CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216185Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	December 12, 2022
Application Type and Number:	NDA 216185
Product Name and Strength:	Motpoly XR (lacosamide) Extended-release capsules, 50 mg, 100 mg, 150 mg and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Aucta Pharmaceuticals, Inc. (Aucta)
PNR ID #:	2022-1044724778
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Motpoly XR, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Aucta did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 28, 2022, and proposed prescribing information received on October 4, 2022.

- Intended Pronunciation: mot poe'lee XR
- Active Ingredient: lacosamide
- Indication of Use: Treatment of partial-onset seizures in patients 17 years of age and older
- Route of Administration: oral
- Dosage Form: Extended-release capsules
- Strength: (b) (4) 100 mg, 150 mg and 200 mg
- Dose and Frequency: Adults (17 years and older):

Age and Body Weight	Initial Dosage	Titration Regimen	Maintenance Dosage
Adults (17 years and older)	**Monotherapy**:** 200 mg once daily **Adjunctive Therapy:** 100 mg once daily (b) (4)	Increase by 100 mg once daily every week	**Monotherapy**:** 300 mg to 400 mg once daily **Adjunctive Therapy:** 200 mg to 400 mg once daily

*when not specified, the dosage is the same for monotherapy for partial-onset seizures and adjunctive therapy for partial-onset seizures.

**Monotherapy for partial-onset seizures only

(b) (4)

Dosage Information for Patients with Renal Impairment: For patients with mild to moderate renal impairment, no dosage adjustment is necessary. For patients with severe

renal impairment [creatinine clearance (CLCR) less than 30 mL/min as estimated by the Cockcroft-Gault equation for adults; CLCR less than 30 mL/min/1.73m2 as estimated by the Schwartz equation for pediatric patients] or end-stage renal disease, (b) (4)

Hemodialysis: Lacosamide Extended-Release Capsules are effectively removed from plasma by hemodialysis. Following a 4-hour hemodialysis treatment, dosage supplementation of up to 50% should be considered

Dosage Information for Patients with Hepatic Impairment: For patients with mild or moderate hepatic impairment, (b) (4) The dose titration should be performed with caution in patients with hepatic impairment. Lacosamide Extended-Release Capsules use is not recommended in patients with severe hepatic impairment.

- How Supplied:

  (b) (4)

  - 100 mg are (b) (4) yellow opaque cap and white opaque body with "A" printed in black ink on the cap and "100" printed in black ink on the body, containing white or off-white beads, supplied as bottles of 60
  - 150 mg are brown opaque cap and white opaque body with "A" printed in black ink on the cap and "150" printed in black ink on the body, containing white or off-white beads, supplied as bottles of 60
  - 200 mg are blue opaque cap and white opaque body with "A" printed in black ink on the cap and "200" printed in black ink on the body, containing white or off-white beads, supplied as bottles of 60
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]
- Reference Listed Drug/Reference Product: Vimpat tablets (NDA 022253)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Motpoly XR would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Motpoly XR.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Motpoly XR.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name, Motpoly XR, is comprised of two components: 1) the root name, Motpoly, and (2) the modifier "XR". The Applicant indicates in their submission that the proposed proprietary name, Motpoly XR is not derived from any one particular concept, and that the intended meaning of the proprietary name modifier, XR, is "extended-release product." We note that there is precedence for the use of the modifier XR which is approved by FDA for other extended-release products.

Additionally, we note that the proposed root name, Motpoly contains the letter string "po" in the infix, which is a commonly used medical abbreviation to indicate the oral route of administration. Although we typically discourage the inclusion of medication abbreviations in proprietary name, we determined that the location of the "po" letter string in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Further, the proposed product is an extended-release capsule intended for oral administration and the "po" letter string is common in drug nomenclature of existing drug products, therefore, it is unlikely that this would lead to any confusion or errors. Thus, we do not object to the inclusion of the letters "po" in this case.

2.2.3 Comments from Other Review Disciplines at Initial Review

On October 18, 2022, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to Motpoly XR at the initial phase of the review.

2.2.4 Safety Assessment of the Modifier "XR"

The Applicant proposes the modifier "XR" to denote that the product is an extended-release formulation with a once daily frequency of administration. We note that the use of the modifier "XR" to convey that the proposed product is an extended-release dosage form is contingent upon the product meeting the Agency's criteria for this designation. Assuming these criteria are met, we note that products with the modifier "XR" have been approved in cases where a product is an extended-release formulation that is administered "every 12 hours", "twice daily", or "once daily". Based on the Institute for Safe Medication Practices (ISMP) List of Products with Drug Name Suffixes, the modifier "XR" is typically used to convey the meaning "extended-release" for products with modified-release formulations.[b] As the proposed product will be dosed once

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[a] USAN stem search conducted on October 17, 2022.

[b] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

daily, the use of the modifier "XR" is consistent with its existing meaning and is appropriate for conveying the extended-release characteristic of this product formulation.

Therefore, we do not object to the use of modifier "XR" for the proposed proprietary name "Motpoly XR", and find that the modifier "XR" is acceptable for conveying this characteristic of the product formulation.

2.2.5 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA's prescription studies for Motpoly XR. 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 prescription simulation studies.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We conducted two POCA searches[c] for this review. We did a search of the root name "Motpoly" and a search of the root name plus modifier "Motpoly XR". Our POCA searches identified 122 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. The combined list was de-duplicated for names that fell within the same highly similar, moderately similar, or low similarity POCA score categories and are included in Table 1 below. Although we de-duplicated the search results, because the independent searches yielded different similarity scores for some of the names retrieved, some names may be counted twice in Table 1.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA searches. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	107
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 122 names identified in our POCA searches determined none of the names will pose a risk for confusion with Motpoly XR as described in Appendices C through H.

[c] POCA search conducted on October 17, 2022 in version 5.0.

2.2.9 Communication of DMEPA's Determination

On December 12, 2022, DMEPA 2 communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

The proposed proprietary name, Motpoly XR, is conditionally acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240-402-0012.

3.1 COMMENTS TO AUCTA PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 28, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by 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. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***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 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 55% 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 ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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) may be limited when the strength or dose overlaps. DMEPA reviews 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.

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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.

   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 ≥55% 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 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
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

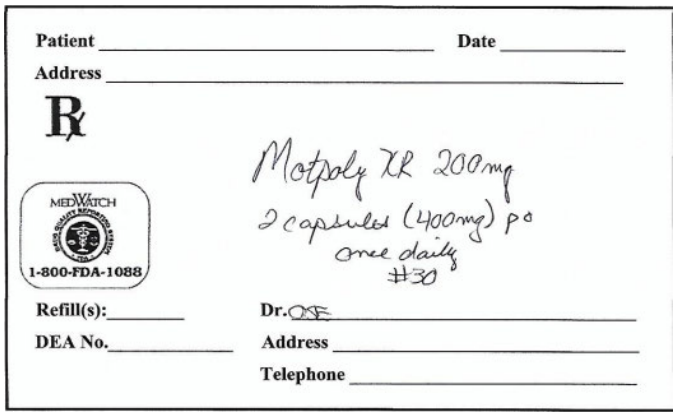
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Motpoly XR Study (Conducted on October 14, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Motpoly XR Take 2 capsules or 400 mg by mouth once daily Dispense 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Motpoly XR	

FDA Prescription Simulation Responses (Aggregate Report)

265 People Received Study
93 People Responded

Study Name: Motpoly XR

Total	26	27	17	23	93
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
MATPALY XR	0	0	0	1	1
MATPOLY XR	1	0	0	0	1
MOCPOLY XR	0	0	1	0	1
MOKPOLI XR	0	0	1	0	1
MOPOLLY XR	0	0	1	0	1

MOTPALY XR	0	0	0	1	1
MOTPDY XR	1	0	0	0	1
MOTPOLEY XR	0	0	3	0	3
MOTPOLI XR	0	0	4	0	4
MOTPOLY	1	0	0	1	2
MOTPOLY XR	23	27	6	18	74
MOTPOLY XR 200 MG	0	0	0	2	2
MYPOLYE XR	0	0	1	0	1

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

No.	**Proposed name:** Motpoly XR **Established name:** lacosamide **Dosage form:** Extended-release capsules **Strength(s):** (b) (4) 100 mg, 150 mg and 200 mg **Usual Dose:** Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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.**
		POCA Search "Motpoly XR"	**POCA Search "Motpoly"**	
1.	Motpoly XR	100	74	This name (root name plus modifier) is the subject of this review.
2.	Motpoly	71	100	This is the root name of the proposed name, Motpoly XR, which is the subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)	
		POCA Search "Motpoly XR"	**POCA Search "Motpoly"**
1.	Metasol		64
2.	Mitosol		64
3.	(b) (4) ***		63
4.	Menthol		62
5.	Menthol, (+)-		62
6.	Imotil		58
7.	Mertodol		57
8.	Mecholyl		56
9.	Monocal		56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Motpoly XR **Established name:** lacosamide **Dosage form:** Extended-release capsules **Strength(s):** (b) (4) 100 mg, 150 mg and 200 mg **Usual Dose:** Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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**
		POCA Search "Motpoly XR"	**POCA Search "Motpoly"**	
1.	Toprol-XL	65		This name pair has sufficient orthographic and phonetic differences.
2.	Mannitol		60	This name pair has sufficient orthographic and phonetic differences.
3.	Mannitol 10%		60	This name pair has sufficient orthographic and phonetic differences.
4.	Mannitol 15%		60	This name pair has sufficient orthographic and phonetic differences.
5.	Mannitol 20%		60	This name pair has sufficient orthographic and phonetic differences.
6.	Mannitol 25%		60	This name pair has sufficient orthographic and phonetic differences.
7.	Mannitol 5%		60	This name pair has sufficient orthographic and phonetic differences.
8.	Metoprolol	56	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the length of the names (root name 7 letters vs. 10 letters) are dissimilar when scripted. Motpoly contains

No.	**Proposed name:** Motpoly XR **Established name:** lacosamide **Dosage form:** Extended-release capsules **Strength(s):** (b) (4) 100 mg, 150 mg and 200 mg **Usual Dose:** Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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**
		POCA Search "Motpoly XR"	**POCA Search "Motpoly"**	
				2 downstroke letters and 1 upstroke letter ('p-ly'), while Metoprolol contains 1 downstroke letter and 2 upstroke letters ('p--l-l'), giving the names different shapes when scripted. Phonetically, the onset of the second syllables (poe' vs. tow) and third syllables (lee vs. pruh) sound different when spoken. Additionally, Motpoly contains three syllables, whereas Metoprolol contains four syllables where the extra syllable 'laal' in metoprolol provides phonetic difference. Additionally, Motpoly contains the modifier "XR" which may provide additional orthographic and phonetic differentiation, if included.
9.	(b) (4) ***		60	(b) (4)

No.	Proposed name: Motpoly XR Established name: lacosamide Dosage form: Extended-release capsules Strength(s): (b) (4) 100 mg, 150 mg and 200 mg Usual Dose: Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
				(b) (4)

No.	**Proposed name:** Motpoly XR **Established name:** lacosamide **Dosage form:** Extended-release capsules **Strength(s):** (b) (4), 100 mg, 150 mg and 200 mg **Usual Dose:** Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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**
		POCA Search "Motpoly XR"	**POCA Search "Motpoly"**	
				(b) (4)
10.	Poly-Rx	59		This name pair has sufficient orthographic and phonetic differences.
11.	Mektovi		58	This name pair has sufficient orthographic and phonetic differences.
12.	Metozolv		58	This name pair has sufficient orthographic and phonetic differences.
13.	Minotal		58	This name pair has sufficient orthographic and phonetic differences.
14.	Mozobil		58	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4)***		58	This name pair has sufficient orthographic and phonetic differences.
16.	Neopolydex	57		This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Motpoly XR Established name: lacosamide Dosage form: Extended-release capsules Strength(s): (b) (4) 100 mg, 150 mg and 200 mg Usual Dose: Initial dose of 100 mg or 200 mg once daily increased weekly by 100 mg increments up to a recommended maintenance dose of 200 mg to 400 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
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
17.	Lomotil		56	This name pair has sufficient orthographic and phonetic differences.
18.	Monopril		56	This name pair has sufficient orthographic and phonetic differences.
19.	Polymox	56	42	This name pair has sufficient orthographic and phonetic differences.
20.	Metaprel		55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)	
		POCA Search "Motpoly XR"	POCA Search "Motpoly"
1.	Polytrim	54	46
2.	Pomalyst		52

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
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
1.	Motazol		69	Veterinary product.
2.	Timoptol		69	International product marketed and formerly marketed in multiple countries outside the US.
3.	Timoptol LA		65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Maxolon SR	64		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Metrolyl	56	64	International product marketed in the United Kingdom.
6.	Bp Poly-650		63	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	(b) (4) ***		63	Proposed proprietary name for IND 118906 found unacceptable by DMEPA (OSE# 2017-19129784 dated May 17, 2018). NDA 211281 approved under proprietary name, Pizensy.
8.	Maltol		62	Product is not a drug. It is a naturally occurring organic compound that is used primarily as a flavor enhancer.
9.	Manitol		62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Myrtol	46	62	International product marketed in Germany.
11.	Mysotrol	48	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Maltitol		61	Product is not a drug. It is a sugar alcohol.
13.	Micotil		60	Veterinary product.
14.	Poly D SR	60		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
15.	Modisal XL	59		Modisal (without the Xl modifier) is an international product marketed in the United Kingdom and formerly marketed in Switzerland.
16.	Monomax SR	58		Monomax (without the Sr modifier) is an international product marketed in the United Kingdom and formerly marketed in Ireland.
17.	Mucolex	58		International product marketed in Malaysia, Hong Kong and Thailand and formerly marketed in Portugal and Ireland.
18.	Natrilix SR	58		Natrilix (without the SR modifier) is an international product marketed in multiple countries outside the US and formally marketed in New Zealand.
19.	Monit LS		57	Monit (without the Ls modifier) is an international product marketed in India.
20.	Movodyl		57	Veterinary product.
21.	Sympatol		57	International product marketed in Germany and formerly marketed in Italy, Austria and Switzerland.
22.	Mandol		56	Brand discontinued with no generic equivalents available. NDA 050504 and ANDA 062560 withdrawn FR effective March 13, 2009 and December 7, 2007, respectively.
23.	Poloxamer	56		Product is not a drug. It is a nonionic triblock copolymer composed of a central hydrophobic chain of polyoxypropylene (poly(propylene oxide)) flanked by two hydrophilic chains of polyoxyethylene (poly(ethylene oxide)).
24.	Poloxamer 105	56		Product is not a drug. It is a surfactant.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
25.	Poloxamer 124	56		Product is not a drug. It is a surfactant and emulsifying agent. It belongs to a group of compounds known as poloxamers that are made up of three polymer blocks. In cosmetic and personal care product formulations, it functions as a surfactant - emulsifying agent and surfactant - solubilizing agent. It can be used in soaps and cleansers.
26.	Poloxamer 181	56		Product is not a drug. It is a surfactant.
27.	Poloxamer 182	56		Product is not a drug. It is a nonionic triblock copolymer composed of a central hydrophobic chain of polyoxypropylene flanked by two hydrophilic chains of polyoxyethylene. It belongs to a group of compounds known as poloxamers that are made up of three polymer blocks. In cosmetic and personal care product formulations, it functions as a surfactant - cleansing agent. It can be used in soaps and cleansers. It is partially soluble in water.
28.	Poloxamer 184	56		Product is not a drug. It is a nonionic triblock copolymer composed of a central hydrophobic chain of polyoxypropylene flanked by two hydrophilic chains of polyoxyethylene. It belongs to a group of compounds known as poloxamers that are made up of three polymer blocks. In cosmetic and personal care product formulations, it functions as a surfactant - cleansing agent and surfactant - solubilizing agent. It can be used in hair care products and cleansers. It is soluble in water.
29.	Poloxamer 188	56		Product is not a drug. It is a copolymer of polyoxyethylene and polyoxypropylene used for drug delivery as formulation excipients.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
30.	Poloxamer 234	56		Product is not a drug. It is a surfactant.
31.	Poloxamer 237	56		Product is not a drug. It is a surfactant.
32.	Poloxamer 331	56		Product is not a drug. It is a nonionic triblock copolymer. It is made up of a main hydrophobic chain of polyoxypropylene bordered on each side by two hydrophilic chains of polyoxyethylene. It is a surfactant.
33.	Poloxamer 335	56		Product is not a drug. It is polyoxyethylene, polyoxypropylene block polymer used as a surfactant.
34.	Poloxamer 338	56		Product is not a drug. It is a surfactant.
35.	Poloxamer 403	56		Product is not a drug. It is a surfactant.
36.	Poloxamer 407	56		Product is not a drug. It is a hydrophilic non-ionic surfactant of the more general class of copolymers known as poloxamers. Poloxamer 407 is a triblock copolymer consisting of a central hydrophobic block of polypropylene glycol flanked by two hydrophilic blocks of polyethylene glycol (PEG).
37.	(b) (4) ***	55		(b) (4)
38.	Metosyn		55	International product marketed in Denmark, Norway, and the United Kingdom and formerly marketed in Singapore and Ireland.
39.	Mobiflex	55		International product marketed in Canada, Indonesia, the United Kingdom, and Austria and formerly marketed in Ireland.
40.	Motilium		55	International product marketed in multiple countries outside the US and formerly marketed in Canada.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Motpoly XR"	POCA Search "Motpoly"	
41.	Mytokey***		55	Proposed proprietary name for CBER IND 17367.66 found unacceptable by CBER on July 7, 2020. IND 17367.66 is pending, and no new names have been submitted.
42.	Polyflex	55		Veterinary product.
43.	Polytar	55		Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
44.	(b) (4) ***	53		Proposed proprietary name for NDA 215429 found unacceptable by DMEPA (OSE # 2021-1044724162 dated November 30, 2021). NDA 215429 was approved under the established name venlafaxine.
45.	Poly D		52	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
46.	Poly DM		50	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	POCA Score (%)	
		POCA Search "Motpoly XR"	POCA Search "Motpoly"
1.	Osmolex ER	64	
2.	Nobatol		62
3.	Totamol		62
4.	Optil XL	61	
5.	Control Rx	60	
6.	Lamictal XR	60	
7.	(b) (4) ***	60	
8.	Oxtellar XR	60	

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)	
		POCA Search "Motpoly XR"	POCA Search "Motpoly"
9.	Tegretol-XR	59	
10.	Bronkolixir	58	
11.	Dutoprol		58
12.	Topicool		58
13.	Doptelet		57
14.	Epsolay		57
15.	1-Naphthol		56
16.	(b) (4) **	56	
17.	Betimol		56
18.	Butisol		56
19.	Dofsol-A		56
20.	Emetrol		56
21.	Hemoplex F	56	
22.	Nytol		56
23.	(b) (4) ***		56
24.	Optil		56
25.	Optil SR	56	
26.	Osmolex	56	
27.	Pasmol		56
28.	Postprophy		56
29.	Toprol		56
30.	Vontrol		56
31.	Amoxil		55
32.	Bystolic		55
33.	Complex B	55	
34.	Optiflex-G	55	
35.	Ponstel		55

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/s/

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