: 100,000 Units/g; 0.1% Usual dose: Apply to affected area twice daily	Orthographic similarity to Myalept When scripted the letter strings 'Myal' and 'Mycol' may look similar. Additionally, the letter 'p' may look similar to 'g'.	Orthographic differences The shape of Myalept is different than Mycolog. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Mycolog is comprised of 2 upstrokes and 2 downstroke. Dosage form Single dosage form vs. multiple dosage forms and no overlap in dosage form. Thus, the dosage form of Mycolog II must be specified whereas the dosage form of Myalept may be omitted. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myidyl Oral Syrup (Triprolidine) Dosage form: Oral syrup Strength: 1.25 mg/5 mL Usual dose: Take 2 teaspoonful by mouth every 4-6 hours OR Take 2 mg by mouth every 4-6 hours	Orthographic similarity to Myalept When scripted the letter string 'Mya' and 'Myi' may look similar. Additionally, the names Myalept and Myidyl have a similar shape and length. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed.	Orthographic differences When scripted the letter string 'lept' may look different from 'dyl'. Dose Myalept is administered as a single dose compared to Myidyl which requires 2 units for a dose. Frequency of Administration Myalept is administered once daily compared to oral administration up to 6 times daily. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mykacet Cream and Ointment (Nystatin and Triamcinolone) Dosage form: Cream and Ointment Strength: 100,000 Units/g; 0.1% Usual dose: Apply to affected area(s) twice daily	Orthographic similarity to Myalept Myalept and Mykacet begin with the prefix 'My'.	Orthographic differences When scripted the letter string 'lept' may look different from 'dyl'. Dosage form Single dosage form vs. multiple dosage forms and no overlap in dosage form. Thus, the dosage form of Mykacet must be specified whereas the dosage form of Myalept may be omitted. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mylanta Oral suspension and Tablets (Aluminum Hydroxide/Magnesium Hydroxide/Simethicone) Dosage form: Oral suspension and Tablets Strength: 200 mg/200 mg/20 mg, 400 mg/400 mg/40 mg Usual dose: Take 2 to 4 teaspoonful by mouth every 4 to 6 hours OR Take 1-2 capsules by mouth every 4 to 6 hours.	Orthographic similarity to Myalept Myalept and Mylanta begin with the prefix 'My'.	Orthographic differences When scripted the string letter string 'alept' may look different than 'lanta'. The shape of Myalept is different than Mylanta. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Mylanta is comprised of 3 upstrokes and 1 downstroke. Dose Myalept is administered as a single dose compared to Mylanta which requires 2 to 4 units for a dose. Dosage form Single dosage form vs. multiple dosage forms and no overlap in dosage form. Thus, the dosage form of Myalanta must be specified whereas the dosage form of Myalept may be omitted. Frequency of Administration Myalept is administered once daily compared to oral administration up to 6 times daily. Route of administration Subcutaneous injection compared to oral administration. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myobloc Solution for Injection (Rimabotulinutoxin B) Dosage form: Solution for Injection Strength: 2500 Units/0.5 mL, 5000 Units/mL Usual dose: Inject 2500 Units into affected muscles.	Orthographic similarity to Myalept When scripted the letter string 'Myal' may look similar to 'Myob'. Route of administration Both products are administered parenterally.	Orthographic differences When scripted the letter string 'ept' may look different than 'loc'. The shape of Myalept is different than Myobloc. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myobloc is comprised of 3 upstrokes and 1 downstroke. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose. Strength Single strength vs. multiple strengths and no overlap in strengths. Thus, the strength of Myalept may be omitted, but the strength of Myobloc must be specified.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myoflex Cream (Trolamine) Dosage form: Cream Strength: 10 % Usual dose: Apply to affected area twice daily.	Orthographic similarity to Myalept The letter string 'Myal' may look similar to 'Myof' when scripted. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Strength (b) (4)	Orthographic differences When scripted the letter string 'ept' may look different from 'lex'. The shape of Myalept is different than Myoflex. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myoflex is comprised of 3 upstrokes and1 downstroke. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myoleptin CLA Dosage form: Capsule Strength: 1000 mg, 1500 mg Usual dose: Take 1 capsule by mouth 2 to 4 times daily with meals.	Orthographic similarity to Myalept When scripted the letter string 'Myalept' may look similar to 'Myolept'. The names have the same shape and share 6 of 7 letters. Phonetic similarity to Myalept When spoken the letter string 'Mya' and 'Myo' may sound similar. Additionally, both names contain the letter string 'lept'. Dose Both products are administered as a single unit for a dose e.g. 1 mL compared to 1 capsule Strength (b) (4)	Frequency of Administration Myalept is administered once daily compared to oral administration up to 4 times daily.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myophen Solution for Injection, Tablets (Orphenadrine) Dosage form: Solution for Injection and Tablets Strength: 100 mg, 30 mg/mL Usual Dose: Take 1 tablet by mouth twice daily OR Inject 60 mg intravenously or intramuscularly every 12 hours	Orthographic similarity to Myalept The letter string Mya may look similar to 'Myo' when scripted. Dose Both products are administered as a single unit for a dose, e.g. 1 mL vs. 1 tab Route of administration Both products are administered parenterally. Strength (b) (4)	Orthographic differences When scripted the letter string 'lept' may look different than 'phen'.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Myotrol Cream (Trolamine) Dosage form: Cream Strength: 10% Usual dose: Apply to affected area twice daily	Orthographic similarity to Myalept The letter string Myal may look similar to 'Myot' when scripted. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Strength (b) (4)	Orthographic differences When scripted the letter string 'ept'may look different than 'rol'. The shape of Myalept is different than Myotrol. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myotrol is comprised of 3 upstrokes and 1 downstroke. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mysoline Tablet (Primidone) Dosage form: Tablet Strength: 50 mg, 250 mg Usual dose: Take 2 tablets by mouth 3 times daily	Orthographic similarity to Myalept The letter string Mya may look similar to 'Myso' when scripted. Dose vs. Strength 5 mL vs 50 mg 2.5 mL vs. 250 mg	Orthographic differences When scripted the letter string 'lept' may look different than 'sline'. Additionally, the shape of Myalept is different than Myosline. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myosline is comprised of 2 upstrokes and 1 downstroke. Frequency of Administration Myalept is administered once daily compared to oral administration up to 6 times daily.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mytelase (Ambenonium Chloride) Dosage form: Caplet Strength: 10 mg Usual dose: Take 5 mg by mouth 3-4 times per day	Orthographic similarity to Myalept Both names begin with the letters, 'My'. When scripted the names appear similar in length. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed. Dose Numerical overlap in dose, 5 mL compared to 5 mg Strength (b) (4)	Orthographic differences When scripted the letter string 'alept' may look different than 'telase'. Additionally, the shape of Myalept is different than Myosline. Myalept is compromised of 3 upstrokes and 2 downstrokes. Whereas, Myosline is comprised of 2 upstrokes and 1 downstroke. Frequency of Administration Myalept is administered once daily compared to oral administration up to 4 times daily.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Nydrazid Tablets (Isoniazid) Dosage form: Tablet Strength: 300 mg Usual dose: Take 1 tablet by mouth daily OR Take 3 tablets by mouth twice weekly	Orthographic similarity to Myalept When scripted the letter string 'Myal' may look similar to 'Nyd'. Additionally, the shape of Myalept and Nydrazid are similar. Both names are compromised of 3 upstrokes and 2 downstrokes when 'z' is scripted as a downstroke. Dosage form Both products are available as a single dosage form, thus maybe omitted when prescribing. Frequency of Administration Both products are administered once daily.	Orthographic differences When scripted the letter string 'alept' may look different than 'razid'. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose. Strength There are no overlapping product strengths between products.

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.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Nystatin Cream, Ointment, Topical Powder Dosage form: Cream, Ointment, Oral suspension, Topical Powder Strength: 100,000 Units/gram Usual dose: Topical Preparations Apply to affected area 3 times daily Oral Preparation Place 1 mL to inside of each cheek 4 times daily	Orthographic similarity to Myalept When scripted the letters 'My' and 'Ny' may look similar. Myalept and Nystop are similar in length, 7 letters compared to 6 letters. Dose Overlap in dose 1 mL	Orthographic differences When scripted the letter string 'alept' may look different than 'statin'. Dosage form Single dosage form vs. multiple dosage forms and no overlap in dosage form. Thus, the dosage form of Nystatin must be specified whereas the dosage form of Myalept may be omitted. Frequency of Administration Myalept is administered once daily compared to oral administration up to 4 times daily. Strength There are no overlapping product strengths between products. Route of administration Subcutaneous administration compared to oral administration or topical application.

Proposed name: Myalept (Metreleptin) **Dosage Form(s):** Lyophilized Powder **Strength(s):** (b) (4) **Usual Dose:** 2.5 mg sub-q daily or 0.5 mL (men) OR 5 mg sub-q daily or 1 mL (women) OR 0.06 mg/kg or 0.012 mL/kg (< 40 kg)	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Nystop Topical Powder (Nystatin) Dosage form: Topical Powder Strength: 100,000 Units/gram, 100,000 Units/mL Usual dose: Apply to affected area 3 times daily	Orthographic similarity to Myalept When scripted the letters 'My' and 'Ny' may look similar. Myalept and Nystop are similar in length, 7 letters compared to 6 letters. Dosage form Both products are available as a single dosage form. Thus the dosage form maybe omitted when prescribed.	Orthographic differences When scripted the letter string 'alept' may look different than 'stop'. Dose Myalept is dosed based on gender or weight. The dose of Myalept must be specified when prescribed. There is no overlap in dose. Frequency of Administration Myalept is administered once daily compared to oral administration up to 3 times daily. Route of administration Subcutaneous administration compared to topical application. Strength There are no overlapping product strengths between products.

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/s/

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