

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

200677Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: November 28, 2012

Reviewer: Reasol S. Agustin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Signifor (Pasireotide) Injection, 0.3 mg/mL, 0.6 mg/mL, and 0.9 mg/mL

Application Type/Number: NDA 200677

Applicant/Sponsor: Novartis

OSE RCM #: 2012-2248

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Signifor is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, *Signifor*, acceptable in OSE Review #2012-472 dated May 11, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review #2012-472. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded one new name (Lipitor) thought to look and sound similar to Signifor and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Signifor and lead to medication errors. This analysis determined that the name similarity between Signifor and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 27, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on October 4, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

4 REFERENCES

1. OSE Reviews

- #2012-472 Signifor (Pasireotide) Injection Proprietary Name Review (NDA 200677) dated May 11, 2012- Acceptable

- [REDACTED] (b) (4)

- [REDACTED] (b) (4)

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

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

3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

No.	Proposed name: <i>Signifor</i> (Pasireotide) Dosage Form and Strength: Injection solution: 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Pre-diabetes/Diabetes: Initial doses of 0.6 mg subcutaneously twice daily. Child-Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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.	Lipitor (Atorvastatin) Dosage Form and Strength: Oral tablets: 10 mg, 20 mg, 40 mg, 80 mg Usual dose: Initial: 10 mg to 20 mg by mouth once daily. Maintenance: 10 mg to 80 mg once daily	Orthographic similarity: The beginning letter strings ‘Sig’ and ‘Lip’ and the ending letter strings ‘for’ and ‘tor’ appear orthographically similar when scripted, specifically if the letter ‘f’ is scripted without a downstroke.	Orthographic difference: Signifor contains an additional letter ‘n’ which makes the middle letter strings ‘ni’ and ‘i’ appear orthographically different when scripted. Strength: Both are available in multiple strengths, thus an order for Signifor and Lipitor will require a strength for a complete prescription. There is no numerical overlap between the strengths. Dose: Inject xx mg vs. Take 1 tablet

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/s/

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11/28/2012

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

Proprietary Name Review

Date: May 11, 2012

Reviewer(s): Jamie Wilkins Parker, Pharm.D.
Division of Medication Error Prevention and Analysis

Acting Team Leader: Yelena Maslov, Pharm.D.
Division of Medication Error Prevention and Analysis

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

Drug Name(s) and Strength(s): Signifor (Pasireotide) Injection, 0.3 mg/mL,
0.6 mg/mL and 0.9 mg/mL

Application Type/Number: NDA 0200677

Applicant/Sponsor: Novartis

OSE RCM #: 2012-472

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The proprietary name, Signifor was previously reviewed and found conditionally acceptable (b) (4). It was re-submitted for consideration under IND (b) (4) 068635, however the request was withdrawn as of February 4, 2011. The proprietary name is now being considered under the NDA application.

1.2 PRODUCT INFORMATION

The following product information is provided in the February 17, 2012 proprietary name submission.

- Active Ingredient: Pasireotide
- Indication of Use: Somatostatin analogue indicated for the treatment of patients with Cushing's disease who require medical therapeutic intervention.
- Route of Administration: Subcutaneous injection
- Dosage Form: solution for injection
- Strength: 0.3 mg/mL, 0.6 mg/mL, 0.9 mg/mL
- Dose and Frequency: The recommended initial dose is 0.9 mg subcutaneously twice daily. An initial dose of 0.6 mg twice a day may be considered for patients with pre-diabetes or diabetes mellitus. The recommended initial dose for patients with moderate hepatic impairment (Child Pugh Class B) is 0.3 mg twice daily. A maximum dose of 0.6 mg twice daily is recommended for patients with moderate hepatic impairment.
- How Supplied: Boxes of 60 ampules
- Storage: Store at 77° F, protect from light

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) SEARCH*

On April 26, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Signifor, is not coined with any specific relevance or link to the product. 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*

32 practitioners participated in DMEPA's prescription studies. The interpretations did overlap with or appear or sound similar to the currently marketed product, Singulair. Two prescribers in the voice study also interpreted the name to begin with the letter 'C'. 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, March 2, 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, Signifor. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Signifor identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines, which were not initially identified and evaluated in OSE Review #2009-340.

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

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	FDA	Segontin	FDA	NeoProfen	FDA
(b) (4)	FDA	Digoxin	FDA	(b) (4)	FDA
Tegopen	FDA	Tagamet	FDA	Tasigna	FDA

Lipofen	FDA	Naprelan	FDA	Sensipar	FDA
Singulair	FDA				
Sound Similar					
<i>Name</i>	<i>Source</i>				
Silenor	FDA				
(b) (4)	FDA				

Our analysis of the fifteen names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all fourteen 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 via e-mail on April 26, 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 May 10, 2012 they stated no additional concerns with the proposed proprietary name, Signifor.

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 Ermias Zerislassie, OSE project manager, at 301-796-0097

COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Signifor, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your February 17, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

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

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

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

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

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

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

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

17. Walgreens (www.walgreens.com)

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

18. Rx List (www.rxlist.com)

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

19. Dogpile (www.dogpile.com)

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	- 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 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 possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

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

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

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

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

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

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

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

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

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

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

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

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Signifor	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'S'	A, C, G, and I	'C,' 'Ps,' 'X,' or 'Z'
lower case 's'	a, g, l, n, or r	'C,' 'X,' or 'Z'
lower case 'i'	c, e, l	any vowel
lower case 'g'	s, q, y, or z	'c,' 'ck,' 'gh,' or 'k'
lower case 'n'	h, m, r, s, u, v, or x	'l' or 'm'
lower case 'f'	t or x	'ph' or 'v'
lower case 'o'	a, v, and u	any vowel
lower case 'r'	n, s, t, v, or x	

Appendix C: Prescription Simulation Samples and Results

Figure 1. Signifor Study (Conducted on March 1, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> <i>Signifor 0.9mg SP BID</i>	Signifor 0.9 mg/mL Take as directed Dispense 1 box
<u>Outpatient Prescription:</u> <i>Signifor 0.9mg/mL</i> <i>UAD</i> <i>#1 box</i>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Signifor

As of Date 4/26/2012

84 People Received Study

32 People Responded

Study Name: Signifor

Total	10	13	9	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CIGNACORE	0	1	0	1
CYNGATHOR	0	1	0	1
SIGMIFAR	0	0	2	2
SIGMIFAR O	0	0	1	1
SIGNAFOR	0	7	0	7
SIGNAFOUR	0	1	0	1
SIGNIFAR	7	0	3	10
SIGNIFIER	0	0	1	1
SIGNIFOR	1	0	1	2
SIGNIFORE	0	1	0	1
SINGAPHOR	0	1	0	1
SINGULAIR	0	0	1	1
SINNAFOR	0	1	0	1
SIYNIFAR	2	0	0	2

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 Signifor	Failure preventions
(b) (4)			
(b) (4)			
(b) (4)			
Tegopen	Cloxacillin Sodium	Orthographic	Product associated with NDA 050192, Withdrawn, FR effective 9/29/1995, and ANDA 061453, Withdrawn, FR effective 5/10/1999; no remaining generics on the market.
(b) (4)			

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: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
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Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Digoxin -0.05, 0.1, 0.2 mg capsules, 0.125, 0.25 mg tablets, 0.05 mg/mL oral solution, 0.1 mg/mL, 0.25 mg/mL solution for injection Maintenance doses: 0.125-0.375 mg once daily (oral) or 0.1-0.4 mg intravenously once daily. Pediatric: 5-15 mcg/kg per day (oral) 2-12 mcg/kg intravenously per day (average dose for 30 kg child= 60-450 mcg per day)	Orthographic name similarity - Both names begin with letters which can be similarly shaped, contain a downstroke in the third position, and a cross stroke in a similar position at the end of the name. Product characteristics -Route of administration (oral) -Dosage Form (solution for injection)	Product Characteristic Differences -Strength (0.3 mg, 0.6 mg, or 0.9 mg vs. 0.05, 0.1, 0.125, 0.2, 0.25 mg) -Dose (0.3 mg, 0.6 mg, or 0.9 mg vs. (when written in mg) 0.1-0.5 mg) -Route of administration (subcutaneous vs. oral or intravenous)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Tagamet (Cimetidine) -200 mg, 300 mg, 400 mg, 800 mg oral tablet, 300 mg/5 mL oral solution, 300 mg in Sodium Chloride 0.9% solution for injection -Oral: 200 mg prior to meals, up to 800 mg twice daily. -Intravenous: 300 mg intravenously over no less than 5 minutes every 6 hours or 50 mg/hour by continuous infusion or 150 mg as a single intravenous bolus dose followed by 37.5 mg/hour continuous infusion. Pediatric: 5-40 mg/kg/day every 6-12 hours (average dose for 50 kg child = 150-1200 mg)	Orthographic similarities: -Both names begin with letters which can be similarly shaped when scripted, as well as contain a downstroke in the third position, and a cross stroke in a similar position at the end of the name. Product Characteristics: -Dosage form (solution for injection) -Frequency (twice daily)	Orthographic Differences -The ending letter strings ('for' vs. 'met') appear different when scripted. Product Characteristic Differences: -Strength (0.3 mg, 0.6 mg, or 0.9 mg vs. 200 mg, 500 mg, 800 mg, 300 mg/5 mL or 300 mg in 0.9% NaCl)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Napreelan (Naproxen) -375 mg, 500 mg, 750 mg controlled- release tablet -750 or 1000 mg by mouth once daily. Minimum dosage 375 mg once daily, maximum dosage 1500 mg once daily (for limited periods of time)	Orthographic name similarity -Both names begin with letters that can be similarly scripted, contain a downstroke in the third position, and an upstroke in the sixth.	Product Characteristic Differences -Strength and Dose (0.3 mg, 0.6 mg, or 0.9 mg vs. 375 mg, 500 mg, or 750 mg)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
NeoProfen (Ibuprofen Lysine) -10 mg/mL solution for injection -10 mg/kg intravenously, followed, if necessary by 2 doses of 5 mg/kg intravenously at 24 hour intervals. Average dose for neonate at < or equal to 32 weeks gestation (based upon weight of 1.7 kg) = 8.7- 17.4 mg	Orthographic name similarity -Both names begin with letters that can be similarly scripted, contain a downstroke in a similar position, and an f in the sixth position. Product Characteristics -Dosage form (solution for injection)	Orthographic Differences -The initial downstroke in Signifor occurs in the third position whereas the initial downstroke in Neoprofen occurs in the fourth. Although the occurrences are only one position in difference, the letter string ‘epro’ in Neoprofen appears longer when scripted. Product Characteristic Differences -Strength (0.3 mg, 0.6 mg, or 0.9 mg vs. single strength which would not be required for a prescription) -Frequency (twice daily vs. once, then once daily if necessary)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
(b) (4) [Redacted] [Redacted] [Redacted]	[Redacted] [Redacted]	[Redacted] [Redacted] [Redacted] [Redacted]

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Tasigna (Nilotinib) -150 mg, 200 mg capsule -300-400 mg by mouth twice daily	Orthographic similarities -Both names begin with letters which could be similarly scripted, and contain a downstroke Product Characteristics -Frequency (twice daily)	Orthographic Differences -Although both names contain a downstroke 'g', they occur in different positions (3rd position vs. 5th position) therefore conferring orthographic difference to the name pair. Product Characteristic Differences -Strength (0.3 mg, 0.6 mg, or 0.9 mg vs. 150 mg or 200 mg) -Dose (0.3 mg, 0.6 mg, or 0.9 mg vs. 300 or 400 mg)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Sensipar (Cinacalcet) -30 mg, 60 mg, 90 mg tablets -Initial dose 30 mg twice daily, increased to 60 mg or 90 mg twice daily, up to 90 mg 3-4 times per day to normalize calcium levels.	Orthographic Similarities -Both names begin with S, and contain a letter in the 6th position that can be scripted with a downstroke. Product Characteristics -Frequency (twice daily)	Orthographic Differences -Signifor contains a downstroke (g) in the third position, whereas Sensipar does not contain a downstroke until the sixth position, therefore conferring orthographic difference to the name pair.

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Lipofen (Fenofibrate) -50 mg and 150 mg capsule -50-150 mg by mouth once daily with a meal	Orthographic Similarities -Both names begin with letters which can be scripted similarly, contain a downstroke in the third position, and an f in similar positions within the name.	Product Characteristic Differences -Frequency (twice daily vs. once daily) -Strength (0.3, 0.6, or 0.9 mg vs. 50 or 150 mg) -Dose (one ampoule or one mL vs. one tablet)

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Silenor (Doxepin) -3 mg, 6 mg tablet -6 mg by mouth once daily within 30 minutes of bedtime; a lower dose of 3 mg may benefit some patients	Phonetic Similarities -Both names begin with the letter string 'Si' followed by a consonant, which gives the letter string the same phonetic sound when spoken. Both names also end with the letter strong 'or'. Product Characteristics Strength similarities (0.3 mg, 0.6 mg vs. 3 mg, 6 mg)	Phonetic Differences Although both names begin with the letter string 'Si', Signifor contains the hard consonant sound 'g', which differentiates it from the 'l' sound in Silenor in their first syllable.

Proposed name: Signifor (Pasireotide) Dosage Form(s): Solution for Injection Strength(s): 0.3 mg/mL, 0.6 mg/mL and 0.9 mg/mL Usual Dose: Initial dose of 0.9 mg subcutaneously twice daily. Initial doses of 0.6 mg subcutaneously twice daily may be considered for patients with pre- diabetes or diabetes. Patients with Child- Pugh Class C hepatic impairment: 0.3 mg subcutaneously twice daily.	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
Singulair (Montelukast) -4 mg, 5 mg, 10 mg tablets -4 mg granules -Adults: 10 mg by mouth once daily in the evening Peds: 1-5 years 4 mg by mouth once daily in the evening, 6-14 years 5 mg by mouth once daily in the evening	Orthographic Similarities -Both names begin with the letter S, contain downstrokes in similar positions in the name, letters that can be upstrokes in similar positions in the name, and end with the letter r.	Product Characteristic Differences -Strength (0.3 mg, 0.6 mg, or 0.9 mg vs. 4 mg, 5 mg, or 10 mg) -Frequency (twice daily vs. once daily)

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/s/

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