CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216655Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

*** This document contains proprietary information that cannot be released to the public***

Date of This Review:	June 24, 2024
Application Type and Number:	NDA 216655
Product Name, Dosage Form, and Strength:	Opipza (aripiprazole) oral film, 2 mg, 5 mg, and 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Xiamen LP Pharmaceutical Co., Ltd. (Xiamen)
PNR ID #:	2024-1044725705
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Opipza, 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. Xiamen did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Xiamen previously submitted the proposed proprietary name, [redacted] (b) (4), under NDA 216655 on December 22, 2023. However, on March 15, 2024, we found the name, [redacted] (b) (4) unacceptable due to misbranding concerns with the proprietary name, [redacted] (b) (4).[a]

Thus, Xiamen submitted the proposed proprietary name, Opipza, for review on March 28, 2024 under NDA 216655.

1.2 PRODUCT INFORMATION

The following product information is provided in the prescribing information received on April 19, 2024[b].

Table 1. Relevant Product Information for Opipza	
Intended pronunciation:	ō-ˈ**pip**-sə
Active ingredient:	aripiprazole
Indication:	Treatment of: • Schizophrenia • Adjunctive Treatment of Major Depressive Disorder • Irritability Associated with Autistic Disorder • Treatment of Tourette's Disorder
Dosage Form:	oral [redacted] (b) (4) film[c]
Strengths:	2 mg, 5 mg, and 10 mg
Route of administration:	oral

[a] Holmes, L. Proprietary Name Review for [redacted] (b) (4) (NDA 216655). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 15. PNR ID No. 2023-1044725538.

[b] Proposed prescribing information for Opipza. Xiamen (China): Xiamen LP Pharmaceutical Co., Ltd.; 2024 Apr 19. Available from: \\CDSESUB1\EVSPROD\nda216655\0017\m1\us\draft-labeling-text.pdf.

[c] Per the Office of Pharmaceutical Quality, the dosage form is "oral film" and not [redacted] (b) (4) as proposed by the Applicant.

Table 1. Relevant Product Information for Opipza

Dose and frequency:

Administer once daily without regard to meals. Do not cut or divide film. (b) (4)

		Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia – adults		10 to 15 mg/day	10 to 15 mg/day	30 mg/day
Schizophrenia – adolescents		2 mg/day	10 mg/day	30 mg/day
Major Depressive Disorder – Adults adjunct to antidepressants		2 to 5 mg/day	5 to 10 mg/day	15 mg/day
Irritability associated with autistic disorder – pediatric patients		2 mg/day	5 to 10 mg/day	15 mg/day
Tourette's disorder –	Patients < 50 kg	2 mg/day	5 mg/day	10 mg/day
	Patients ≥ 50 kg	2 mg/day	10 mg/day	20 mg/day

Known CYP2D6 poor metabolizers: Half of the usual dose, (b) (4) (b) (4)

How Supplied:

Strength	Film Color/Shape	Printed Blue Mark	Pack Size	NDC Code
2 mg	1 cm × 1.2 cm Rectangular thin white film	A2	(b) (4)	71034-016- (b) (4)
5 mg	2 cm × 1.5 cm Rectangular thin white film	A5		71034-010-
10 mg	2 cm × 3 cm Rectangular thin white film	A10		71034-011-

Storage: Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Listed Drug: Abilify (aripiprazole) tablets NDA 021436

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Opipza would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Opipza. The Division of Psychiatry (DP) did not comment on the findings of OPDP's assessment for Opipza.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Xiamen indicated in their submission that the proposed proprietary name, Opipza, *"was chosen to avoid confusion with any current pharmaceutical product in either written or spoken form. Besides, it contains the syllable PIP which may help the practitioner remember the name of the active ingredient, aripiprazole. The name is short, easy to pronounce and remember."*

This proprietary name is comprised of a single word that contains the letters "opi" which is the medical abbreviation for "opiates". We typically discourage the inclusion of medical abbreviations in proprietary names. However, we evaluated the potential risk of misinterpreting the proposed proprietary name Opipza as "Opi [drug name similar to pza]" given the name begins with the letters "Opi" and did not identify any names of concern.[e]

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On May 3, 2024, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Opipza at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-six (96) practitioners participated in DMEPA's prescription simulation studies for Opipza. 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.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[f] identified 34 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

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[d] USAN stem search conducted on May 23, 2024.

[e] POCA search for "pza" conducted on June 5, 2024 in version 5.9

[f] POCA search conducted on May 23, 2024 in version 5.9.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	32
Low similarity name pair: combined match percentage score ≤54%	1

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

We determined 33 of the 34 names will not pose a risk for confusion with Opipza as described in Appendices C through H. However, the proposed proprietary name could be confused with the pending name (b) (4) for the reasons described below. Thus, the ultimate acceptability of the proposed proprietary name, Opipza, is dependent upon which underlying application is approved first.

Opipza vs. (b) (4)

The proposed proprietary name, Opipza, may be confused with another pending proposed proprietary name that is also under review, (b) (4)

(b) (4)

We are aware of postmarketing reports of errors involving confusion between similarly named drug products. For example, name confusion has been reported between Avandia and Prandin due to orthographic similarity despite the names having different first letters.[g]

[g] Institute for Safe Medication Practices. 1999 Sep 08. Safety Briefs. ISMP Med Saf Alert. 4(18):1.

(b) (4) Thus, the application PDUFA date for Opipza (NDA 216655) will precede (b) (4) which is not currently under a review timeline. Based on the above, we do not object to the proposed proprietary name, Opipza, at this time.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On June 24, 2024, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Opipza, is conditionally acceptable.

3.1 COMMENTS TO XIAMEN LP PHARMACEUTICAL CO., LTD.

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

If any of the proposed product characteristics as stated in your submission, received on March 28, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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.[h]

*Table 3. 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.

[h] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. 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 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, Cerner RxNorm, Purple Book, 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 4-6) 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 4).
- 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[i]. 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 are 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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-

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

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 OPQ 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 Safety Evaluator 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 4. 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?		

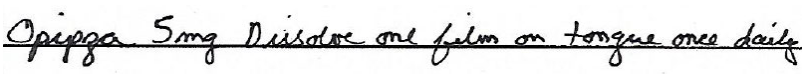
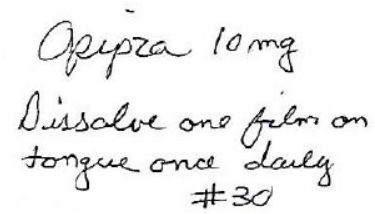
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>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 with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><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</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>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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?	

Table 6. 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. Opipza Study (Conducted on 4/16/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Opipza 10 mg Dissolve one film on tongue once daily Dispense 30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Opipza	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Opipza People Received Study: 188 People Responded: 96					
Total	23	22	24	27	96
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
APIPZA	0	9	0	0	9
APRIPZA	0	1	0	0	1
OEMPSA	0	0	1	0	1
OFIPZA	0	2	0	0	2
OIPSA	0	0	1	0	1
OPEMSA	0	0	1	0	1
OPEPSIA	0	0	1	0	1
OPIPRA	0	1	0	0	1
OPIPSA	0	0	15	0	15
OPIPSAA	0	0	1	0	1
OPIPZA	23	8	1	27	59
OPISYA	0	0	1	0	1
OPIZA	0	1	0	0	1
OPYPSA	0	0	2	0	2

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Opipza Pronunciation: ō-ˈpip-sə Established name: aripiprazole Dosage form: oral film Strength: 2 mg, 5 mg, and 10 mg Dosage: Dosage range is 2 mg to 30 mg orally 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.	Opipza	100	This name 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 (%)
1.	Tepezza	62
2.	Omeza	55

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: Opipza Pronunciation: ō-ˈpip-sə Established name: aripiprazole Dosage form: oral film Strength(s): 2 mg, 5 mg, and 10 mg Dosage: Dosage range is 2 mg to 30 mg orally 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.	Opuviz	63	This name pair has sufficient orthographic and phonetic differences.
2.	Optivar	60	This name pair has sufficient orthographic and phonetic differences.
3.	Opana	58	This name pair has sufficient orthographic and phonetic differences.
4.	Opdivo	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Opipza Pronunciation: ō-ˈpip-sə Established name: aripiprazole Dosage form: oral film Strength(s): 2 mg, 5 mg, and 10 mg Dosage: Dosage range is 2 mg to 30 mg orally 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
5.	(b) (4)	58	This name pair has sufficient orthographic and phonetic differences.
6.	Copiktra	56	This name pair has sufficient orthographic and phonetic differences.
7.	Opcon-A	56	This name pair has sufficient orthographic and phonetic differences.
8.	Otezla	56	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**—N/A

APPENDIX G. Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)	69	Proposed proprietary name withdrawn by the Applicant. NDA 212154 approved under the proprietary name, Viltepso.
2.	Piptal	65	International product marketed in Australia.
3.	Epipram	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Atopica	58	Veterinary product.
5.	Opiates	58	This is not the name of a specific drug product. An opiate is an alkaloid drug (such as morphine or codeine) that contains or is derived from opium, binds to cell receptors primarily of the central nervous system and gastrointestinal tract, acts to block pain, induce sedation or sleep, depress respiration, and produce calmness or euphoria, and is associated with physiological tolerance, physical and psychological dependence, and addiction upon repeated or prolonged use.

No.	Name	POCA Score (%)	Failure preventions
6.	Otiprio	58	Brand discontinued with no generic equivalents available. On 10/11/2022, the Applicant requested withdrawal of NDA 207986.
7.	Opipramol	57	International product marketed in Australia, Germany, India, and other foreign countries.
8.	(b) (4)	56	(b) (4)
9.	(b) (4)	53	(b) (4)

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

No.	Name	POCA Score (%)
1.	Apidra	63
2.	(b) (4)	61
3.	Epimaz	60
4.	(b) (4)	60
5.	Avinza	58
6.	Uplizna	58
7.	Amitiza	56
8.	Atripla	56
9.	Pokonza	56
10.	Potiga	56
11.	(b) (4)	56
12.	(b) (4)	55
13.	Pep-Back	55

[j] 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

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	March 15, 2024
Application Type and Number:	NDA 216655
Product Name, Dosage Form, and Strengths:	(b) (4) (aripiprazole) oral (b) (4) film, 2 mg, 5 mg, and 10 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Xiamen LP Pharmaceutical Co., Ltd. (Xiamen)
PNR ID #:	2023-1044725538
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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