

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125522Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	September 22, 2014
Application Type and Number:	IND #105188/BLA #125522
Product Names and Strength:	Repatha (evolocumab) Injection, 140 mg/mL (b) (4) Repatha SureClick (evolocumab) Injection, 140 mg/mL [Autoinjector] (b) (4)
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Amgen
Submission Date:	May 27, 2014 (IND #105188) September 16, 2014 (BLA #125522)
Panorama #:	2014-17394, 2014-17395, 2014-17396 (IND #105188) 2014-26440, 2014-26441 (BLA #125522)
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1 INTRODUCTION

This review evaluates the proposed proprietary names, Repatha, Repatha SureClick, and (b)(4) from a safety and promotional perspective. The proposed proprietary name “Repatha” is considered the root name; “SureClick” and “(b)(4)” are proposed proprietary names for devices that will deliver the drug product. 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) Inc. for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary names, (b)(4) on March 26, 2014. However, the sponsor formally withdraw the request for proprietary name review and subsequently submitted the names, Repatha, Repatha SureClick, and (b)(4) for review on May 27, 2014. In the BLA submission (BLA #125522), the sponsor submitted the names, Repatha and Repatha SureClick, for review on September 16, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 27, 2014 proprietary name submission.

Intended Pronunciation	ri-PATH-a
Active Ingredient	Evolocumab
Indications of Use	<p>Evolocumab is indicated in adults with primary hyperlipidemia (heterozygous familial and nonfamilial) or mixed dyslipidemia, as an adjunct to diet to reduce elevated LDL-C, total cholesterol, ApoB, non-HDL-C, VLDL-C, triglycerides and Lp(a), and to increase HDL-C and ApoA1:</p> <ul style="list-style-type: none">• As monotherapy, or• In combination with an HMG CoA reductase inhibitor (statin), or• Alone or in combination with a statin or other lipid-lowering therapies in patients who are statin-intolerant or unable to tolerate an effective dose of a statin. <p>Evolocumab is indicated in patients at least 12 years of age with homozygous familial hypercholesterolemia to reduce elevated LDL</p>
Route of Administration	subcutaneous injection
Dosage Form	solution for injection
Strengths	<ul style="list-style-type: none">• 140 mg/mL

	(b) (4)
Dose and Frequency	<p>The proposed dosing regimens for primary hyperlipidemia and mixed dyslipidemia are:</p> <ul style="list-style-type: none"> • 140 mg subcutaneously every 2 weeks • 420 mg subcutaneously once monthly. <p>The proposed dosing regimens for homozygous familial hypercholesterolemia are:</p> <ul style="list-style-type: none"> • 420 mg subcutaneously once monthly • 420 mg subcutaneously every 2 weeks
How Supplied	<p>Prefilled syringe (PFS):</p> <ul style="list-style-type: none"> • The PFS is a prefilled, single-use, disposable, handheld, injection device that is provided ready to use. <p>Autoinjector(AI)/pen:</p> <ul style="list-style-type: none"> • The AI/pen is a prefilled, single-use, disposable, handheld, mechanical (spring-based) injection device that is provided ready to use, pre-assembled with the prefilled syringe. <p>(b) (4)</p>
Storage	<p>Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. If removed from the refrigerator, evolocumab should be kept at controlled room temperature (up to 25°C [77°F]) in the original carton and must be used within 30 days. Protect evolocumab from direct light and do not expose to temperatures above 25°C (77°F). Do not freeze.</p>
Container and Closure Systems	<p>Prefilled syringe (PFS):</p> <ul style="list-style-type: none"> • The PFS consists of a 1mL Type 1 glass syringe with a staked needle covered with an (b) (4) needle shield and a (b) (4) plunger-stopper (b) (4) • The (b) (4) needle shield is made from (b) (4), and may be supplemented with an outer plastic rigid cover. • (b) (4) <p>Autoinjector(AI)/pen:</p> <ul style="list-style-type: none"> • The AI/pen is a modified version of the SureClick autoinjector currently approved for Enbrel (etanercept).

	<ul style="list-style-type: none">• The AI/pen differs from the SureClick autoinjector in color  <p>(b) (4)</p>  <p>(b) (4)</p>
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2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

Repatha

The Office of Prescription Drug Promotion (OPDP) determined the proposed root name, Repatha, is acceptable from a promotional perspective. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP’s promotional assessment of the proposed root name.

Repatha SureClick

The Office of Prescription Drug Promotion (OPDP) noted that the device name “SureClick” is already part of an approved product, Enbrel SureClick, from the same sponsor. Therefore, while OPDP found the proposed proprietary name, Repatha SureClick, problematic from a promotional perspective, OPDP did not object to the name. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP’s promotional assessment of the proposed device name.



2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary names¹.

2.2.2 *Components of the Proposed Proprietary Name*

Repatha

The Applicant did not provide a derivation or intended meaning for the proposed root name, Repatha, in their submission. This proprietary root 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.

Repatha SureClick

The Applicant did not provide a derivation or intended meaning for the proposed name, Repatha SureClick, in their submission. This proprietary name is comprised of multiple words that do 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*

Repatha

100 practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Seventy-eight (78) participants interpreted the name correctly (outpatient n=27, voice n=23, inpatient n=28). Thirteen participants misinterpreted the letter string 'Re'; 12 for 'Ri' (voice n=7, inpatient n=5) and 1 for 'Ra' (voice n=1). Five participants misinterpreted the

¹USAN stem search conducted on June 30, 2014.

last letter ‘a’ for an ‘o’ (outpatient n=5). Appendix B contains the results from the verbal and written prescription studies.

Repatha SureClick

One hundred and four (104) practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Fifty-nine (59) participants interpreted the entire name correctly (outpatient n=37, voice n=7, inpatient n=15). Thirty-five (35) participants interpreted only the *root* name correctly (outpatient n=4, voice n=17, inpatient n=14). Three participants interpreted only the *device* name correctly (voice n=2, inpatient n=1). Twenty-six (26) participants misinterpreted the device name as ‘Sure Click’ (voice n=16, inpatient n=10) and two participants misinterpreted the name as ‘Sure-Click’ (voice n=2). Two participants misinterpreted the letter string ‘lick’ as ‘lik’ (voice n=2). Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

Repatha, Repatha SureClick

In response to the OSE, June 4, 2014 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary root name, Repatha or the proposed proprietary name Repatha SureClick, at the initial phase of the review.

(b) (4)

In response to the OSE, June 12, 2014 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of the Office of Prescription Drug Promotion in that the device name (b) (4) is unacceptable from a promotional perspective.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the external study conducted by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	4
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	243
Low similarity name pair: combined match percentage score $\leq 49\%$	2

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

Our analysis of the 249 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Metabolism and Endocrinology (DMEP) via e-mail on August 7, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on August 7, 2014, they stated no additional concerns with the proposed proprietary root name, Repatha, or the proposed proprietary name Repatha SureClick.

3 CONCLUSIONS

Repatha

The proposed proprietary root name, Repatha, is acceptable from both a promotional and safety perspective.

Repatha SureClick

The proposed proprietary name, Repatha 'SureClick' is unacceptable from a promotional perspective. However, because 'SureClick' is already part of an approved product, Enbrel SureClick, there are no objections to the proposed proprietary name.

(b) (4)

The proposed proprietary name, (b) (4) is unacceptable from a promotional perspective. The sponsor will be notified of FDA's decision to object to the name based on promotional concerns via letter.

3.1 COMMENTS TO THE APPLICANT

Repatha, Repatha SureClick

We have completed our review of the proposed proprietary root name, Repatha, and the proposed proprietary name Repatha SureClick and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your May 27, 2014 IND submission or September 16, 2014 BLA submission are altered prior to approval of the marketing application, the names must be resubmitted for review.

(b) (4)

We have completed our review of the proposed proprietary name, (b) (4) and have concluded that this name is unacceptable for the following reasons:

(b) (4)



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

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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment:** For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE 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 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.²

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

- 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

- 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 $\geq 70\%$).

Answer the questions in the checklist below. Affirmative answers to 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 (see Step 1 of the Moderately Similar Checklist).

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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 $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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 have a higher potential for confusion and should be evaluated further (see Step 2).</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any combination drug products, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names with overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Repatha Study (Conducted on June 6, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Repatha 140mg subQ x1</i></p>	<p>Repatha 140 mg subQ every 2 weeks</p> <p>Dispense #2</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Repatha 140mg sub-Q every 2 weeks # 2</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

266 People Received Study				
100 People Responded				
Study Name: Repatha				
Total	34	32	34	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
RAPATHA	0	1	0	1
REPARTHA	0	0	1	1
REPATA	0	1	0	1
REPATHA	27	23	28	78
REPATHO	5	0	0	5
REPATHOR	1	0	0	1
REPATLA	1	0	0	1
RIPATHA	0	7	5	12

Figure 2. Repatha SureClick Study (Conducted on June 13, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Repatha SureClick 140mg subQ x1</i></p>	<p>Repatha SureClick</p> <p>Inject 140 mg subcutaneously every 2 weeks</p> <p>Dispense #2</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Repatha Sureclick 140 mg subQ every 2 weeks Dispense #2</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

					266 People Received Study
					104 People Responded
Study Name: Repatha SureClick					
Total	41	32	31		
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL	
RAPATHA SURECLICK	0	1	0	1	
RAPTHA SURE CLICK	0	1	0	1	
REBASH SURE CLICK	0	1	0	1	
REPACLASUCLIK	0	1	0	1	
REPATA SURE CLICK	0	1	0	1	
REPATHA	0	0	2	2	
REPATHA GURECLICK	1	0	0	1	
REPATHA SHORCLICK	0	1	0	1	
REPATHA SHORT CLICK	0	1	0	1	
REPATHA SURE CHECK	0	0	1	1	
REPATHA SURE CLICK	0	12	9	21	
REPATHA SURE CLICKS	0	0	1	1	

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
REPATHA SURECLICK	37	7	15	59
REPATHA SURE-CLICK	0	1	0	1
REPATHA SURECLICKS	0	0	1	1
REPATHA SURECLIK	0	2	0	2
REPATHA SURECLLICK	1	0	0	1
REPATHA SUREDICK	2	0	0	2
REPATHAA SURECLICK	0	0	1	1
REPAV SURECLICK	0	1	0	1
REPES SURE CLICK	0	1	0	1
RIPATHA SURE CLICK	0	0	1	1
RIPATHA SURE-CLICK	0	1	0	1

Appendix C: Highly Similar Names (i.e., combined POCA score is $\geq 70\%$)

No.	Proposed Root Name: Repatha Strength(s): <ul style="list-style-type: none"> 140 mg/mL (b) (4) 	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion	Product Characteristics (Dosage Form, Strength, Dose)
	Usual Dose: <ul style="list-style-type: none"> 140 mg subcutaneously every 2 weeks 420 mg subcutaneously every 2 weeks 420 mg subcutaneously once monthly 			
1.	Repatha	100	N/A	Subject of Review
2.	Respa-SA	80	<ul style="list-style-type: none"> The length of the names differs by two letters, if the modifier 'SA' is omitted. The infixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'path' does not appear similar to 'spa' when scripted or spoken. In terms of phonetic differences, Repatha has three syllables whereas Respa has two syllables. 	Active ingredient(s): diphenhydramine/ pseudoephedrine HCl SR tablets Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Raptiva	70	<ul style="list-style-type: none"> The infixes of the names have sufficient orthographic and phonetic differences to minimize confusion: 'path' does not appear similar to 'tiv' when spoken. 	Active ingredient(s): efalizumab Strength and Dosage Form: 125 mg/vial (125 mg/1.25 mL) Dose and Frequency: 0.7 mg/kg SC dose, followed by weekly 1 mg/kg SC dose

No.	Proposed Root Name: Repatha Strength(s): <ul style="list-style-type: none"> • 140 mg/mL • _____ (b) (4) Usual Dose: <ul style="list-style-type: none"> • 140 mg subcutaneously every 2 weeks • 420 mg subcutaneously every 2 weeks • 420 mg subcutaneously once monthly 	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion	Product Characteristics (Dosage Form, Strength, Dose)
				(maximum dose: 200 mg)
4.	Replesta	70	<ul style="list-style-type: none"> • The infixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘plest’ when spoken. 	Active ingredient(s): cholecalciferol (Vitamin D3) Strength and Dosage Form: 50,000 IU chewable wafer Dose and Frequency: Loading doses: adults - 1 wafer once weekly x 8 weeks or as directed; children 10-17 yrs - 1 wafer once weekly x 2 weeks or as directed Maintenance doses: as directed by health care provider

Appendix D: Moderately Similar Names (i.e., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)***	69
2.	(b) (4)***	68
3.	Rapaflo	66
4.	Retin-A	66
5.	Rapivab***	64
6.	Repan	63
7.	Repan CF	62
8.	Respa-1st	62
9.	(b) (4)***	62
10.	Rynesa	62
11.	Relpax	61
12.	Retet	61
13.	Rezipas	61
14.	Renova	60
15.	Respa-GF	60
16.	Revatio	60
17.	Reyataz	60
18.	Rhopressa	60
19.	Rifater	60
20.	Ranexa	59
21.	(b) (4)***	59
22.	RotaTeq	59
23.	Rebetol	58
24.	Renaf	58
25.	Respa C&C	58
26.	Respi-Tann	58

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No.	Name	POCA Score (%)
27.	Retavase	58
28.	Ritifed	58
29.	Rowasa	58
30.	(b) (4) ***	56
31.	Rectasol	56
32.	(b) (4) ***	56
33.	Reme-T	56
34.	Respa AR/Respa A.R.	56
35.	Restasis	56
36.	Retisert	56
37.	Revina	56
38.	(b) (4) ***	56
39.	Ridaura	56
40.	Rosadan	56
41.	R-Tanna	56
42.	R-Tanna 12	56
43.	Rynatan	56
44.	(b) (4) ***	56
45.	Redisol	55
46.	Respa-PE	55
47.	Raxar	54
48.	Re Tann	54
49.	Reclast	54
50.	Renese-R	54
51.	Respa DM	54
52.	Revia	54
53.	Rezira	54

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

No.	Name	POCA Score (%)
54.	Ri-Tussin	54
55.	Robafen	54
56.	Vascepa	54
57.	Rapamune	53
58.	RE-10 Wash	53
59.	Rebif	53
60.	Rectiv	53
61.	Rescula	53
62.	Revitol	53
63.	ReadyBath	52
64.	Renvela	52
65.	Respa-BR	52
66.	Revonto	52
67.	Rid-A-Pain	52
68.	Riopan	52
69.	Ritalin	52
70.	Cepastat	52
71.	Zetacet	52
72.	Readi-Cat 2	51
73.	Recofen	51
74.	Recothrom	51
75.	Relafen	51
76.	(b) (4)***	51
77.	RabAvert	50
78.	Relenza	50
79.	Relera	50
80.	Resaid	50

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No.	Name	POCA Score (%)
81.	Resperal	50
82.	Respigam	50
83.	Ridifed	50
84.	Robitet	50
85.	Robitet 500	50
86.	Ron Acid	50
87.	Rytary ^{***}	50
88.	Sepasoothe	50
89.	Campath	50
90.	Tenathan	50

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Appendix E: Moderately Similar Names (i.e., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed Root Name: Repatha, Strength(s): 140 mg/mL _____ (b) (4) Usual Dose: 140 mg subcutaneously every 2 weeks 420 mg subcutaneously every 2 weeks 420 mg subcutaneously once monthly	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.	RibaTab	65	<ul style="list-style-type: none"> The infix and suffix of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘ba’ and ‘a’ does not appear similar to ‘tab’ when scripted or spoken. Repatha has a downstroke letter, which is absent in RibaTab. RibaTab has an additional upstroke letter, not present in Repatha.
2.	ReFacto	64	<ul style="list-style-type: none"> The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘tha’ does not appear similar to ‘to’ when scripted or spoken. Repatha has a downstroke letter, which is absent in ReFacto.
3.	RibaPak	62	<ul style="list-style-type: none"> The infix and suffix of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘ba’ and ‘a’ does not appear similar to ‘Pak’ when scripted or spoken. Repatha has a downstroke letter, which is absent in RibaPak. RibaPak has an additional upstroke letter, not present in Repatha.
4.	(b) (4) ***	60	(b) (4)

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No.	Proposed Root Name: Repatha, Strength(s): 140 mg/mL (b) (4) Usual Dose: 140 mg subcutaneously every 2 weeks 420 mg subcutaneously every 2 weeks 420 mg subcutaneously once monthly	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
			(b) (4)
5.	(b) (4) ***	58	(b) (4)
6.	Rituxan	56	<ul style="list-style-type: none"> • The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘tux’ and ‘a’ does not appear similar to ‘xan’ when written or spoken. • Repatha has a downstroke letter, which is absent in Rituxan. Additionally, Repatha has upstroke letters located at the end of the name whereas Rituxan has upstroke letters located at the beginning of the name.
7.	Rocephin	55	<ul style="list-style-type: none"> • The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘ceph’ and ‘a’ does not appear similar to ‘in’ when written or spoken. • Repatha has an additional upstroke letter, which is absent in Rocephin.
8.	Restall	54	<ul style="list-style-type: none"> • The suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘tha’ does not appear

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No.	Proposed Root Name: Repatha, Strength(s): 140 mg/mL (b) (4) Usual Dose: 140 mg subcutaneously every 2 weeks 420 mg subcutaneously every 2 weeks 420 mg subcutaneously once monthly	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
			<p>similar to ‘stall’ when written or spoken.</p> <ul style="list-style-type: none"> • In terms of phonetic differences, Repatha has three syllables whereas Restall has two syllables. • Repatha has a downstroke letter, which is absent in Restall. Restall has an additional upstroke letter, which is not present in Repatha.
9.	(b) (4) ***	52	(b) (4)
10.	(b) (4) ***	52	
11.	Renocal-76	51	<ul style="list-style-type: none"> • The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘no’ and ‘a’ does not appear similar to ‘cal’ when written or spoken.

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No.	Proposed Root Name: Repatha, Strength(s): 140 mg/mL <hr style="width: 200px; margin-left: 0;"/> (b) (4) Usual Dose: 140 mg subcutaneously every 2 weeks 420 mg subcutaneously every 2 weeks 420 mg subcutaneously once monthly	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
			<ul style="list-style-type: none"> • Repatha has a downstroke letter and an additional upstroke letter, which are absent in Renocal.
12.	RiaSTAP	51	<ul style="list-style-type: none"> • The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘as’ and ‘a’ does not appear similar to ‘tap’ when written or spoken. • Repatha has a downstroke letter, which is absent in RiaSTAP. RiaSTAP has two additional upstroke letters, which are absent in Repatha.
13.	Rifadin	51	<ul style="list-style-type: none"> • The infixes and suffixes of the names have sufficient orthographic and phonetic differences to minimize confusion: ‘path’ does not appear similar to ‘fad’ and ‘a’ does not appear similar to ‘in’ when written or spoken. • Repatha has a downstroke letter, which is absent in Rifadin.

Appendix F: Low Similarity Names (i.e., combined POCA score is $\leq 49\%$)

No.	Name	POCA Score (%)
1.	Robaxin	40%
2.	Yaz	14%

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) ***	68	Proposed proprietary name withdrawn by Applicant.
2.	(b) (4) ***	65	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, (b) (4), was approved.
3.	Respa	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	(b) (4) ***	62	Application inactive (unknown whether the Proprietary Name Review was completed, although consult was requested).
5.	Rispas	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	61	Proposed proprietary name found unacceptable by DMEPA (OSE# 2007-1324/2007-1325); product's proposed proprietary name, (b) (4), was approved.
7.	(b) (4) ***	60	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, (b) (4), was found unacceptable and secondary proposed proprietary name was not submitted for review.
8.	(b) (4) ***	60	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, (b) (4), was approved.
9.	(b) (4) ***	60	Proposed proprietary name found unacceptable by DMEPA (OSE# 2007-1324/2007-1325); product's proposed proprietary name, (b) (4), was approved.
10.	Rimapam	60	International product marketed in the United Kingdom.
11.	Rynessa	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	(b) (4) ***	59	This is a secondary proposed proprietary name, which was found unacceptable from a promotional perspective

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No.	Name	POCA Score (%)	Failure Preventions
			(OSE# 2011-2475); product's proposed proprietary name, (b) (4), was approved.
13.	(b) (4) ***	58	Proposed proprietary name found unacceptable by DMEPA (OSE# 2012-1649); product's proposed proprietary name, (b) (4) was approved.
14.	Rexall	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. Product deactivated in 1993 per Micromedex Redbook.
15.	(b) (4) ***	58	Proposed proprietary name withdrawn by Applicant.
16.	(b) (4) ***	58	Proposed proprietary name withdrawn by Applicant; product's proposed proprietary name, (b) (4) was approved.
17.	(b) (4) ***	58	Proposed proprietary name found unacceptable by DMEPA (OSE# 2010-791).
18.	(b) (4) ***	56	Proposed proprietary name found unacceptable by DMEPA (OSE# 2013-1324).
19.	Ricola	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Rimacid	55	International product marketed in the United Kingdom.
21.	Rinatec	55	International product marketed in the United Kingdom and Ireland.
22.	(b) (4) ***	55	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, Lumason, was approved.
23.	(b) (4) ***	55	Name entered by Safety Evaluator. Unable to find in AIMS/Panorama/L:Drive as the root name; name may be considered a modifier.
24.	(b) (4) ***	54	Proposed proprietary name withdrawn by Applicant.
25.	(b) (4) **	54	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, Mitigare, was approved.
26.	Rimafen	54	International product marketed in the United Kingdom.

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No.	Name	POCA Score (%)	Failure Preventions
27.	(b) (4)***	54	Proposed proprietary name withdrawn by Applicant.
28.	(b) (4)***	54	Name entered by Safety Evaluator. Unable to find in AIMS/Panorama/L:Drive.
29.	Rebalance	53	International product marketed in Switzerland.
30.	(b) (4)***	53	Proposed proprietary name found unacceptable by DMEPA (OSE# 2009-2461).
31.	Renitec	53	International product marketed in multiple countries.
32.	Rovera	53	Veterinary product.
33.	Depakota	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Raphtre	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	(b) (4)***	52	Name entered by Safety Evaluator. Unable to find in AIMS/Panorama/L:Drive.
36.	(b) (4)***	52	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, Ryanodex, was approved.
37.	(b) (4)***	52	Proposed proprietary name withdrawn by Applicant. Product approved under proprietary name Inlyta.
38.	Rennet	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Renotec	52	Name identified in Drugs@FDA database – product discontinued. Unable to find product characteristics in commonly used drug databases.
40.	Respimat***	52	Name entered by Safety Evaluator. Unable to find in AIMS/Panorama/L:Drive as the root name; name may be considered a modifier.
41.	(b) (4)***	52	Name entered by Safety Evaluator. Unable to find in AIMS/Panorama/L:Drive.
42.	(b) (4)***	52	Proposed proprietary name withdrawn by Applicant.

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No.	Name	POCA Score (%)	Failure Preventions
43.	(b) (4)***	52	This is a tertiary proposed proprietary name. The product's primary proposed proprietary name, Auvi-Q, was approved.
44.	(b) (4)***	52	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, Auvi-Q, was approved.
45.	(b) (4)***	52	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, Prepopik, was approved.
46.	RenoCal	51	International product marketed in Canada.
47.	(b) (4)***	51	This is a proposed proprietary name of a device for Omnitrope (somatropin) for injection. Proposed proprietary name withdrawn by Applicant.
48.	(b) (4)***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# 2009-1398); product's proposed proprietary name, Incivek, was approved.
49.	(b) (4)**	50	This is a proposed proprietary name of an (b) (4) for Rebif (interferon beta 1a) for injection. Proposed proprietary name found unacceptable by DMEPA (OSE# 2013-793).
50.	Recuvyra	50	Veterinary product.
51.	(b) (4)***	50	This is a quaternary proposed proprietary name. The product's primary proposed proprietary name, Injectafer, was approved.
52.	(b) (4)***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# 2011-321).
53.	(b) (4)***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# 2010-339); product's proposed proprietary name, Incivek, was approved.
54.	(b) (4)***	50	This is a secondary proposed proprietary name. The product's primary proposed proprietary name, (b) (4) was found unacceptable by DMEPA (OSE# 2011-2203).

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

No.	Name	POCA Score (%)
1.	Propa P.H.	62
2.	Trituss A	62
3.	(b) (4) ***	60
4.	(b) (4) ***	57
5.	Latuda	56
6.	Propacet	56
7.	Propacet 100	56
8.	Levitra	55
9.	Propecia	55
10.	TriNessa	55
11.	Vepesid	55
12.	Zebeta	55
13.	Arcapta	54
14.	(b) (4) ***	54
15.	Duratuss A	54
16.	Pradaxa	54
17.	Septa	54
18.	(b) (4) ***	54
19.	(b) (4) ***	54
20.	Tri-Pase	54
21.	Urispas	54
22.	(b) (4) ***	54
23.	(b) (4) ***	54
24.	(b) (4) ***	53
25.	Levacet	53
26.	Leventa	53
27.	Prometa	53

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No.	Name	POCA Score (%)
28.	Propet	53
29.	Triphasil-21	53
30.	Triphasil-28	53
31.	(b) (4) ***	53
32.	(b) (4) ***	53
33.	Vitekta ***	53
34.	(b) (4) ***	52
35.	Certiva	52
36.	Genesa	52
37.	Legacy	52
38.	Lemtrada ***	52
39.	Pentasa	52
40.	(b) (4) ***	52
41.	(b) (4) ***	52
42.	Septra	52
43.	Ser-ap-es	52
44.	Tripedia	52
45.	Vidaza	52
46.	Zerbaxa ***	52
47.	Zetacet	52
48.	cresatin	51
49.	Lexiva	51
50.	(b) (4) ***	51
51.	Prevpac	51
52.	Prezista	51
53.	Truvada	51
54.	Vitapap	51
55.	(b) (4) ***	51
56.	(b) (4) ***	51

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No.	Name	POCA Score (%)
57.	Betasal	50
58.	Betatan	50
59.	(b) (4) ***	50
60.	(b) (4) ***	50
61.	Capacet	50
62.	Eradacin	50
63.	(b) (4) ***	50
64.	Glatopa ***	50
65.	Grape Seed	50
66.	(b) (4) ***	50
67.	(b) (4) ***	50
68.	(b) (4) ***	50
69.	Lecithin	50
70.	(b) (4) ***	50
71.	Lipanthyl	50
72.	Lovaza	50
73.	Lynparza ***	50
74.	Nepenthe	50
75.	Orbexa	50
76.	Predator	50
77.	Prefest	50
78.	PreNexa	50
79.	Profasi	50
80.	(b) (4) ***	50
81.	Prop-A-Tane	50
82.	Trecator	50
83.	Trexall	50
84.	(b) (4) ***	50
85.	Vetalar	50

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No.	Name	POCA Score (%)
86.	(b) (4)***	50

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/s/

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09/22/2014

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