CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211448Orig1s000

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:	April 9, 2025
Application Type and Number:	NDA 211448
Product Name, Dosage Form, and Strengths:	Mezofy (aripiprazole) oral films, 5 mg, 10 mg, and 15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMG Pharmaceutical Co., Ltd (CMG)
PNR ID #:	2025-1044726245
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

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Mezofy, 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. CMG submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

CMG previously submitted the proposed proprietary name [redacted] (b) (4) *** under IND 119610 and NDA 211448 on July 23, 2018 and October 18, 2019, respectively. The proposed name was found conditionally acceptable on January 7, 2019[b] and January 7, 2020.[c] However, the Agency issued a Complete Response Letter on August 18, 2020. In response, CMG submitted a Class 2 resubmission of the NDA on October 14, 2024. However, during the interim, prior to resubmission of the NDA application, the proposed name [redacted] (b) (4) *** was found unacceptable on October 3, 2024 due to orthographic similarities and overlapping product characteristics with the newly approved product, [redacted] (b) (4)

Thus, CMG withdrew the name [redacted] (b) (4) *** on October 23, 2024 and submitted the proposed proprietary name, Mezofy, for review on January 23, 2025 under NDA 211448.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 23, 2025[e] and the prescribing information received on October 18, 2019.[f]

Table 1. Relevant Product Information for Mezofy	
Intended pronunciation:	meh' zoe fye
Active ingredient:	aripiprazole

[a] Proprietary Name Safety Summary for Mezofy. [redacted] (b) (4) 2025 Jan 16. Available from: \\CDSESUB1\EVSPROD\nda211448\0035\m1\us\118-proprietary-names\proprietary-name-safety-summary.pdf.

[b] Holmes, L. Proprietary Name Review for [redacted] (b) (4) *** (IND 119610). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jan 7. PNR ID No. 2018-24729552.

[c] Holmes, L. Proprietary Name Review for [redacted] (b) (4) *** (NDA 211448). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Jan 7. PNR ID No. 2019-35234392.

[d] Holmes, L. Proprietary Name Memorandum for [redacted] (b) (4) *** (NDA 211448). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); October 3, 2024. PNR ID No. 2019-35234392-1.

[e] Request for Proprietary Name Review (Mezofy NDA 211448). Seoul (Korea): CMG Pharmaceutical Co., Ltd; 2025 Jan 23. Available from: \\CDSESUB1\EVSPROD\nda211448\0035\m1\us\118-proprietary-names\118-name-request.pdf.

[f] Proposed prescribing information for Mezofy. Seoul (Korea): CMG Pharmaceutical Co., Ltd; 2019 Oct 18. Available from: \\CDSESUB1\EVSPROD\nda211448\0001\m1\us\114-labeling\114a-draft-label\labeling-insert-draft-word.docx.

<table>
<tr><th colspan="2">Table 1. Relevant Product Information for Mezofy</th></tr>
<tr><td>Indication:</td><td>Treatment of schizophrenia</td></tr>
<tr><td>Dosage Form:</td><td>Oral film</td></tr>
<tr><td>Strength:</td><td>5 mg, 10 mg, and 15 mg</td></tr>
<tr><td>Route of administration:</td><td>Oral</td></tr>
<tr><td>Dose and frequency:</td><td>Administer once daily.
Schizophrenia (adults):
Initial Dose: 10-15 mg/day
Recommended Dose: 10-15 mg/day
Maximum Dose: 30 mg/day
Schizophrenia (pediatric patients-13 to 17 years):
Initial Dose: 2 mg/day (with another aripiprazole product)
Recommended Dose: 10 mg/day
Maximum Dose: 30 mg/day</td></tr>
<tr><td>How Supplied:</td><td>
<table>
<tr><th>Strength</th><th>Film Color/Shape</th><th>Print</th><th>Pack Size</th><th>NDC Code</th></tr>
<tr><td>5 mg</td><td>white rectangular</td><td>CMG ARF5</td><td>one strip (film) per pouch, box of 30 pouches</td><td>xxxx-xxxx-xxx</td></tr>
<tr><td>10 mg</td><td>white rectangular</td><td>CMG ARF10</td><td>one strip (film) per pouch, box of 30 pouches</td><td>xxxx-xxxx-xxx</td></tr>
<tr><td>15 mg</td><td>white rectangular</td><td>CMG ARF15</td><td>one strip (film) per pouch, box of 30 pouches</td><td>xxxx-xxxx-xxx</td></tr>
</table>
</td></tr>
<tr><td>Storage:</td><td>Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [USP controlled room temperature].</td></tr>
<tr><td>Listed Drug:</td><td>Abilify Oral Tablets (aripiprazole) NDA 021436</td></tr>
</table>

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Mezofy 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 Mezofy. The Division of Psychiatry (DP) did not comment on the findings of OPDP's assessment for Mezofy.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

CMG indicated in their submission that the proposed proprietary name, Mezofy, is "derived from medicated oral film." 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 can contribute to medication errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Psychiatry (DP) did not forward any comments or concerns relating to Mezofy at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-eight (98) practitioners participated in DMEPA's prescription simulation studies for Mezofy. One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name Mefoxin. However, the participant entered an incorrect sequence of letters, "Mef" when searching for the study name. As a result, the CPOE generated picklist did not contain Mezofy as a choice. The participant proceeded to incorrectly select Mefoxin as their response after 34 seconds in order to proceed with the FDA prescription stimulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Despite this, we further evaluated Mezofy vs. Mefoxin and determined that this name pair has sufficient orthographic and phonetic differences. This is supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) system, which calculates a combined score of 54%, orthographic score of 54%, and phonetic score of 54%, indicating low similarity.[h]

Orthographically, the names have a different shape. The third position letters ("z" vs. "f") look different when scripted due to the optional downstroke or in-line letter "z" vs. upstroke of the letter "f". Similarly, the fifth position letters ("f" vs. "x") look different due to the upstroke of the letter "f" and the cross-stroke letter "x". Additionally, Mezofy does not contain the dotted letter "i" which is present in Mefoxin. Moreover, the ending letters ("y" vs. "n") do not look similar due to the downstroke of the letter "y" and in-line letter "n". Phonetically, the second syllables ("-zo-" vs. "-fo-") and third syllables ("-fy" vs. "-xin") sound different.

The products differ in route of administration (oral vs. intravenous), dosage form (oral film vs. for injection or injection), and indication of use (treatment of schizophrenia vs. treatment of serious infections caused by susceptible strains of designated microorganisms). Thus, we determined the risk for a medication error between this name pair is adequately minimized (see Appendix E).

---

[g] USAN stem search conducted on February 3, 2025.

[h] POCA search conducted on March 31, 2025 in version 5.9.1

The remaining 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[i] identified 19 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 (19 names), FDA Prescription Simulation Study (1 name), and (b) (4) external study (1 name). These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

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%	18
Low similarity name pair: combined match percentage score ≤54%	2

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

We determined that 19 of the 21 names will not pose a risk for confusion with Mezofy as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4)*** and (b) (4)*** and this evaluation is still pending review.

We evaluated the status of the underlying applications of the conflicting names, (b) (4)*** and (b) (4)*** and determined that if NDA 211448 for Mezofy is approved on or before Mezofy's goal date of April 15, 2025, this application approval will precede approval of the application with the conflicting proposed name (b) (4) ** (application is in IND status) and (b) (4) ** (marketing application is not anticipated to be approved on or before April 15, 2025). Based on the application goal date for NDA 211448 and the status of the underlying applications for (b) (4) ** and (b) (4)***, we do not object to the proposed proprietary name, Mezofy, at this time.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On April 9, 2025, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

[i] POCA search conducted on February 3, 2025 in version 5.9.

3 CONCLUSION

The proposed proprietary name, Mezofy, is conditionally acceptable.

3.1 COMMENTS TO CMG PHARMACEUTICAL CO., LTD

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

If any of the proposed product characteristics as stated in your submission, received on January 23, 2025, 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.[j]

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.

[j] 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 (Tables 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 that 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[k]. 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 and 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-

[k] 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

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 as 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?		

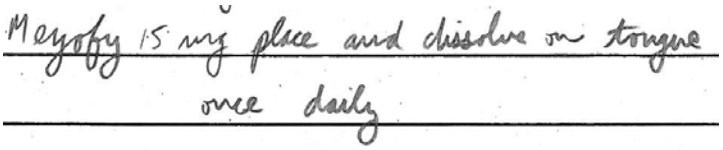
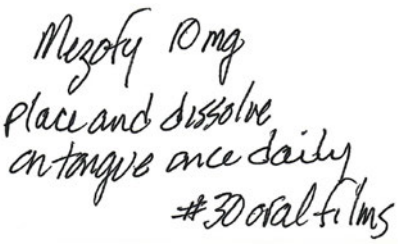
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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 as 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 names 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. Mezofy Study (Conducted on 1/31/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Mezofy 10 mg Place and dissolve on tongue once daily Dispense 30 oral films
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Mezofy	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Mezofy People Received Study: 166 People Responded: 98					
Total	21	28	22	27	98
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
MAZOFI	0	0	1	0	1
MEFOXIN	0	0	0	1	1
MERZOFY	0	1	0	0	1
MESOFI	0	0	1	0	1
MESOFY	0	0	1	0	1
MESOPHI	0	0	1	0	1
MEYOFY	20	0	0	0	20
MEZOFI	0	0	7	0	7
MEZOFY	1	27	5	26	59
MEZOPHY	0	0	1	0	1
MEZOPIE	0	0	1	0	1
MISOFY	0	0	1	0	1
MIZOFI	0	0	1	0	1
MIZOFY	0	0	2	0	2

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

No.	Proposed name: Mezofy Pronunciation: meh' zoe fye Established name: aripiprazole Dosage form: oral films Strength(s): 5 mg, 10 mg, and 15 mg Dosage: 5 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.	Mezofy	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 – N/A

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: Mezofy Pronunciation: meh' zoe fye Established name: aripiprazole Dosage form: oral films Strength: 5 mg, 10 mg, and 15 mg Dosage: 5 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.	(b) (4) **	64	Phonetically, the first syllables ("Me-"vs. (b) (4) and second syllables ("-zo-" vs. (b) (4)) sound different. Additionally, the products differ in strength [5 mg, 10 mg, and 15 mg vs. (b) (4)], route of administration (oral vs. (b) (4) (b) (4) frequency of administration (once daily vs. (b) (4), and indication of use (treatment of schizophrenia vs. (b) (4) (b) (4)

No.	Proposed name: Mezofy Pronunciation: meh' zoe fye Established name: aripiprazole Dosage form: oral films Strength: 5 mg, 10 mg, and 15 mg Dosage: 5 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
			(b) (4) Thus, the risk of name confusion is minimized in this case.
2.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4)***	60	See Section 2.2.7
4.	(b) (4)***	60	See Section 2.2.7
5.	(b) (4)**	58	This name pair has sufficient orthographic and phonetic differences.
6.	Motofen	58	This name pair has sufficient orthographic and phonetic differences.
7.	Merzee	57	This name pair has sufficient orthographic and phonetic differences.
8.	Mytesi	56	This name pair has sufficient orthographic and phonetic differences.
9.	(b) (4)***	55	This name pair has sufficient orthographic and phonetic differences.
10.	Mefoxin	54	See FMEA in Section 2.2.4.

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.	Metosyn	64	International product marketed in Sweden, Ireland, and other foreign countries.
2.	(b) (4)***	64	(b) (4)
3.	(b) (4)***	63	(b) (4)
4.	(b) (4)***	58	Proposed proprietary name for IND 107331 found unacceptable by DMEPA (OSE #2018-24830509). NDA 208171 approved under the proprietary name Monoferric.
5.	M-Oxy	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Myozyme	56	BLA 125141 license revoked on 09/08/2020.
7.	Mezlocillin	44	Brand discontinued with no generic equivalents available. NDA 050549 withdrawn FR effective 4/04/2005.

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

No.	Name	POCA Score (%)
1.	(b) (4)***	60
2.	Ezfe	56
3.	(b) (4)***	56

[I] 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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORETTA HOLMES
04/10/2025 11:54:41 AM

YEVGENIYA M KOGAN
04/10/2025 12:23:32 PM

IDALIA E RYCHLIK
04/10/2025 12:26:26 PM

PROPRIETARY NAME MEMORANDUM

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:	October 3, 2024
Application Type and Number:	NDA 211448
Product Name, Dosage Form, and Strength:	(b) (4) (aripiprazole) oral film, 5 mg, 10 mg, and 15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMG Pharmaceutical Co., Ltd (CMG)
PNR ID #:	2019-35234392-1
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

2 Page(s) have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORETTA HOLMES
10/03/2024 01:12:31 PM

YEVGENIYA M KOGAN
10/07/2024 06:06:54 PM

IDALIA E RYCHLIK
10/07/2024 08:20:20 PM

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:	January 7, 2020
Application Type and Number:	NDA 211448
Product Name and Strength:	(b) (4) (aripiprazole) oral soluble film, 5 mg, 10 mg, and 15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	CMG Pharmaceutical Co., Ltd (CMG)
Panorama #:	2019-35234392
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

16 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

LORETTA HOLMES
01/07/2020 03:05:23 PM

SEVAN H KOLEJIAN
01/07/2020 03:07:51 PM