

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208471Orig1s000

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

Date of This Review: June 13, 2016
Application Type and Number: NDA 208471
Product Name and Strength: Adlyxin (Lixisenatide) Injection,
150 mcg/3 mL (50 mcg/mL) and
300 mcg/3 mL (100 mcg/mL)
Product Type: Combination (Drug + Device)
Rx or OTC: Rx
Applicant/Sponsor Name: Sanofi
Panorama #: 2016-8384948
DMEPA Primary Reviewer: Sarah K. Vee, PharmD
**DMEPA Team Leader
(Acting):** Hina Mehta, PharmD
DMEPA Deputy Director: Lubna Merchant, M.S., PharmD

1 INTRODUCTION

The proposed proprietary name, Adlyxin, was reviewed by DMEPA on October 26, 2015¹ and was found that it could result in medication errors due to confusion with another product (i.e. (b)(4)***) under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Adlyxin, was dependent upon which underlying application was approved first. The applicant subsequently withdrew the name Adlyxin and submitted the proposed name (b)(4)***, which was found acceptable by DMEPA on February 3, 2016². Nevertheless, on June 9, 2016 the applicant withdrew the name (b)(4)*** and re-submitted the proposed name Adlyxin for evaluation.

We note that the application for the proposed name (b)(4)*** (IND (b)(4)) is still in the IND phase and would need to be resubmitted for review at the time of NDA submission. The PDUFA date for Adlyxin is July 27, 2016 and thus would be approved prior to the application for (b)(4)***.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 8, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we find that the proposed proprietary name, Adlyxin, is acceptable.

If you have any 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, Adlyxin, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your June 3, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

¹ Vee, S. Proprietary Name Review for Adlyxin NDA 208471. 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); 2015 OCT 26. Panorama No. 2015-127657.

² Conrad, A. Proprietary Name Review for (b)(4) NDA 208471. 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); 2016 FEB 3. Panorama No. 2015-2242540.

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.

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/s/

SARAH K VEE
06/13/2016

HINA S MEHTA
06/14/2016

LUBNA A MERCHANT
06/14/2016

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: February 3, 2016
Application Type and Number: NDA 208471
Product Name and Strength: (b)(4), lixisenatide, solution for injection
50 mcg/mL and 100 mcg/mL
Total Product Strength: 150 mcg/3 mL and 300 mcg/3 mL prefilled pens
Product Type: Single ingredient product and Combination product
Rx or OTC: RX
Applicant/Sponsor Name: Sanofi-Aventis US LLC
Panorama #: 2015-2242540
DMEPA Primary Reviewer: Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader: Yelena Maslov, PharmD

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/s/

ARIANE O CONRAD
02/03/2016

YELENA L MASLOV
02/09/2016

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:	October 26, 2015
Application Type and Number:	NDA 208471
Product Name and Strength:	Adlyxin (Lixisenatide) Injection, 150 mcg/3 mL (50 mcg/mL) and 300 mcg/3 mL (100 mcg/mL)
Product Type:	Combination (Drug + Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sanofi
Panorama #:	2015-127657
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS
DMEPA Director:	Todd Bridges, RPh

Contents

1	INTRODUCTION.....	1
1.1	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment.....	1
2.2	Safety Assessment.....	1
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	4
4	REFERENCES.....	5
	APPENDICES.....	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Adlyxin, 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 [REDACTED]^{(b) (4)} for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 20, 2015 proprietary name submission.

- Intended Pronunciation: ad-LIX-in
- Active Ingredient: Lixisenatide
- Indication of Use: a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- Route of Administration: subcutaneous injection
- Dosage Form: solution
- Strength: 150 mcg/3 mL (50 mcg/mL) and 300 mcg/3 mL (100 mcg/mL)
- Dose and Frequency: 10 mcg once daily for 14 days, then 20 mcg once daily
- How Supplied: Supplied in a disposable pen containing a sterile solution for subcutaneous administration. Each prefilled pen contains 3 mL solution. The green starter pen delivers 14 doses of 10 mcg, and the burgundy maintenance pen delivers 14 doses of 20 mcg.
- Storage: Prior to first use, Adlyxin should be stored in a refrigerator, 36°–46°F (2°C–8°C). Do not freeze. Keep the prefilled pen in the original package to protect it from light. After first use, store below 86°F (30°C). Replace the pen cap after each use to protect from light. Discard pen 14 days after first use.

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 name¹.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Adlyxin, is derived from the concept of adding lixisenatide to basal insulin. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Sixty-eight 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. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 10, 2015 e-mail, DMEP did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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 search² organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from 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 $\leq 69\%$	251
Low similarity name pair: combined match percentage score $\leq 49\%$	0

¹USAN stem search conducted on September 18, 2015.

² POCA search conducted on September 4, 2015.

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

We determined 254 of the 255 names contained in Table 1 will not pose a risk for confusion as described in Appendix C through H. However, the proposed name could be confused with (b) (4)***. The rationale for the risk of confusion is described below:

The proposed proprietary name, Adlyxin, is orthographically similar to another product that is also under review, (b) (4)*** (b) (4) and the products (b) (4) that may increase the risk of wrong drug errors.

In terms of (b) (4) similarity between the two names.

Additionally, since (b) (4) we are concerned that selection errors may occur by healthcare providers when utilizing Computerized Physician Order Entry (CPOE) systems (b) (4)

(b) (4)

(b) (4)

⁴ Institute for Safe Medication Practices. Safety briefs: Include purpose on Rx. ISMP Med Saf Alert Acute Care. 2011; 16(17):1-2.

We recognize this conclusion differs from that of (b) (4) name study submitted in support of the proposed proprietary name. However, (b) (4) did not identify (b) (4) *** because (b) (4) *** is a proprietary name that is currently under review.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DMEP via e-mail on October 20, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on October 26, 2015, they stated no additional concerns with the proposed proprietary name, Adlyxin.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4) ***. Therefore, the decision to deny the name will be communicated to the Applicant via a letter (See Section 3.1).

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, Adlyxin, and conclude that this name could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Adlyxin, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name of Adlyxin, you will be requested to submit another name.

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.

3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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 DNDP. OPDP or DNDP 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 DNDP 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.⁵

⁵ 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 $\geq 70\%$.
 - 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. 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 $\geq 70\%$).

<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 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 $\geq 50\%$ 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 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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</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 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.</p>

	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)
	<ul style="list-style-type: none"> • 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 <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? 	<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?

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, 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. Adlyxin Study (Conducted on 9/3/2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p>Medication Order:</p> <hr/> <p><i>Adlyxin 20 mcg sub-Q once daily</i></p>	<p>Adlyxin Inject 10 mcg subcutaneously once daily</p> <p>Disp #1</p>
<p>Outpatient Prescription:</p> <p><i>Adlyxin inject 10mcg sub-Q once daily #1</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Adlyxin

244 People Received Study

68 People Responded

Total	24	18	26	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
ABLEXIN	0	1	0	1
ABLIXEN	0	1	0	1
ABLIXIN	0	6	0	6
ADLEXIN	0	1	0	1
ADLEXIN INJECTION	0	1	0	1
ADLIXIN	0	8	0	8
ADLYNIN	1	0	0	1
ADLYNX	1	0	0	1
ADLYXIN	20	0	26	46
ADLYXIR	2	0	0	2

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

No.	Proposed name: Adlyxin Established name: lixisenatide Dosage form: solution Strength(s): 150 mcg/3 mL (50 mcg/mL) and 300 mcg/3 mL (100 mcg/mL) Usual Dose: 10 mcg once daily for 14 days, then 20 mcg once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Adlyxin***	100	Subject of this review.
2.	Aflaxen	74	Name identified in RxNorm and Redbook. Product is discontinued and deactivated (1996). Strengths/dose are different and must be specified for both products [50 mcg/mL (10 mcg/injection) or 100 mcg/mL (20 mcg/injection) vs. 220 mg or 550 mg] The first and second syllables of this name pair sound different.
3.	Delaxin	72	Proprietary name for ANDA 85454 withdrawn FR Effective 5/26/1993. The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair have sufficient phonetic differences.
4.	Amlactin	70	Adlyxin requires strength/dose while Amlactin is an OTC topical lotion product. The prefixes, infixes, suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair have sufficient phonetic differences.

Appendix D: Moderately Similar Names (e.g., 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.	Eulexin	68

No.	Name	POCA Score (%)
2.	Aplenzin	65
3.	Floxin	65
4.	Plexion	62
5.	(b) (4)***	60
6.	Avelox I.V.	60
7.	Yodoxin	60
8.	Digoxin	59
9.	Lanoxin	59
10.	Aliclen	58
11.	Amikacin	58
12.	Prolixin	58
13.	Biaxin	57
14.	Cardoxin	57
15.	Adapin	56
16.	Addaprin	56
17.	Adriamycin	56
18.	Alogliptin	56
19.	Alyacen 1/35	56
20.	Alyacen 7/7/7	56
21.	Alyacen 777	56
22.	Cephalexin	56
23.	Robaxin	56
24.	Robaxin-750	56
25.	Tolectin	56
26.	Trioxin	56
27.	Apple Pectin	55
28.	Atrac-Tain	55
29.	Myoxin	55
30.	Skelaxin	55
31.	Abraxane	54

No.	Name	POCA Score (%)
32.	Ala-Quin	54
33.	Aloxi	54
34.	Amikin	54
35.	Avastin	54
36.	Quixin	54
37.	Aloquin	53
38.	Altafrin	53
39.	Sumaxin	53
40.	Acticin	52
41.	Adrenalin	52
42.	Aldroxicon	52
43.	Amlexanox	52
44.	Atralin	52
45.	Noroxin	52
46.	Prudoxin	52
47.	(b) (4) ***	52
48.	Uramaxin	52
49.	Allfen	51
50.	Ana-Lex	51
51.	Arestin	51
52.	Azelex	51
53.	Glyxambi	51
54.	Akne-Mycin	50
55.	Albatussin	50
56.	Aldesleukin	50
57.	Allerx-D	50
58.	Antitussin	50
59.	(b) (4) ***	50
60.	Ascriptin	50
61.	Polymyxin B	50

No.	Name	POCA Score (%)
62.	Primaxin	50

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

No.	Proposed name: Adlyxin Established name: lixisenatide Dosage form: solution Strength(s): 150 mcg/3 mL (50 mcg/mL) and 300 mcg/3 mL (100 mcg/mL) Usual Dose: 10 mcg once daily for 14 days, then 20 mcg once daily	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.	Agrylin	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
2.	(b) (4)***	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
3.	Adagen	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
4.	Aygestin	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

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

N/A

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.	Aclacin	66	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
2.	Alexan	66	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
3.	Alexan-100	66	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
4.	Paloxin	66	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
5.	Afaxin	65	ANDA 83187 withdrawn FR effective 11/19/1997
6.	Duraxin	64	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
7.	Hydroxin	63	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
8.	Aldex An	62	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases

No.	Name	POCA Score (%)	Failure preventions
9.	Eltroxin	62	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
10.	Relaxin	62	Name identified in Rx Norm database. Unable to find product characteristics in commonly used databases
11.	Advocin	61	Veterinary product
12.	Adult Pain	60	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
13.	Dynaxin	60	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
14.	Evoxin	60	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
15.	Raudixin	60	NDA 8842 w/d FR effective 9/29/1995 with no generics
16.	Razoxin	59	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
17.	Ansolysen	58	NDA 9372 withdrawn FR effective 11/5/1992 no generics
18.	Anxon	58	International product marketed in UK, Italy, Argentina
19.	Draxxin	58	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases

No.	Name	POCA Score (%)	Failure preventions
20.	Hyrexin	58	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
21.	Mylaxen	58	NDA 9789 withdrawn FR effective 3/2/1994 with no generics
22.	Clonixin	57	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
23.	Adlone-40	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
24.	Adlone-80	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
25.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found unacceptable in OSE RCM # (b) (4). Application withdrawn as of (b) (4)
26.	Alidrin	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
27.	Antepsin	56	International product marketed in UK, Italy, Argentina
28.	Asellacrin 10	56	NDA 17726 withdrawn FR effective 11/12/2002 with no generics

No.	Name	POCA Score (%)	Failure preventions
29.	Asellacrin 2	56	NDA 17726 withdrawn FR effective 11/12/2002 with no generics
30.	Choloxin	56	NDA 12302 withdrawn FR effective 7/8/2011 with no generics
31.	Flunixin	56	Veterinary product
32.	Alcortin	54	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
33.	Allantoin	54	Product is not a drug but a compound used as an active ingredient in over the counter cosmetic products.
34.	Allethrin	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
35.	Aloxiprin	54	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases
36.	Amoxidin	54	Name identified in RxNorm database. This is an international amoxicillin product.
37.	Azlin	54	NDA 50562 withdrawn FR effective 9/25/1997 with no generics
38.	Sulsoxin	54	ANDA 80040 w/d FR effective 12/22/1993

No.	Name	POCA Score (%)	Failure preventions
39.	Allerx Am	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Amlactin Ap	53	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
41.	Anacin	53	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
42.	Apexicon	53	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
43.	Azlocillin	53	NDA 50562 withdrawn FR effective 9/25/1997 with no generics
44.	Actacin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Agri-Cillin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
46.	Ak-Tracin	52	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
47.	Allerfrin	52	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
48.	Artracin	52	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
49.	Flucloxin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	Medigoxin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Momexin	52	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
52.	Neutrexin	52	NDA 20326 withdrawn FR effective 3/13/2009 with no generics
53.	Nioxin	52	Name identified in RxNorm database. This is a line of hair care and styling products.

No.	Name	POCA Score (%)	Failure preventions
54.	Zeroxin	52	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
55.	Zoxin	52	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases
56.	Adequan	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
57.	Adphen	51	ANDA 83655 withdrawn FR effective 5/21/1993 not an RLD
58.	A-G Tussin	51	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
59.	Aleudrin	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Amylopectin	51	Name identified in RxNorm database. Not a drug, a type of starch found in plants.
61.	Chibroxin	51	NDA 19757 withdrawn FR effective 6/4/2004 with no generics
62.	Molipaxin	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
63.	A-Cillin	50	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
64.	Actin-N	50	NDA 17343 withdrawn FR effective 9/19/1996 with no generics
65.	Aknemycin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
66.	Albamycin	50	NDA 50339 withdrawn FR effective 3/13/2009 with no generics
67.	Alcloxa	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
68.	(b) (4) ***	50	Proposed proprietary name for IND (b) (4) found unacceptable in OSE RCM # (b) (4) *** found acceptable for this product. Application withdrawn effective (b) (4).
69.	Altresyn	50	Veterinary product
70.	Amtussin	50	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
71.	Amygdalin	50	Not a drug. Component found in almonds

No.	Name	POCA Score (%)	Failure preventions
72.	Apsifen	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Aricin	50	Name identified in RxNorm and Redbook. Product is discontinued and deactivated. No generic is available. No other information for product characteristics found in other commonly used databases.
74.	Arthroxen	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Ciproxin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
76.	Floxin I.V.	50	NDA 20087 withdrawn FR effective 6/18/2009 with no generics

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

No.	Name	POCA Score (%)
1.	Ed-Mycin	62
2.	Endoxan	60
3.	Glyquin	60
4.	Glytrin	60
5.	Ilex Skin	59
6.	Del-Mycin	58
7.	(b) (4) ***	58

No.	Name	POCA Score (%)
8.	Edecrin	58
9.	Elixicon	58
10.	Elixomin	58
11.	Flexon	58
12.	Setlakin	58
13.	Oradexon	56
14.	Tolectin 600	56
15.	Trypsin	56
16.	U-Lactin	56
17.	Zilactin	56
18.	Desoxyn	55
19.	Dilantin	55
20.	Dilantin-125	55
21.	Dilantin-30	55
22.	Doloxene	55
23.	Platosin	55
24.	Ciloxan	54
25.	Clistin	54
26.	Doxidan	54
27.	Dyphysin	54
28.	Eloxatin	54
29.	E-Mycin	54
30.	Flexgen	54
31.	Fluxid	54
32.	Gavilyte-N	54
33.	Glycerin	54
34.	Glycron	54
35.	Idoxene	54
36.	Ofloxacin	54
37.	Oxytocin	54
38.	Poly-Tussin	54
39.	Silybin	54

No.	Name	POCA Score (%)
40.	Triactin	54
41.	Glycogen	53
42.	Idamycin	53
43.	Ilotycin	53
44.	Lyphocin	53
45.	Redoxon	53
46.	Baltussin	52
47.	Cydectin	52
48.	Dexacen-4	52
49.	Dexium	52
50.	Dodicin	52
51.	Doxepin	52
52.	Dryphen	52
53.	Dynacin	52
54.	Ed Flex	52
55.	Edoxaban	52
56.	Elestrin	52
57.	Eradacin	52
58.	Gablofen	52
59.	Gallimycin	52
60.	Glycine	52
61.	Helicin	52
62.	Naproxen	52
63.	Panmycin	52
64.	Podactin	52
65.	Zonulysin	52
66.	Baclofen	51
67.	Biloptin	51
68.	Detussin	51
69.	Diglycerin	51
70.	Laidlomycin	51
71.	Lypressin	51

No.	Name	POCA Score (%)
72.	Polydatin	51
73.	Salicin	51
74.	Siltussin	51
75.	Benzaclin	50
76.	Cloxapen	50
77.	Colistin	50
78.	Dexone	50
79.	Dexone 0.5	50
80.	Dexone 0.75	50
81.	Dexone 1.5	50
82.	Dexone 4	50
83.	Dextran	50
84.	Dextran 1	50
85.	Dextran 110	50
86.	Dextran 40	50
87.	Dextran 70	50
88.	Dextran 75	50
89.	Dioctyn	50
90.	Dristan	50
91.	Duradrin	50
92.	Endoxana	50
93.	Epidrin	50
94.	Equalactin	50
95.	Excedrin	50
96.	Glyoxide	50
97.	Gly-Oxide	50
98.	Habekacin	50
99.	Leptin	50
100.	Lugacin	50
101.	Oxyfrin	50
102.	Plicamycin	50
103.	Polycin-B	50

No.	Name	POCA Score (%)
104.	Raplixa	50
105.	Tinactin	50
106.	Viractin	50
107.	Wal-Proxen	50
108.	(b) (4)***	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

N/A

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

/s/

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