

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217347Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	March 6, 2024
Application Type and Number:	NDA 217347
Product Name, Dosage Form, and Strength:	Sofdra (sofpironium) ^a topical gel, 12.45% ^b
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Botanix SB Inc. (Botanix)
PNR ID #:	2023-1044725531
DMEPA 1 Safety Evaluator:	Madhuri R. Patel, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

^a The Applicant provided the established name as sofpironium bromide. However, per the Office of Pharmaceutical Quality (OPQ), the established name will be sofpironium.

^b The Applicant provided the strength as 15%. However, per OPQ, the strength will be expressed as 12.45%.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Sofdra, which was found conditionally acceptable under NDA 217347 on August 24, 2023.^c However, NDA 217347 received a complete response letter (CRL) on September 22, 2023. Thus, Botanix responded to the CRL and concurrently submitted the proposed proprietary name, Sofdra, under NDA 217347 for re-review on December 20, 2023, along with an external name study, conducted by (b) (4).^d The submitted external name study was previously reviewed under NDA 217347 (see Section 1.1 below). We note that all product characteristics remain the same.

1.1 REGULATORY HISTORY

Brickell Biotech, Inc. (company ownership has since been transferred to Botanix) previously submitted the proposed proprietary name, (b) (4) ***, for review on November 10, 2020 under IND 121256. However, on December 11, 2020, we found the name, (b) (4) ***, unacceptable because it would misbrand the proposed product.^e

Subsequently, Brickell Biotech submitted the proposed proprietary name, (b) (4) ***, for review on April 27, 2021 under IND 121256. However, on August 11, 2021, we found the name (b) (4) ***, unacceptable because it would misbrand the proposed product.^f

Thereafter, Botanix submitted the proposed proprietary name, (b) (4) *** under NDA 217347 on October 7, 2022. However, on January 3, 2023, we found the name, (b) (4) *** unacceptable because it would misbrand the proposed product.^g

Then, Botanix submitted the proposed proprietary name, (b) (4) *** under NDA 217347 on February 8, 2023. However, on May 1, 2023, we found the name (b) (4) *** unacceptable from a safety perspective as it is vulnerable to name confusion with the marketed name (b) (4).^h

^c Mena-Grillasca, C. Proprietary Name Review for Sofdra (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 AUG 24. PNR ID No. 2023-1044725175.

^d Proprietary Name Safety Summary for SOFDRA (NDA 217347). (b) (4)
Available from: <\\CDSESUB1\EVSPROD\nda217347\0024\m1\us\118-proprietary-names\proprietary-name-summary-sofdra.pdf>.

^e Patel, M. Proprietary Name Review for (b) (4) *** (IND 121256). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Dec 11. Panorama No.: 2020-43841806.

^f Patel, M. Proprietary Name Review for (b) (4) *** (IND 121256). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 11. Nexus PNR ID No.: 2021-1044723941.

^g Holmes, L. Proprietary Name Review for (b) (4) *** (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 JAN 03. Nexus PNR ID No. 2022-1044724796.

^h Patel, M. Proprietary Name Review for (b) (4) *** (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 May 01. Nexus PNR ID No.: 2023-1044724985.

On June 7, 2023, Botanix submitted the name, Sofdra***, for review under NDA 217347 and was found conditionally acceptable on August 24, 2023.ⁱ However, NDA 217347 received a complete response (CR) on September 22, 2023.

Thus, Botanix responded to the CR and concurrently submitted the proposed proprietary name, Sofdra, under NDA 217347 for re-review on December 20, 2023.^j

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Sofdra 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 Sofdra. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Sofdra.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Sofdra, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The February 27, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Sofdra.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On March 6, 2024, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Sofdra, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

ⁱ Mena-Grillasca, C. Proprietary Name Review for Sofdra (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 AUG 24. PNR ID No. 2023-1044725175.

^j Proprietary Name Safety Summary for SOFDRA (NDA 217347). (b) (4)
Available from: <\\CDSESUB1\EVSPROD\nda217347\0024\m1\us\118-proprietary-names\proprietary-name-summary-sofdra.pdf>.

3.1 COMMENTS TO BOTANIX SB INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 20, 2023, are altered prior to approval of the marketing application, the name proprietary must be resubmitted for review.

4 REFERENCE

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>.

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/

MADHURI R PATEL
03/06/2024 12:47:56 PM

YEVGENIYA M KOGAN
03/06/2024 03:31:26 PM

MISHALE P MISTRY
03/08/2024 12:04:18 PM

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:	August 24, 2023
Application Type and Number:	NDA 217347
Product Name and Strength:	Sofdra (sofpironium) ^a topical gel, 12.45% ^b
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Botanix SB Inc. (Botanix)
Nexus PNR ID #:	2023-1044725175
DMAMES Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Acting Team Leader:	Madhuri Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

^a The Applicant provided the established name as sofpironium bromide. However, per the Office of Pharmaceutical Quality (OPQ), the established name will be sofpironium.

^b The Applicant provided the strength as 15%. However, per OPQ, the strength will be expressed as 12.45%.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Sofdra, 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. Botanix submitted an external name study, conducted by the (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Brickell Biotech, Inc. (company ownership has since been transferred to Botanix) previously submitted the proposed proprietary name, (b) (4)***, for review on November 10, 2020 under IND 121256. However, on December 11, 2020, we found the name, (b) (4)***, unacceptable because it would misbrand the proposed product^c.

Subsequently, Brickell Biotech submitted the proposed proprietary name, (b) (4)***, for review on April 27, 2021 under IND 121256. However, on August 11, 2021, we found the name (b) (4)***, unacceptable because it would misbrand the proposed product^d.

Thereafter, Botanix submitted the proposed proprietary name, (b) (4)*** under NDA 217347 on October 7, 2022. However, on January 3, 2023, we found the name (b) (4)*** unacceptable because it would misbrand the proposed product^e.

Then, Botanix submitted the proposed proprietary name, (b) (4)*** under NDA 217347 on February 8, 2023. However, on May 1, 2023, we found the name (b) (4)*** unacceptable from a safety perspective as it is vulnerable to name confusion with the marketed name (b) (4).

Thus, Botanix submitted the name, Sofdra, for review on June 7, 2023 under NDA 217347.

^c Patel, M. Proprietary Name Review for (b) (4)*** (IND 121256). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Dec 11. Panorama No.: 2020-43841806.

^d Patel, M. Proprietary Name Review for (b) (4)*** (IND 121256). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 11. Nexus PNR ID No.: 2021-1044723941.

^e Holmes, L. Proprietary Name Review for (b) (4)*** (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 JAN 03. Nexus PNR ID No. 2022-1044724796.

^f Patel, M. Proprietary Name Review for (b) (4)*** (NDA 217347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 May 01. Nexus PNR ID No.: 2023-1044724985.

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1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 7, 2023.

- Intended Pronunciation: sof' drah
- Active Ingredient: sofipironium
- Indication of Use: topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older
- Route of Administration: topical
- Dosage Form: topical gel
- Strength: 12.45%^g
- Dose and Frequency: one pump actuation to each underarm once a day at bedtime (total 2 pumps), for a total dose of 144 mg^h
- How Supplied: bottle with a multi-dose metered pump, applicator, and cap. Each bottle contains 50 mL of gel with a multi-dose pump capable of dispensing 60 pump actuations. Each pump actuation dispenses 0.67 mL of gel.
- Storage: stored at 20°C to 25°C (68°F-77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

2 RESULTS

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

^g The Applicant provided the strength as 15%. However, per the Office of Pharmaceutical Quality (OPQ), the strength will be expressed as 12.45%.

^h The Applicant provided the dose as 1 pump actuation per underarm once a day at bedtime, for a daily dose of 174 mg of sofipironium bromide. However, per the Office of Pharmaceutical Quality (OPQ), the daily dose will be 144 mg of sofipironium.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Sofdra 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 Sofdra. The Division of Dermatology and Dentistry (DDD) did not comment on the findings of OPDP's assessment for Sofdra.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary nameⁱ.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On July 13, 2023, the Division of Dermatology and Dentistry (DDD) did not forward any comments or concerns relating to Sofdra at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-five (n=75) practitioners participated in DMEPA's prescription studies for Sofdra. 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.

ⁱ USAN stem search conducted on August 3, 2023.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA searchⁱ identified 48 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. 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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	45
Low similarity name pair: combined match percentage score $\leq 54\%$	4

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

Our analysis of the 50 names contained in Table 1 determined none of the names will pose a risk for confusion with Sofdra as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On August 24, 2023, DMEPA 1 communicated our determination to the Division of Dermatology and Dentistry (DDD).

3 CONCLUSION

The proposed proprietary name, Sofdra, is conditionally acceptable.

ⁱ POCA search conducted on July 21, 2023 in version 5.2.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO BOTANIX SB INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 7, 2023, 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.^k

***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.

^k National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

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, 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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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^{7F}. 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).

⁷ Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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 $\geq$ 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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?

Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>ŋ</i>), 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 $\geq 55\%$ to $\leq 69\%$).

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.

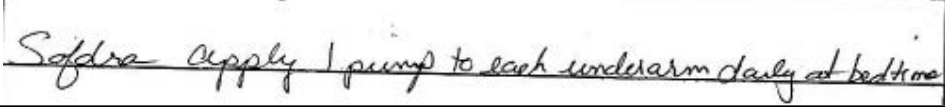
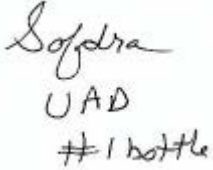
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. - Considering variations in scripting of some letters (such as <i>z</i> and <i>h</i>), 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 as 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 $\leq 54\%$).

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. Sofdra Study (Conducted on July 12, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Sofdra Use as directed. Dispense #1 bottle
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Sofdra	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Sofdra - 2023-07-12					
People Received Study: 253					
People Responded: 75					
Total	22	18	18	17	75
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
SOFDRA	21	18	12	17	68
SOFSTRA	0	0	1	0	1
SOFTDRA	0	0	4	0	4
SOFTRA	0	0	1	0	1
SOLDRA	1	0	0	0	1

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

No.	Proposed name: Sofdra Established name: sofipirionium Dosage form: topical gel Strength(s): 12.45% Usual Dose: one pump actuation to each underarm once a day at bedtime (total 2 pumps), for a total dose of 144 mg	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.	Sofdra	100	Proposed name subject of this review.

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

N/A

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

No.	Proposed name: Sofdra Established name: sofipirionium Dosage form: topical gel Strength(s): 12.45% Usual Dose: one pump actuation to each underarm once a day at bedtime (total 2 pumps), for a total dose of 144 mg	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.	Septra	66	This name pair has sufficient orthographic and phonetic differences.
2.	Stendra	60	This name pair has sufficient orthographic and phonetic differences.
3.	Syfovre	58	This name pair has sufficient orthographic and phonetic differences.
4.	Cordran	58	This name pair has sufficient orthographic and phonetic differences.
5.	Safyral	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Sofdra Established name: sofipirionium Dosage form: topical gel Strength(s): 12.45% Usual Dose: one pump actuation to each underarm once a day at bedtime (total 2 pumps), for a total dose of 144 mg	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
6.	Corphedra	57	This name pair has sufficient orthographic and phonetic differences.
7.	Selfemra Note: Discontinued fluoxetine hcl capsules with generic equivalents available.	56	This name pair has sufficient orthographic and phonetic differences.
8.	Sudodrin	56	This name pair has sufficient orthographic and phonetic differences.
9.	Sogroya	56	This name pair has sufficient orthographic and phonetic differences.
10.	Azedra	55	This name pair has sufficient orthographic and phonetic differences.
11.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Xiidra	52
2.	Sfrowasa	48
3.	Oforta	54
4.	3TC	0

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) ***	74	Proposed proprietary name withdrawn by the Applicant. NDA 210933 approved under the proprietary name, Eysuvis.
2.	Lusedra	62	Brand discontinued with no generic equivalents available. NDA 022244 withdrawn effective 11/03/2016.
3.	(b) (4) ***	59	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA for misbranding the product (OSE #: (b) (4) dated (b) (4)). Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable by DMEPA 2 (Nexus PNR ID No. (b) (4) dated (b) (4)).
4.	Cordran N	56	Brand discontinued with no generic equivalents available. NDA 050345 (ointment) and NDA 050346 (cream) withdrawn FR effective 09/25/1998.
5.	Sanfed A	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Suphera	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Safrole	55	Not a drug, but a flavoring agent in drugs, beverages and foods, and to make other chemicals.
8.	Sano-Drol	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Sorbid Sa	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Zofran	64
2.	Vistra	63
3.	Fasenra	62
4.	Lofibra	62
5.	Lustra	61
6.	Tosymra	60
7.	Tuss Da	59
8.	Testro	58
9.	(b) (4) ***	58
10.	Fudr	58
11.	Fostril	57
12.	Tusso-Zr	57
13.	(b) (4) ***	57
14.	Dofsol-A	57
15.	Fludara	57
16.	Phoslyra	56
17.	(b) (4) ***	56
18.	Fortral	56
19.	Estra-D	56
20.	Estro-A	56
21.	Odactra	56
22.	Softsoap	56
23.	Codar Ar	56
24.	Aftera	55
25.	Soft Care	55

^m 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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/s/

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MISHALE P MISTRY
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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:	May 1, 2023
Application Type and Number:	NDA 217347
Product Name and Strength:	(b) (4) (sofpironium) ^a topical gel, 12.45% ^b
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Botanix SB Inc. (Botanix)
PNR ID #:	2023-1044724985
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

^a The Applicant provided the established name as sofpironium bromide. However, per the Office of Pharmaceutical Quality (OPQ), the established name will be sofpironium.

^b The Applicant provided the strength as 15%. However, per OPQ, the strength will be expressed as 12.45%.

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MADHURI R PATEL
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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)

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Date of This Review:	January 3, 2023
Application Type and Number:	NDA 217347
Product Name and Strength:	(b) (4) (sofpironium bromide) topical gel, 15%
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Botanix SB Inc. (Botanix)
PNR ID #:	2022-1044724796
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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MISHALE P MISTRY
01/03/2023 02:56:08 PM