CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208051Orig1s000

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:	August 25, 2016
Application Type and Number:	NDA 208051
Product Name and Strength:	Nerlynx (neratinib) tablets, 40 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Puma Biotechnology Inc.
Panorama #:	2016-9288674
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Nerlynx, 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 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Nerlynx, on December 24, 2014 under IND 066783, which was found conditionally acceptable on May 21, 2015[a].

Thus, the Applicant submitted the name, Nerlynx, for review on July 19, 2016 under NDA 208051. We note additional product characteristics about dose modification information in NDA 208051 that was not submitted under IND 066783. In addition to the recommended usual dose of 240 mg given orally once daily, Nerlynx dose may be reduced for the adverse event diarrhea (reduced from 240 mg/day to [redacted] (b) (4) mg/day or from 160 mg/day to 120 mg/day). All other product characteristics remain the same as the product characteristics information provided in IND 066783.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 19, 2016 proprietary name submission.

- Intended Pronunciation: ner links'
- Active Ingredient: Neratinib
- Indication of Use: for the extended adjuvant treatment of patients with early-stage [redacted] (b) (4) HER2-overexpressed/amplified [redacted] (b) (4) breast cancer who have received prior adjuvant trastuzumab-based therapy.
- Route of Administration: oral
- Dosage Form: tablets
- Strength: 40 mg
- Dose and Frequency: 240 mg (6 tablets) once daily
    - Dose modification for diarrhea: reduced dose (reduced from 240 mg/day to [redacted] (b) (4) mg/day or from 160 mg/day to 120 mg/day) for diarrhea that resolves to Grade 1 or Grade 0 in longer than one week
- How Supplied: Bottle of 180 tablets.
- Storage: Store at controlled room temperature, 25°C (77°F); excursions permitted to 15–30°C (59–86°F).

[a] Mathew, D. Proprietary Name Review for Nerlynx (IND 066783). 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 MAY 21. Panorama No. 2014-46335.

- Container and Closure Systems: NERLYNX 40 mg film-coated tablets are packaged in a white, 60 mL high density polyethylene (HDPE) round bottle with [redacted] foil induction inner seal for a tamper-evident seal. An [redacted] desiccant [redacted] is enclosed with the tablets in each bottle. Each bottle contains 180 tablets.

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 Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Nerlynx, is a derivation from the combination of the established name (Neratinib) and a large cat (Lynx). 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

Seventy-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. In the written studies, 52 of 53 participants correctly interpreted the proposed name as "Nerlynx". In the voice study, none of the 25 participants correctly interpreted the proposed name as "Nerlynx". Common misinterpretations in the voice study include misinterpretation of the proposed name "Nerlynx" as "Nerlinks" (n=3), "Nerlinx" (n=5), "Neurlinx" (n=2), and "Nurlinx" (n=6). 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, August 10, 2016 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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[b] USAN stem search conducted on August 10, 2016.

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 ≥50% retrieved from our POCA search[c] 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 ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	101
Low similarity name pair: combined match percentage score ≤49%	8

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

Our analysis of the 110 names contained in Table 1 determined 110 names will not 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 Oncology Products 1 (DOP1) via e-mail on August 17, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on August 24, 2016, they stated no additional concerns with the proposed proprietary name, Nerlynx.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

[c] POCA search conducted on August 3, 2016.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 19, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

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.

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

The electronic Drug Registration and Listing System (eDRLS) was established to supports 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. [d]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted?	**Y/N**	Do the names have different syllabic stresses?

	*****FDA considers the length of names different if the names differ by two or more letters.*		
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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

<table>
<tr><td></td><td colspan="2">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</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
• Is there different number or placement of cross-stroke or dotted letters present in the names?
• Do the infixes of the name appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

	• Do the suffixes of the names appear dissimilar when scripted?	

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Nerlynx Study (Conducted on August 5, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Nerlynx 160 mg po once daily	Nerlynx Take six tablets by mouth once daily. Dispense number one hundred eighty.
Outpatient Prescription: Nerlynx 6 tabs po once daily #180	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Nerlynx

As of Date 8/15/2016

310 People Received Study

78 People Responded

Total	23	25	30	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
MERLINSE	0	1	0	1
NERLINKS	0	3	0	3
NERLINX	0	5	0	5
NERLINZ	0	1	0	1
NERLYNK	0	0	1	1
NERLYNX	23	0	29	52
NEURALINX	0	1	0	1
NEURLINKS	0	1	0	1
NEURLINX	0	2	0	2
NEURLIX	0	1	0	1
NEURLYNX	0	1	0	1
NORLINX	0	1	0	1
NURLINKS	0	1	0	1
NURLINX	0	6	0	6
NURLYNX	0	1	0	1

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

No.	**Proposed name:** Nerlynx **Established name:** Neratinib **Dosage form:** Tablets **Strength(s):** 40 mg **Usual Dose:** 240 mg once daily, 160 mg once daily, 120 mg 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.	Nerlynx	100	Name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Nasonex	51
2.	Neo-Rx	54
3.	Norlestrin 21 1/50	50
4.	Norlestrin 21 2.5/50	50
5.	Norlestrin 28 1/50	50
6.	Norlutin	56
7.	Norlyroc	57
8.	Norplant	58
9.	Northyx	63
10.	Nutrimix	52
11.	Perloxx	57

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

No.	**Proposed name:** Nerlynx **Established name:** Neratinib **Dosage form:** Tablets **Strength(s):** 40 mg **Usual Dose:** 240 mg once daily, 160 mg once daily, or 120 mg 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.	Lynox	52	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
2.	Nail-Ex	58	The suffix of this name pair has sufficient orthographic difference. The second syllables of this name pair sound different.
3.	Nalex	60	The infix of this name pair has sufficient orthographic difference. The dose of Nalex is 1 tablet every twelve hours vs. Nerlynx is 3, 4 or 6 tablets once daily.
4.	Neo-Dex	50	The infix of this name pair has sufficient orthographic difference. The second syllable of this name pair sound different.
5.	Neopolydex	56	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different, and Neopolydex contains extra syllables.
6.	Nexiclon XR	50	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different, and Nexiclon XR contains extra syllables.
7.	Niferex	55	The infix of this name pair has sufficient orthographic difference. The second syllable of this name pair sound different, and Niferex contains an extra syllable.
8.	Niferex-150	55	The infix of this name pair has sufficient orthographic difference. The second syllable of this name pair sound different, and the root name Niferex contains an extra syllable.
9.	Nolvadex	54	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different, and Nolvadex contains an extra syllable.

No.	**Proposed name:** Nerlynx **Established name:** Neratinib **Dosage form:** Tablets **Strength(s):** 40 mg **Usual Dose:** 240 mg once daily, 160 mg once daily, or 120 mg 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**
10.	Norflex	66	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sound different.
11.	Notuss-Nx	50	When considering the root name alone, the infix and suffix of this name pair have sufficient orthographic differences. When considering the modifier, the infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sound different, and Notuss-Nx contain extra syllables from the modifier "Nx".
12.	Nutralox	55	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sound different, and Nutralox contains an extra syllable.

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

No.	Name	POCA Score (%)
1.	Naloxone	42
2.	Naprosyn	48
3.	Neulasta	38
4.	Neurontin	49
5.	Neuroleptic	44
6.	Nevanac	44
7.	Norvasc	44
8.	Norvir	36

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.	Kerledex	60	Application (NDA 019807) withdrawn FR effective 8/19/2013. No generic equivalents available.
2.	Kerlix	64	Name identified in the (b) (4) external name study. Product is not a drug. It is gauze bandage rolls.
3.	(b) (4)***	66	Proposed proprietary name for IND 120467 found unacceptable by DMEPA (OSE# 2014-26095). NDA 207931 approved under new proprietary name Technivie.
4.	Naldecon Cx	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Naldex	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Narvox	61	Product is discontinued and there are no generic equivalents available.
7.	Natrilix	58	International product marketed in several foreign countries not including the United States.
8.	Nemex	51	Veterinary product.
9.	Nemex 2	51	Veterinary product.
10.	Nephrox	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	(b) (4)***	54	Proposed proprietary name for IND (b) (4) found conditionally acceptable on (b) (4) in OSE RCM (b) (4) under IND (b) (4). However, the Applicant withdrew IND (b) (4) on (b) (4), and will no longer be pursuing development of this drug. IND (b) (4) is withdrawn as of (b) (4).
12.	Nervine	52	International product marketed in Canada.
13.	(b) (4)***	61	This is an alternate proposed proprietary name for ANDA (b) (4) and ANDA (b) (4) was conditionally approved under proprietary name (b) (4). ANDA (b) (4) is pending.
14.	Nordox	59	International product marketed in United Kingdom and Chile.
15.	Norel EX	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Norgalax	59	International product marketed in Belgium, France, Netherlands, Switzerland, United Kingdom, and Ukraine.
17.	Nortuss-Nx	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Norvaxs	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
19.	Novolin N (b) (4) ***	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
20.	Nuromax	58	Nuromax is discontinued with no generic equivalents available. Application (NDA 019946) withdrawn FR effective 4/18/2012.
21.	Nydamax	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Anaflex	52
2.	Ana-Lex	53
3.	Anaplex	50
4.	Anorex	52
5.	Arlex	56
6.	Beflex	52
7.	Burinex	54
8.	Cerebyx	52
9.	De-Chlor Nx	53
10.	Declinax	56
11.	Deflux	52
12.	Delflex	52
13.	Dorflex	53
14.	Drymax	50
15.	Duralex	54
16.	Enablex	52
17.	Enzymax	50
18.	Eprinex	50
19.	Erymax	54
20.	Everflex	52
21.	Feridex	50
22.	Fertinex	53
23.	Fiber Lax	54
24.	Ganirelix	50
25.	Herplex	50
26.	Malix	53
27.	Marax	51
28.	Mar-Zinc	54

No.	Name	POCA Score (%)
29.	Medilax	52
30.	Medinex	52
31.	Melamix	54
32.	Melanex	58
33.	Mepranix	51
34.	Mesnex	50
35.	Metanx	54
36.	Miralax	54
37.	Orlex	54
38.	Peranex	56
39.	Peridex	52
40.	Permax	50
41.	Pernox	52
42.	Poly-Dex	52
43.	Polymox	54
44.	Pyrlex	56
45.	Salinex	52
46.	Serax	50
47.	(b) (4) ***	52
48.	Starlix	56
49.	Talwin Nx	56
50.	Terbinex	56
51.	Terfinax	56
52.	Tretin X	54
53.	Unilax	51
54.	Unna-Flex	50
55.	Venelex	50
56.	Vermox	52
57.	Zervalx	54

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

No.	Name
1.	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/

TINGTING N GAO
08/25/2016

CHI-MING TU
08/25/2016