CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209269Orig1s000

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:	October 13, 2016
Application Type and Number:	NDA 209269
Product Name and Strength:	Minolira (minocycline hydrochloride) extended release tablets, 105mg and 135mg
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Dr. Reddy's Laboratories, Inc.
Panorama #:	2016-9346159
DMEPA Primary Reviewer:	Madhuri R. Patel, Pharm.D.
DMEPA Team Leader:	Mishale Mistry, Pharm.D., MPH
DMEPA Deputy Director:	Lubna Merchant, Pharm.D., MS

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the July 28, 2016, proprietary name submission.

- Intended Pronunciation: min oh li' rah
- Active Ingredient: minocycline hydrochloride
- Indication of Use: Acne vulgaris
- Route of Administration: Oral
- Dosage Form: Extended release tablets
- Strength: 105 mg, 135 mg
- Dose and Frequency: Approximately 1mg/kg once daily for up to 12 weeks
    - Dosing Table-

Patient's Weight (lbs.)	Patient's Weight (kg)	Tablet Strength (mg)	Actual mg/kg Dose
(b) (4)	45 – 59	(b) (4)	1.16 – 0.88
	60 – 89		1.13 – 0.76
	90 – 125	105	1.17 – 0.84
	126 – 136	135	1.07 – 0.99

- How Supplied: Bottles of 30 (commercial package); Bottles of 10 (physician sample)
- Storage: 20°C - 25°C (68°F - 77°F), excursions permitted to 15°C - 30°C (59°F - 86°F)
- Container and Closure Systems: n/a
- Reference Listed Drug: Solodyn NDA 050808

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 Dermatology and Dental Products (DDDP) 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[a].

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

Ninety-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. Fifteen participants correctly interpreted the proposed name as "Minolira" (voice n=14, outpatient n=1). 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 1, 2016 e-mail, the Division of Dermatology and Dental Products (DDDP) 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 ≥50% retrieved from our POCA search[b] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by the (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%	150
Low similarity name pair: combined match percentage score ≤49%	2

[a] USAN stem search conducted on August 3, 2016.

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

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Minolira, will be available in strengths of 105 mg and 135 mg. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Minolira that were not identified in POCA.

Table 1A. eDRLS Search Results[c]	**POCA Score (%)**
N/A	N/A

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

Our analysis of the 153 names contained in Table 1 determined 153 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Evaluation of the Need for a Modifier

This product is an extended-release formulation of the currently marketed product minocycline. As proposed, the Applicant does not include a modifier with the name to convey that Minolira is an extended-release dosage form. Additionally, there are no immediate release formulations of minocycline with the proprietary name Minolira that would require this product name to be differentiated. However, we note that there are immediate release formulations of minocycline that are dosed as 200 mg initially, followed at 100 mg every 12 hours. Thus, we evaluated if a modifier is needed for the root name Minolira to signal the extended-release nature of this proposed product or if the lack of a modifier raises any potential concerns.

Additionally, we also identified two extended-release minocycline formulations that are currently marketed with proprietary names that contain no modifier, Solodyn and Ximino, and are dosed once daily as the proposed product. We have not identified any safety concern with these products with respect to the lack of modifier. Therefore, we do not anticipate the absence of a modifier in this instance would introduce any new or additional risk of medication errors involving this minocycline extended release product.

Therefore, in this instance, given the totality of the factors considered above, there is no compelling evidence to support the necessity of a modifier for the proposed proprietary name, Minolira, at this time.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Dermatology and Dental Products (DDDP) via e-mail on September 22, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the

[c] eDRLS search conducted on August 5, 2016.

DDDP on September 27, 2016, they stated no additional concerns with the proposed proprietary name, Minolira.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 204-402-3726.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 28, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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]

***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.

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

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? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing

<table>
<tr><td></td><td colspan="2">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</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>

Reference ID: 3998338

	• 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. Minolira Study (Conducted on 8/12/2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Minolira 135mg PO QD	Minolira 105mg Take half tablet orally once daily. Dispense #15.
Outpatient Prescription: Minolira 105mg ½ tab PO QD #15	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

310 People Received Study
98 People Responded

Study Name: Minolira

Total	40	31	27	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
MENALOREA	0	1	0	1
MENOLIRA	0	2	0	2
MERNALIRA	0	1	0	1
MIDOLIRA	0	1	0	1
MINALIRA	0	1	0	1
MINALYRA	0	1	0	1
MINDERA	0	1	0	1
MINDIRA	0	0	26	26
MINIDIRA	0	0	1	1
MINOLEERA	0	2	0	2

MINOLERA	1	3	0	4
MINOLIRA	1	14	0	15
MINOLUA	1	0	0	1
MINOLYRA	0	2	0	2
MINORLERA	0	1	0	1
MINORLIRA	0	1	0	1
MIOLERA	1	0	0	1
MIROLARA	1	0	0	1
MIROLERA	2	0	0	2
MIROLINA	9	0	0	9
MIROLIRA	4	0	0	4
MIROLIVA	1	0	0	1
MIROLNA	1	0	0	1
MIROLUA	2	0	0	2
MIROLURA	1	0	0	1
MISOLIRA	1	0	0	1
MISOLIVA	1	0	0	1
MUIILINA	1	0	0	1
MUOLINA	2	0	0	2
MUOLIRA	7	0	0	7
MUOLNA	1	0	0	1
MUSLIRA	2	0	0	2

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

No.	**Proposed name:** Minolira **Established name:** Minocycline hydrochloride **Dosage form:** Extended-release tablets **Strength(s):** 105 mg, 135 mg **Usual Dose:** 1 mg/kg once daily (1 tablet once daily or ½ tablet 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.	Minolira	100	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 (%)
2.	Midol IB	66
3.	Myzilra	64
4.	Cinolar	64
5.	Ninlaro	63
6.	(b) (4)***	62
7.	Minivelle	61
8.	Menactra	60
9.	Menostar	60
10.	Minirin	60
11.	Minitran	60
12.	Minotal	60
13.	Mono-Linyah	60
14.	(b) (4)***	60
15.	Menopur	58
16.	Mononessa	58
17.	Midchlor	57
18.	Gynol II	56

No.	Name	POCA Score (%)
19.	Midol	56
20.	Mitrolan	56
21.	Mandelay	54
22.	Menaval-20	54
23.	Miniprin	54
24.	Moderiba	54
25.	Monopril	54
26.	Anabolin La	54
27.	Anolor	54
28.	Midol Teen	53
29.	Mintezol	53
30.	Marinol	52
31.	Marlissa	52
32.	Menadol	52
33.	Mepolizumab	52
34.	Milnacipran	52
35.	Mineral Ice	52
36.	Mineral Oil	52
37.	Minipress	52
38.	Miranel Af	52
39.	Monojel	52
40.	Monurol	52
41.	Myolin	52
42.	Minidyne	51
43.	Menthol	50
44.	Metolazone	50
45.	Mibelas 24 Fe	50
46.	Micanol	50
47.	Midamor	50
48.	Midodrine	50

Reference ID: 3998338

No.	Name	POCA Score (%)
49.	Miglitol	50
50.	Milkinol	50
51.	(b) (4)***	50
52.	Mitigare	50
53.	Mitosol	50
54.	Mycinaire	50
55.	Disulfiram	50
56.	Quinora	50

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

No.	**Proposed name: Minolira** **Established name: Minocycline hydrochloride** **Dosage form: Extended-release tablets** **Strength(s): 105 mg, 135 mg** **Usual Dose: 1 mg/kg once daily (1 tablet once daily or ½ tablet 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**
57.	Minocin	62	The suffixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The third/fourth syllable of this name pair sound different. Dosage Form/Route: Oral Extended-release tablets vs. Oral Pellet-filled capsules and Lyophilized powder for intravenous injection Strength: 105 mg and 135 mg vs. 50 mg, 75 mg, 100 mg Dose: 1 mg/kg once daily (1 tablet once daily or ½ tablet once daily) vs. 4 mg/kg initially followed by 2 mg/kg every 12 hours or 200mg initially followed by 100mg every 12 hours or 50mg 4 times daily.

No.	Proposed name: Minolira Established name: Minocycline hydrochloride Dosage form: Extended-release tablets Strength(s): 105 mg, 135 mg Usual Dose: 1 mg/kg once daily (1 tablet once daily or ½ tablet 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
58.	Miraluma	60	The suffixes of this name pair have sufficient orthographic differences. The third/fourth syllable of this name pair sound different. Dosage Form/Route: Oral capsule vs Lyophilized powder for intravenous injection. Dose: xxx mg vs. xxx MBq or XX mCi Indication: Acne vulgaris vs. Breast imaging (radiopharmaceutical)
59.	Minodyl	59	The suffixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The third/fourth syllable of this name pair sound different,
60.	Myleran	59	The prefixes and infixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The second/third/fourth syllable of this name pair sound different.
61.	Mircera	58	The infixes and suffixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The second/third/fourth syllable of this name pair sound different.
62.	(b) (4)***	58	The prefixes and infixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The first/second syllable of this name pair sound different.

No.	Proposed name: Minolira Established name: Minocycline hydrochloride Dosage form: Extended-release tablets Strength(s): 105 mg, 135 mg Usual Dose: 1 mg/kg once daily (1 tablet once daily or ½ tablet 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
63.	Novolin R	57	Position 7 has an upstroke in the Novolin R name, which is not present in Minolira***. The first syllables of this name pair sound different. Dosage Form/Route: Oral capsule vs Solution for subcutaneous injection, intravenous route, or for use with insulin pumps. Dose: xxx mg vs. xx units before meals or UAD
64.	Zemaira	56	The prefixes and infixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The first/second/third syllables of this name pair sound different.
65.	Midazolam	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The second/third/fourth syllables of this name pair sound different.
66.	Millipred	54	The infixes and suffixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The second/third/fourth syllable of this name pair sound different.
67.	Minoxidil	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The third /fourth syllables of this name pair sound different.
68.	Mellaril	50	The infixes and suffixes of this name pair have sufficient orthographic differences. Minolira*** contains an extra syllable. The second/third/fourth syllables sound different.

No.	Proposed name: Minolira Established name: Minocycline hydrochloride Dosage form: Extended-release tablets Strength(s): 105 mg, 135 mg Usual Dose: 1 mg/kg once daily (1 tablet once daily or ½ tablet 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
69.	Minocycline	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The third/fourth syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
70.	Mylanta	44
71.	Lyrica	31

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
72.	Binora	61	Discontinued benzoyl peroxide product with no generic equivalents available.
73.	Mol-Iron	60	Discontinued ferrous sulfate product with no generic equivalents available.
74.	Monoolein	59	Product is not a drug. It is a lipid.
75.	Minidiab	58	International product marketed in Turkey, France, Australia, Austria, Belgium, Brazil, Chile, China, Czech Republic, Hungary, Italy, Malaysia, New Zealand, Philippines, Portugal, South Africa, Singapore, and Thailand. International product formerly marketed in Hong Kong, Russia, Venezuela, and Netherlands.

No.	Name	POCA Score (%)	Failure preventions
76.	Minogal	58	International product formerly marketed in the United Kingdom.
77.	Monodur	57	International product marketed in Turkey and Australia.
78.	(b) (4)***	56	This is an alternate proposed proprietary name for IND (b) (4). The applicant withdrew name and submitted a single proprietary name, (b) (4)*** for two indications (IND (b) (4) and IND (b) (4)). (b) (4)*** was found acceptable by DMEPA (OSE# (b) (4). The NDA is pending.
79.	Minica	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
80.	Monosulfiram	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
81.	(b) (4)***	54	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
82.	Midazolan	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
83.	Mizollen	54	International product marketed in South Africa, Belgium, Greece, Israel, Italy, Netherlands, Portugal, United Kingdom, France, and China. International product formerly marketed in Austria, Czech, Denmark, Finland, Hungary, Germany, Poland, Sweden, and Switzerland.
84.	Modisal La	54	International product marketed in the United Kingdom. International product formerly marketed in Switzerland with different active ingredients (amiloride hydrochloride, hydrochlorothiazide).
85.	(b) (4)***	54	Proposed proprietary name for NDA 208424 withdrawn by the Applicant (OSE#2016- 7787145). The applicant submitted a new proprietary name GoNitro***, which was found acceptable by DMEPA (OSE# 2016-8228507).

No.	Name	POCA Score (%)	Failure preventions
86.	Amino-Cerv	54	Discontinued cystine; inositol; methionine; sodium propionate; urea product with no generic equivalents available.
87.	Menorest 37.5	53	International product marketed in Austria, Brazil, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK, Denmark, and South Africa containing Estradiol and in Philippines containing Tibolone.
88.	Menorest 50	53	International product marketed in Austria, Brazil, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK, Denmark, and South Africa containing Estradiol and in Philippines containing Tibolone.
89.	Menorest 75	53	International product marketed in Austria, Brazil, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, UK, Denmark, and South Africa containing Estradiol and in Philippines containing Tibolone.
90.	Monocid	53	International product marketed in Portugal and Spain. International product formerly marketed in Belgium, Italy, and Hong Kong. In the United States, it is a discontinued product with no generic equivalents available. Also, formerly marketed with different active ingredients in Austria (clarithromycin) and Israel (malathion bioallethrin).
91.	Aminosol 5%	53	Brand discontinued with no generic equivalent available. NDA 005932 withdrawn FR effective 09/22/1999.
92.	Masnoderm	52	International product formerly marketed in United Kingdom.
93.	Menadiol	52	International product marketed in United Kingdom.
94.	Metrolyl	52	International product marketed in United Kingdom.
95.	Mindal	52	Discontinued guaifenesin-pseudoephedrine product with no generic equivalents available.

No.	Name	POCA Score (%)	Failure preventions
96.	Monocor	52	International product marketed in Canada, Denmark, and United Kingdom.
97.	Mecholyl	51	Discontinued methacholine-methyl salicylate product with no generic equivalents available.
98.	Molcer	51	International product marketed in United Kingdom.
99.	Medilax	50	Effective January 29, 1999, the FDA issued a final ruling establishing that phenolphthalein is not generally recognized as safe and effective.
100.	Menthol, (+)-	50	Racemic product of Menthol
101.	Migran-A	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
102.	Mitoxana	50	International product marketed in United Kingdom and Ireland.
103.	Amidoline	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
104.	Cinolone	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Enomine La	50	Discontinued guaifenesin-phenylpropanolamine product with no generic equivalents available.

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

No.	Name	POCA Score (%)
106.	Nicolar	60
107.	Biclora	58
108.	Nodolor	58
109.	(b) (4) ***	58
110.	Indolar	57
111.	Pemolert	57
112.	Dulera	56

No.	Name	POCA Score (%)
113.	(b) (4)***	56
114.	Complera	55
115.	Brineura***	54
116.	Gingera	54
117.	Nivolumab	54
118.	Dymelor	53
119.	Pentolair	53
120.	(b) (4)***	53
121.	(b) (4)***	52
122.	Bicillin L-A	52
123.	Biclora-D	52
124.	Bitolterol	52
125.	Endolor	52
126.	Genora	52
127.	Genora 1/50	52
128.	Hemlibra***	52
129.	Imidurea	52
130.	Inflectra	52
131.	Pamelor	52
132.	(b) (4)***	52
133.	Singulair	52
134.	Synalar	52
135.	Synalar 1:10	52
136.	Synalar 1:4	52
137.	Zinplava***	52
138.	Denavir	51
139.	Nuelin S.A.	51
140.	Benlysta	50
141.	Benoral	50
142.	Dicloran	50

No.	Name	POCA Score (%)
143.	(b) (4)***	50
144.	(b) (4)***	50
145.	Indinavir	50
146.	Inulin	50
147.	Northera	50
148.	(b) (4)***	50
149.	Pylera	50
150.	Romilar Ac	50
151.	(b) (4)***	50
152.	Synalar-C	50

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

No.	Name
153.	More than Moisture SPF 30

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

/s/

MADHURI R PATEL
10/13/2016

MISHALE P MISTRY
10/14/2016

LUBNA A MERCHANT
10/14/2016