CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125559Orig1s000

PROPRIETARY NAME REVIEW(S)

Proprietary Name Memorandum

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	December 9, 2014
Application Type and Number:	BLA 125559
Product Name and Strength:	Praluent (alirocumab) injection, 75 mg/mL and 150 mg/mL
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sanofi-aventis U.S. LLC
Submission Date:	November 24, 2014
Panorama #:	2014-44221
DMEPA Primary Reviewer:	Mishale Mistry, PharmD, MPH
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Praluent (BLA 125559). DMEPA previously found the name acceptable in OSE Review # 2014-26054[1], dated November 14, 2014.

1.1 PRODUCT INFORMATION

The following product information is provided in the November 24, 2014 proprietary name submission.

- Intended Pronunciation: pruh-LOO-ent
- Active Ingredient: alirocumab
- Indication of Use:
    - Indicated for long-term treatment of adult patients with primary hypercholesterolemia (non-familial and heterozygous familial) or mixed dyslipidemia, including patients with type 2 diabetes mellitus, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (ApoB), triglycerides (TG), and lipoprotein (a) [Lp(a)], and to increase high-density lipoprotein cholesterol (HDL-C) and apolipoprotein A1 (ApoA1).
    - Indicated in combination with a statin (HMG-CoA reductase inhibitor), with or without other lipid-modifying therapy.
    - Indicated as monotherapy, or as add-on to other non-statin lipid-modifying therapy, including in patients who cannot tolerate statins.
- Route of Administration: Subcutaneous injection
- Dosage Form: Solution
- Strength: 75 mg/mL, 150 mg/mL
- Dose and Frequency: Depending on the clinical situation, alirocumab can be started at 75 mg or 150 mg administered once every 2 weeks. If further LDL-C reduction is needed in patients started at 75 mg once every 2 weeks, the dose may be up-titrated to 150 mg once every 2 weeks.
- How Supplied: Alirocumab is intended to be supplied in 2 presentations:
    - Pre-filled syringe for single-use in 75 mg and 150 mg doses
    - Pre-filled pen for single-use in 75 mg and 150 mg doses

[1] Mistry M. Proprietary Name Review for Praluent (IND 105574). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Nov 24. 41 p. OSE RCM No.: 2014-26054.

Alirocumab will be supplied in [redacted] pack sizes to include cartons of one (1), two (2) [redacted] one mL pre-filled pen(s) or pre-filled syringe(s) for the 75 mg and for the 150 mg doses.

- Storage: Alirocumab should be stored at 2°C to 8°C (36°to 46° F). Do not freeze. Do not expose to extreme heat. Store in the unopened original packaging (outer carton) in order to protect from light until time of administration.
- Container and Closure Systems:
    - Pre-filled syringe: composed of the bulk prefilled syringe and the plunger rod inserted into the plunger stopper to allow delivery of the syringe contents
    - Pre-filled pen: composed of the bulk prefilled syringe and the auto-injector to allow delivery of the syringe contents

2 METHODS AND DISCUSSION

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 4) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2014-26054 that have orthographic and phonetic similarities to the proposed name Praluent. Additionally, we re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The December 9, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO THE APPLICANT

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

4 REFERENCES

1. Mistry M. Proprietary Name Review for Praluent (IND 105574). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Nov 24. 41 p. OSE RCM No.: 2014-26054.

2. ***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.

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

   POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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

/s/

MISHALE P MISTRY
12/09/2014

YELENA L MASLOV
12/15/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 14, 2014
Application Type and Number:	IND 105574
Product Name and Strength:	Praluent (alirocumab) injection, 75 mg/mL and 150 mg/mL
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sanofi
Submission Date:	August 5, 2014
Panorama #:	2014-26054
DMEPA Primary Reviewer:	Mishale Mistry, PharmD, MPH
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Praluent, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name, (b) (4) on April 14, 2014. However, during the initial steps of the proprietary name review process, the Office of Prescription Drug Promotion (OPDP) did not recommend the use of the proposed proprietary name (b) (4) because it (b) (4) (OSE Review # 2014-17215, dated May 7, 2014.

Thus, the sponsor submitted the name, Praluent, for review on August 5, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the August 5, 2014 proprietary name submission.

- Intended Pronunciation: pruh-LOO-ent
- Active Ingredient: alirocumab
- Indication of Use:
    - Adjunct therapy to diet, for long term treatment of adult patients with primary hypercholesterolemia (non-familial and heterozygous familial) or mixed dyslipidemia (corresponding to Type IIa and Type IIb hyperlipidemia in the Fredrickson classification), including patients with type 2 diabetes mellitus, to reduce low density lipoprotein (LDL-C), total cholesterol (Total-C), non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (ApoB), triglycerides (TG), and lipoprotein (a) [Lp(a)], and to increase high-density lipoprotein cholesterol (HDL-C) and apolipoprotein A1 (ApoA1).
    - *Combination therapy with a statin:* In combination with a statin (HMG-CoA reductase inhibitor), with or without other lipid modifying therapy (LMT), in patients not appropriately controlled with a statin alone.
    - *Monotherapy:* As monotherapy, or as add-on to other non-statin LMT, including in patients who cannot tolerate statins.
- Route of Administration: Subcutaneous injection
- Dosage Form: Solution
- Strength: 75 mg/mL, 150 mg/mL

- Dose and Frequency: Depending on the clinical situation, alirocumab may be initiated at 75 mg or 150 mg subcutaneously once every 2 weeks. If further LDL-C reduction is needed in patients started at 75 mg once every 2 weeks, the dose may be up-titrated to 150 mg once every two weeks.
- How Supplied: Pre-filled syringe for single-use in 75 mg and 150 mg doses; Pre-filled pen for single-use in 75 mg and 150 mg doses. Alirocumab will be supplied in (b) (4) pack sizes to include cartons of one, two, (b) (4) 1 mL pre-filled pen(s) or pre-filled syringe(s) for the 75 mg and 150 mg doses.
- Storage: Store at 2°C – 8°C (36°F – 46°F). Do not expose to extreme heat. Store in unopened original packaging (outer carton) in order to protect from light until time of administration.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Praluent in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.4 FDA Name Simulation Studies

One hundred seventeen (117) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Forty-two (42) participants interpreted the entire name correctly (outpatient n=22, voice n=3, inpatient n=17). Two participants misinterpreted the capital letter 'P': 1 for an F

[1]USAN stem search conducted on August 15, 2014.

(voice n=1), and 1 for a 'J' (inpatient n=1). Forty-four (44) participants misinterpreted the letter string 'Pral': 5 for 'Perl' (voice n=5), 9 for 'Prel' (voice n=9), 2 for 'Pril' (voice n=2), 23 for 'Prol' (outpatient n=3, voice n=11, inpatient n=9), and 5 for 'Prul' (outpatient n=1, voice n=4). Twenty-seven (27) participants misinterpreted the letter string 'uent' for 'vent' (outpatient n=8, inpatient n=19). Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 22, 2014 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.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	5
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	263
Low similarity name pair: combined match percentage score ≤49%	10

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 278 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on November 3, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on November 13, 2014, they stated no additional concerns with the proposed proprietary name, Praluent.

[2] POCA search conducted on August 15, 2014.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Praluent should be submitted once the BLA is submitted.

If any of the proposed product characteristics as stated in your August 5, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***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.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

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.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: 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.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   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.

d. 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.

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.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

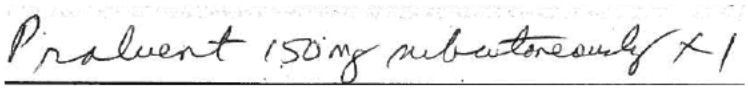
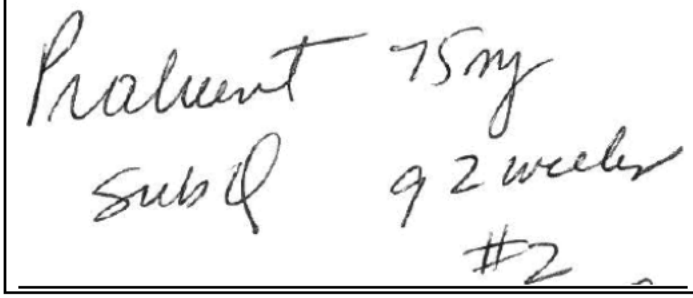
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Praluent Study (Conducted on August 15, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Praluent Inject 75 mg subcutaneously every 2 weeks. Dispense #2.
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received Study
117 People Responded

Study Name: Praluent

Total	35	38	44	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
FOLUINT	0	1	0	1
JULEBER	0	0	1	1

PERLUANT	0	1	0	1
PERLUENT	0	3	0	3
PERLUIT	0	1	0	1
PRAL???	1	0	0	1
PRALRENT	1	0	0	1
PRALUCENT	1	0	0	1
PRALUENT	22	3	17	42
PRALUVENT	1	0	0	1
PRALUVENT?	1	0	0	1
PRALVENT	4	0	16	20
PRAVLUENT	0	0	1	1
PRELUENT	0	7	0	7
PRELUID	0	1	0	1
PRELUIT	0	1	0	1
PRILUANT	0	1	0	1
PRILUENT	0	1	0	1
PROLUENT	2	10	6	18
PROLUINT	0	1	0	1
PROLVENT	1	0	3	4
PRULENT	0	1	0	1
PRULUENT	0	2	0	2
PRULUMENT	0	1	0	1
PRULUVENT	1	0	0	1
PURLUENT	0	2	0	2
PURULENT	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Praluent **Strength(s):** 75 mg/mL, 150 mg/mL **Usual Dose:** 75 mg or 150 mg subcutaneously once every 2 weeks	**POCA Score (%)**	**Failure preventions** **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**	**Product Characteristics (Dosage Form, Strength, Dose)**
1.	Praluent	100	N/A – Subject of review.	N/A – Subject of review.
2.	(b) (4) ***	96	N/A – Name withdrawn by sponsor (Sanofi) on 6/6/2013; (b) (4)	
3.	Pro-vent	74	N/A – International product formerly marketed in UK and Ireland.	
4.	Preludin	70	N/A – Withdrawn, FR effective September 22, 1999.	
5.	Prolensa	70	• The suffixes of the names have sufficient orthographic differences to minimize confusion: 'ensa' does not appear similar to 'uent' when scripted. • Praluent has an additional upstroke letter ('t') located at the end of the proposed name, which is absent in Prolensa. • The second/third syllables of this name pair sound different: 'ensa' does not appear similar to 'luent' when spoken.	**Dosage Form:** Topical ophthalmic solution **Strength:** 0.07% **Usual Dose:** 1 drop into affected eye once daily

*** Contains proprietary information that cannot be released to the public

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Proposed Name	POCA Score (%)
1.	Poly-Vent	68
2.	Prevident	68
3.	Brilinta	66
4.	Eprident	66
5.	Proleukin	66
6.	Duravent	64
7.	Prelief	64
8.	Prilosec	62
9.	Psorent	62
10.	Prefest	61
11.	Atrovent	60
12.	Preven EC	60
13.	Proventil	59
14.	Allent	58
15.	Eluant	58
16.	Oradent	58
17.	Phenavent	58
18.	Prandimet	58
19.	Prazosin	58
20.	Prevalite	58
21.	Puralube	58
22.	Serevent	58
23.	Ferralet	57
24.	Ferralet 90	57
25.	Flovent	57
26.	Atralin	56
27.	Beclovent	56
28.	Prelu-2	56
29.	Procet	56

30.	ProDenRx	56
31.	Pronto	56
32.	Pseudovent	56
33.	Purklenz	56
34.	Duralutin	55
35.	Pepsodent	55
36.	Prascion	55
37.	Prilosec OTC	55
38.	Prolia	55
39.	Prostascint	55
40.	Baciguent	54
41.	Presgen	54
42.	Profen	54
43.	Promacet	54
44.	Propacet	54
45.	TradjentA	54
46.	Keralyt	53
47.	Keralyt 5	53
48.	Pomalyst	53
49.	Prodrin	53
50.	Provenge	53
51.	Votrient	53
52.	Duralex	52
53.	Ludent	52
54.	Phrenilin	52
55.	Poly-Vent DM	52
56.	Prandin	52
57.	Pre-pen	52
58.	Privine	52
59.	Prodium	52
60.	Proglumide	52

61.	Prolex PD	52
62.	Prosed DS	52
63.	PureLax	52
64.	Pyril Tann-12	52
65.	Polycin-B	51
66.	Protilase	51
67.	Benzodent	50
68.	Palpeon	50
69.	Pemirolast	50
70.	Pilostat	50
71.	Plaquenil	50
72.	Prajmaline	50
73.	Pralatrexate	50
74.	Pramcort	50
75.	Prazolamine	50
76.	Prelay	50
77.	Previfem	50
78.	Profenal	50
79.	Proguanil	50
80.	Proloprim	50
81.	Superdent	50
82.	Tri Vent DM	50

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Praluent **Strength(s):** 75 mg/mL, 150 mg/mL **Usual Dose:** 75 mg or 150 mg subcutaneously once every 2 weeks	POCA Score (%)	**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.	Prelone	66	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'lone' does not appear similar to 'luent' when scripted. • Praluent has an additional upstroke letter ('t') located at the end of the proposed name, which is absent in Prelone. • In terms of phonetic differences, Praluent has three syllables whereas Prelone has two syllables. • The second/third syllables of this name pair sound different: 'lone' does not appear similar to 'luent' when spoken.
2.	Proline	66	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'line' does not appear similar to 'luent' when scripted. • Praluent has an additional upstroke letter located at the end of the proposed name, which is absent in Proline. • In terms of phonetic differences, Praluent has three syllables whereas Proline has two syllables. • The second/third syllables of this name pair sound different: 'line' does not appear similar to 'luent' when spoken.
3.	Alupent	63	• The names begin with different first letters: 'A' will likely not be confused for 'P' when written or spoken. • The prefixes of the names have sufficient orthographic differences to minimize confusion: 'Al' does not appear similar to 'Pra' when scripted. • Alupent has a downstroke letter located at the

			middle of the name, which is absent in Praluent. • The first syllables of this name pair sound different: 'Al' does not appear similar to 'Pral' when spoken.
4.	Progest	61	• The suffixes of the names have sufficient orthographic differences to minimize confusion: 'gest' does not appear similar to 'uent' when scripted. • Progest has a downstroke letter located at the middle of the name, which is absent in Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Progest has two syllables. • The second/third syllables of this name pair sound different: 'gest' does not appear similar to 'uent' when spoken.
5.	Probalan	60	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'balan' does not appear similar to 'luent' when scripted. • Praluent has an upstroke letter located at the end of the proposed name. • The second/third syllables of this name pair sound different: 'balan' does not appear similar to 'luent' when spoken.
6.	Prialt	59	• The length of the names differs by two letters. • The suffixes of the names have sufficient orthographic differences to minimize confusion: 'alt' does not appear similar to 'uent' when scripted. • Prialt has an additional upstroke letter, which is absent in Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Prialt has two syllables. • The second/third syllables of this name pair sound different: 'alt' does not appear similar to 'luent' when spoken.
7.	Predalone 50	58	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'dalone' does not appear similar to 'luent' when scripted.

			• The second/third syllables of this name pair sound different: ‘dalone’ does not appear similar to ‘luent’ when spoken.
8.	ProCentra	58	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘Centra’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘Centra’ does not appear similar to ‘luent’ when spoken.
9.	Protein C	58	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘tein’ does not appear similar to ‘uent’ when scripted. • The second/third syllables of this name pair sound different: ‘tein’ does not appear similar to ‘luent’ when spoken.
10.	Ultralente	58	• The names begin with different first letters: ‘U’ will likely not be confused for ‘P’ when written or spoken. • The length of the names differs by two letters. • The prefixes of the names have sufficient orthographic differences to minimize confusion: ‘Ul’ does not appear similar to ‘Pra’ when scripted. • Ultralente has two additional upstroke letters, which are absent in Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Ultralente has four syllables. • The first/second syllables of this name pair sound different: ‘Ultra’ does not appear similar to ‘Pralu’ when spoken.
11.	Prolixin	57	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘lixin’ does not appear similar to ‘luent’ when scripted. • Prolixin has an additional upstroke letter, which is absent in Praluent. • The second/third syllables of this name pair sound different: ‘lixin’ does not appear similar to ‘luent’

			when spoken.
12.	Pramlintide	56	• The length of the names differs by three letters. • The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'lintide' does not appear similar to 'luent' when scripted. • Pramlintide has three additional upstroke letters, which are absent in Praluent. • The second/third syllables of this name pair sound different: 'lintide' does not appear similar to 'luent' when spoken.
13.	Predate-50	56	• The suffixes of the names have sufficient orthographic differences to minimize confusion: 'date' does not appear similar to 'uent' when scripted. • In terms of phonetic differences, Praluent has three syllables whereas Predate has two syllables. • The second/third syllables of this name pair sound different: 'date' does not appear similar to 'luent' when spoken.
14.	Prolastin	56	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'lastin' does not appear similar to 'luent' when scripted. • Prolastin has an additional upstroke letter, which is absent in Praluent. • The second/third syllables of this name pair sound different: 'lastin' does not appear similar to 'luent' when spoken.
15.	Pred-Ject-50	55	• The suffixes of the names have sufficient orthographic differences to minimize confusion: 'Ject' does not appear similar to 'luent' when scripted. • Pred-Ject-50 has an additional upstroke letter, which is absent in Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Pred-Ject has two syllables. • The second/third syllables of this name pair sound

			different: ‘Ject’ does not appear similar to ‘luent’ when spoken.
16.	Duralone	54	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘ralone’ does not appear similar to ‘luent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Duralone. • The first and third syllables of this name pair sound different: ‘Du’ does not appear similar to ‘Pra’ and ‘one’ does not appear similar to ‘ent’ when spoken.
17.	Furalan	54	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘ralan’ does not appear similar to ‘luent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Furalan. • The first/second syllables of this name pair sound different: ‘Fura’ does not appear similar to ‘Pralu’ when spoken.
18.	Perazine	54	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘razine’ does not appear similar to ‘luent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Perazine. • The second/third syllables of this name pair sound different: ‘razine’ does not appear similar to ‘luent’ when spoken.
19.	Predaject-50	54	• The infixes/suffixes of the names have sufficient orthographic differences to minimize confusion: ‘daject’ does not appear similar to ‘luent’ when scripted. • Predaject-50 has an additional upstroke letter and downstroke letter, which are absent in Praluent. • The second/third syllables of this name pair sound

			different: ‘daject’ does not appear similar to ‘luent’ when spoken.
20.	Protenate	54	• The infixes/suffixes of the names have sufficient orthographic differences to minimize confusion: ‘tenate’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘tenate’ does not appear similar to ‘luent’ when spoken.
21.	Dralzine	53	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘zine’ does not appear similar to ‘uent’ when scripted. • In terms of phonetic differences, Praluent has three syllables whereas Dralzine has two syllables. • The second/third syllables of this name pair sound different: ‘zine’ does not appear similar to ‘luent’ when spoken.
22.	Percolone	53	• The infixes/suffixes of the names have sufficient orthographic differences to minimize confusion: ‘colone’ does not appear similar to ‘luent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Percolone. • The second/third syllables of this name pair sound different: ‘colone’ does not appear similar to ‘luent’ when spoken.
23.	Pramine	53	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘mine’ does not appear similar to ‘uent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Pramine. • In terms of phonetic differences, Praluent has three syllables whereas Pramine has two syllables. • The second/third syllables of this name pair sound different: ‘mine’ does not appear similar to ‘luent’

			when spoken.
24.	Praziquantel	53	• The length of the names differs by four letters. • The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'ziquantel' does not appear similar to 'luent' when scripted. • Praziquantel has an additional upstroke letter and downstroke letter, which are absent from Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Praziquantel has four syllables. • The second/third/fourth syllables of this name pair sound different: 'ziquantel' does not appear similar to 'luent' when spoken.
25.	Primalev, Primalev 300/10, Primalev 300/5, Primalev 300/7.5	53	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'malev' does not appear similar to 'luent' when scripted. • The second/third syllables of this name pair sound different: 'malev' does not appear similar to 'luent' when spoken.
26.	Aralast	52	• The names begin with different first letters: 'A' will likely not be confused for 'P' when written or spoken. • The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'alast' does not appear similar to 'luent' when scripted. • The second/third syllables of this name pair sound different: 'alast' does not appear similar to 'luent' when spoken.
27.	Betavent	52	• The names begin with different first letters: 'B' will likely not be confused for 'P' when written. • The prefixes and infixes of the names have sufficient orthographic differences to minimize confusion: 'Betav' does not appear similar to 'Pralu' when scripted. • The first/second syllables of this name pair sound different: 'Betav' does not appear similar to 'Pralu' when spoken.

28.	Gralise	52	• The names begin with different first letters: ‘G’ will likely not be confused for ‘P’ when written or spoken. • The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘lise’ does not appear similar to ‘luent’ when scripted. • Praluent has an upstroke letter located at the end of the proposed name. • In terms of phonetic differences, Praluent has three syllables whereas Gralise has two syllables. • The second/third syllables of this name pair sound different: ‘lise’ does not appear similar to ‘uent’ when spoken.
29.	Pralmorelin	52	• The length of the names differs by 3 letters. • The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘morelin’ does not appear similar to ‘luent’ when scripted. • Pralmorelin has an additional upstroke letter, which is absent in Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Pralmorelin has four syllables.
30.	Prazepam	52	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘zepam’ does not appear similar to ‘luent’ when scripted. • Praluent has two additional upstroke letters, which are absent in Prazepam. Prazepam has a downstroke letter, which is absent in Praluent. • The second/third syllables of this name pair sound different: ‘zepam’ does not appear similar to ‘luent’ when spoken.
31.	Prezista	52	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘zista’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘zista’ does not appear similar to ‘luent’

			when spoken.
32.	Primlev	52	• The suffixes of the names have sufficient orthographic differences to minimize confusion: 'lev' does not appear similar to 'luent' when scripted. • In terms of phonetic differences, Praluent has three syllables whereas Primlev has two syllables. • The second/third syllables of this name pair sound different: 'lev' does not appear similar to 'luent' when spoken.
33.	Privigen	52	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'vigen' does not appear similar to 'luent' when scripted. • Privigen has a downstroke letter, which is absent in Praluent. • The second syllable of this name pair sound different: 'vig' does not appear similar to 'lu' when spoken.
34.	Pro Red AC	52	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'Red AC' does not appear similar to 'luent' when scripted. • Pro Red AC has two additional upstroke letters, which are absent in Praluent. • The second/third syllables of this name pair sound different: 'Red AC' does not appear similar to 'luent' when spoken.
35.	Proglycem	52	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: 'glycem does not appear similar to 'luent' when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Proglycem. Proglycem has two downstroke letters, which are absent in Praluent. • The second/third syllables of this name pair sound different: 'glycem' does not appear similar to 'luent' when spoken.

36.	Prolex DH	52	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘lex’ does not appear similar to ‘uent’ when scripted. • Prolex DH has two additional upstroke letters, which are absent in Praluent. • The second/thirds syllable of this name pair sound different: ‘lex’ does not appear similar to ‘luent’ when spoken.
37.	Prolex DM	52	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘lex’ does not appear similar to ‘uent’ when scripted. • Prolex DM has two additional upstroke letters, which are absent in Praluent. • The second/third syllables of this name pair sound different: ‘lex’ does not appear similar to ‘luent’ when spoken.
38.	Promit	52	• The length of the names differs by two letters. • The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘mit’ does not appear similar to ‘uent’ when scripted. • The second/third syllables of this name pair sound different: ‘mit’ does not appear similar to ‘luent’ when spoken.
39.	Prorex	52	• The length of the names differs by two letters. • The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘rex’ does not appear similar to ‘uent’ when scripted. • Praluent has two additional upstroke letters, which are absent in Prorex. • The second/third syllables of this name pair sound different: ‘rex’ does not appear similar to ‘luent’ when spoken.
40.	Aralen	51	• The names begin with different first letters: ‘A’ will likely not be confused for ‘P’ when written or spoken. • The length of the names differs by two letters.

			• The infixes of the names have sufficient orthographic differences to minimize confusion: ‘ra’ does not appear similar to ‘lu’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Aralen. • The second syllable of this name pair sound different: ‘ral’ does not appear similar to ‘lu’ when spoken.
41.	Paraflex	51	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘raflex’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘raflex’ does not appear similar to ‘luent’ when spoken.
42.	Predone	51	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘done’ does not appear similar to ‘uent’ when scripted. • Praluent has an additional upstroke letter, located at the end of the proposed name, which is absent in Predone. • In terms of phonetic differences, Praluent has three syllables whereas Predone has two syllables. • The second/third syllables of this name pair sound different: ‘done’ does not appear similar to ‘luent’ when spoken.
43.	Prilocaine	51	• The length of the names differs by two letters. • The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘ocaine’ does not appear similar to ‘uent’ when scripted. • Prilocaine has an additional upstroke letter, which is absent in Praluent. • The second/third syllables of this name pair sound different: ‘ocaine’ does not appear similar to ‘luent’ when spoken.
44.	Portalac	50	• The infixes and suffixes of the names have sufficient

			orthographic differences to minimize confusion: ‘alac’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘alac’ does not appear similar to ‘luent’ when spoken.
45.	Predacort 50	50	• The infixes of the names have sufficient orthographic differences to minimize confusion: ‘dacort’ does not appear similar to ‘luent’ when scripted. • The second/third syllables of this name pair sound different: ‘dacort’ does not appear similar to ‘luent’ when spoken.
46.	Procrit	50	• The suffixes of the names have sufficient orthographic differences to minimize confusion: ‘crit’ does not appear similar to ‘uent’ when scripted. • In terms of phonetic differences, Praluent has three syllables whereas Procrit has two syllables. • The second/third syllables of this name pair sound different: ‘crit’ does not appear similar to ‘luent’ when spoken.
47.	Promacot	50	• The infixes and suffixes of the names have sufficient orthographic differences to minimize confusion: ‘macot’ does not appear similar to ‘luent’ when scripted. • Praluent has an additional upstroke letter, which is absent in Promacot. • The second/third syllables of this name pair sound different: ‘macot’ does not appear similar to ‘luent’ when spoken.
48.	Propoven	50	• The infixes of the names have sufficient orthographic differences to minimize confusion: ‘pov’ does not appear similar to ‘lu’ when scripted. • Praluent has two additional upstroke letters, located in the middle and at the end of the proposed name, which are absent in Propoven. Propoven has a downstroke letter in the middle of the name, which is absent from Praluent.

			• The second syllables of this name pair sound different: 'pov' does not appear similar to 'lu' when spoken.
49.	Tri Vent HC	50	• The names begin with different first letters: 'T' will likely not be confused for 'P' when written or spoken. • The prefixes of the names have sufficient orthographic differences to minimize confusion: 'Tri' does not appear similar to 'Pra' when scripted. • Tri Vent HC has three additional upstroke letters, which are absent from Praluent. • In terms of phonetic differences, Praluent has three syllables whereas Tri Vent has two syllables. • The first syllable of this name pair sound different: 'Tri' does not appear similar to 'Pra' when spoken.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Pradaxa	46
2.	Pravachol	44
3.	Prevacid	44
4.	Prasugrel	43
5.	Plavix	42
6.	Pravastatin	42
7.	Provera	41
8.	Effient	40
9.	Pulmicort	38
10.	Triacin-C	49

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	69	Name found unacceptable by OPDP (OSE RCM #2011-(b) (4)); product approved under proprietary name Invokana.
2.	Prascend	67	Veterinary product.
3.	Prulet	67	This product is discontinued in the US. In January 1999, the FDA formally banned phenolphthalein from OTC laxatives.
4.	Dura-Vent	64	This product is discontinued in the US. The FDA recommended that all phenylpropanolamine-containing products (including combination cough-cold and appetite suppressant products) be removed from the US market on November 6, 2000.
5.	(b) (4)***	63	Name found unacceptable by OPDP (OSE RCM #2013-(b) (4)); product approved under proprietary name Epaned.
6.	Prolex	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	(b) (4)***	62	Name found unacceptable by DMEPA (OSE RCM #2011-(b) (4)). Applicant withdrew proposed proprietary name, and submitted proposed proprietary name (b) (4), which was found unacceptable by OPDP (OSE RCM # 2011-(b) (4)). Application received Complete Response; no new proposed proprietary names were submitted.
8.	Radent	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	(b) (4)***	60	Name found unacceptable by DMEPA upon preliminary review (RCM # 2013-(b) (4)); proposed proprietary name withdrawn by Applicant.
10.	(b) (4)***	60	This is a secondary proposed proprietary name; product approved under proprietary name

*** Contains proprietary information that cannot be released to the public

			Prandimet.
11.	Proben-C	60	This product was withdrawn, FR effective.
12.	Prolintane	60	This is the established name of an international product marketed in Belgium, South Africa, Australia, Switzerland, France, and UK.
13.	(b) (4)***	60	This is a secondary proposed proprietary name; Applicant withdrew both primary and secondary proposed proprietary names. Product approved under proprietary name Olux-E.
14.	(b) (4)***	60	This is a secondary proposed proprietary name; product approved under proprietary name Eovist.
15.	Proloid	59	This product was withdrawn, FR effective March 2, 1993.
16.	(b) (4)	58	This is a secondary proposed proprietary name; primary proposed proprietary name found unacceptable by DMEPA. Preliminary review of secondary proposed proprietary name identified that the name may not be acceptable (OSE RCM #2010-(b) (4)). Product approved under proprietary name Binosto.
17.	(b) (4)***	58	This name was found unacceptable by OPDP (OSE RCM #2012-(b) (4)); product approved without proprietary name.
18.	Prolex D	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Protein S	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Proteins	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	ProZinc	58	Veterinary product.
22.	Pyrolite	58	This product was withdrawn, FR effective May 5, 2004.
23.	(b) (4)***	58	This name was found unacceptable by DMEPA (OSE RCM #2010-(b) (4)); proposed proprietary name TheraVision found acceptable.

*** Contains proprietary information that cannot be released to the public

24.	(b) (4)***	58	This name was found unacceptable by DMEPA (OSE RCM #2010-(b) (4) product approved under proprietary name Tradjenta.
25.	Proflex	57	International product marketed in South Africa, Phillipines, Ireland, and UK.
26.	Salbuvent	57	International product marketed in New Zealand, Finland, Norway, Ireland, and Denmark.
27.	Ferralet TD	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Paracets	56	International product marketed in UK.
29.	(b) (4)***	56	This is the fifth proposed proprietary name; primary and secondary proposed proprietary names found unacceptable by DMEPA. Application active.
30.	Pre-Sate	56	This product was withdrawn, FR effective December 7, 1992.
31.	Pro Dine 5000C	56	Veterinary product.
32.	Prolactin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
33.	Prantal	55	This product was withdrawn, FR effective December 17, 1990.
34.	Dura-Vent/A	54	This product is discontinued in the US. The FDA recommended that all phenylpropanolamine-containing products (including combination cough-cold and appetite suppressant products) be removed from the US market on November 6, 2000.
35.	(b) (4)***	54	This is the secondary proposed proprietary name. Preliminary review of secondary proposed proprietary name identified that the name may not be acceptable (OSE RCM # #2009-(b) (4) Product approved under proprietary name Lazanda.
36.	(b) (4)***	54	Proposed proprietary name found unacceptable by DMEPA (OSE RCM #2009-(b) (4) product approved under proprietary name Lazanda.
37.	(b) (4)***	54	Proposed proprietary name found unacceptable by DMEPA upon preliminary review (OSE RCM

*** Contains proprietary information that cannot be released to the public

			#2010-(b) (4) product approved under proprietary name Lazanda.
38.	Platet	54	International product marketed in Singapore and UK.
39.	Poly Tan D	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Polytan D	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	(b) (4) ***	54	This is the sixth proposed proprietary name; product approved under proprietary name Amturnide.
42.	Pro-Fast	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
43.	Propacet 100	54	This product is discontinued in the US. In November 2010, the FDA requested a market withdrawal of all products containing propoxyphene stating that propoxyphene risks outweigh its benefits.
44.	Propylene	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	ProQuin	54	This product was withdrawn, FR effective July 19, 2013.
46.	(b) (4) ***	54	Name found unacceptable by OPDP (OSE RCM #2009-(b) (4) product approved under proprietary name Horizant.
47.	(b) (4) ***	53	This is the secondary proposed proprietary name; product approved under primary proposed proprietary name Caldolor.
48.	Arbralene	52	International product marketed in UK.
49.	(b) (4) ***	52	This is the secondary proposed proprietary name; product approved under primary proposed proprietary name Rybix ODT.
50.	Propagest	52	This product is discontinued in the US. The FDA recommended that all phenylpropanolamine-containing products (including combination cough-cold and appetite suppressant products) be removed

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			from the US market on November 6, 2000.
51.	Propet	52	Veterinary product.
52.	Prophene 65	52	This product is discontinued in the US. In November 2010, the FDA requested a market withdrawal of all products containing propoxyphene stating that propoxyphene risks outweigh its benefits.
53.	(b) (4)***	52	This is the fifth proposed proprietary name; product approved under proposed proprietary name Amturnide.
54.	(b) (4)***	52	This is the secondary proposed proprietary name; primary proposed proprietary name, (b) (4), found acceptable by DMEPA. Application withdrawn by Applicant.
55.	Doralese	51	International product marketed in UK and Ireland.
56.	(b) (4)***	51	This is the secondary proposed proprietary name; product approved under proprietary names, Kabiven (for the central formula), and Perikabiven (for the central/peripheral formula).
57.	Pluset	51	Veterinary product.
58.	Pripsen	51	International product marketed in UK and Ireland.
59.	Profender	51	Veterinary product.
60.	Pullulan	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Product used for tablet coating, as an excipient to aid tableting processes, in the production of edible films, and as an alternative to gelatin in capsule production.
61.	Dralserp	50	This product was withdrawn, FR effective.
62.	Paloxin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
63.	Pariet	50	International product marketed in multiple countries.
64.	Pemolert	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	(b) (4)***	50	This is the secondary proposed proprietary name; primary proposed proprietary name found

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			unacceptable. Product approved without proprietary name.
66.	Predicort-50	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
67.	(b) (4)***	50	This is the secondary proposed proprietary name; application withdrawn by Applicant.
68.	Profen LA	50	This drug is discontinued in the US. The FDA recommended that all phenylpropanolamine-containing products (including combination cough-cold and appetite suppressant products) be removed from the US market on November 6, 2000.
69.	Prompt	50	International product marketed in Brazil.
70.	Prothiaden	50	International product marketed in multiple countries.
71.	(b) (4)***	50	Name found unacceptable by OPDP (OSE RCM #2013-(b) (4)); proposed proprietary name (b) (4) found acceptable. Application received Complete Response.
72.	(b) (4)***	50	Name found unacceptable by OPDP (OSE RCM #2011(b) (4); product approved under proprietary name Unisom.
73.	(b) (4)***	50	This is the secondary proposed proprietary name; primary and secondary proposed proprietary names withdrawn by Applicant. Product approved without proprietary name.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Brolene	58
2.	Dalacin T	58
3.	(b) (4)***	57
4.	Tri-legest 21	57
5.	Viravan-T	57

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6.	Naprelan	56
7.	Striant	56
8.	Trilone	56
9.	AloeMint	55
10.	Balanta	55
11.	Norplant	55
12.	Trilocot	55
13.	(b) (4) ***	54
14.	Supprelin	54
15.	Triclosept	54
16.	Diprolene	53
17.	Tirosint	53
18.	Triolein	53
19.	(b) (4) ***	52
20.	(b) (4) ***	52
21.	Cal Gest	52
22.	Talwin NX	52
23.	Trilafon	52
24.	Trilaurin	52
25.	Trilocort	52
26.	(b) (4) ***	52
27.	(b) (4) ***	52
28.	U-Tri-Lone	52
29.	(b) (4) ***	52
30.	(b) (4) ***	52
31.	Bravecto	51
32.	(b) (4) ***	51
33.	Myalept	51
34.	Relafen	51
35.	Relenza	51

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36.	Tri Levlen	51
37.	(b) (4) ***	51
38.	Trinalin	51
39.	Viracept	51
40.	Altorant	50
41.	Bellaphen-S	50
42.	beractant	50
43.	Bromelains	50
44.	Duratest	50
45.	Enaprilat	50
46.	Formalin	50
47.	Nalgest	50
48.	(b) (4) ***	50
49.	Qualitest	50
50.	S-2 Inhalant	50
51.	Spirolone	50
52.	Talacen	50
53.	Tranilast	50
54.	Trileptal	50
55.	(b) (4) ***	50
56.	Xtra-Lax	50

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/s/

MISHALE P MISTRY
11/14/2014

YELENA L MASLOV
11/17/2014